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 (e-cigarettes) 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.

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<th>Article FCTC</th>
<th>ENDS/ENNDS</th>
<th>Best practice</th>
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| Article 1: Use of Terms | Although ENDS and ENNDS are not classified as tobacco products by WHO, Member States may wish to opt for the regulatory option of treating ENDS/ENNDS (e-cigarettes) as tobacco products for regulatory purposes. Some of the reasons for this option, in addition to the COP recommendation, are listed below:  
    a) ENDS and ENNDS contain or have been generally found to contain nicotine which is a substance predominantly derived from tobacco.  
    b) The use of ENDS and ENNDS mimic tobacco use in terms of physiological and behavioral addiction and method of consumption.  
    c) The evidence surrounding the claims that all ENDS and ENNDS carry reduced health risks are inconclusive and not agreed upon by the scientific and public health community. There is also growing evidence and concern of the negative health effects of these products  
    d) The claim that ENDS and ENNDS can be used as a cessation aid is heavily debated and not substantiated at population level.  
    e) ENDS and ENNDS are attractive to youth; their use has been a gateway to initiation of tobacco use and dual/poly-use of tobacco products in some countries.  
    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 product” | Georgia  
    South Africa  
    Turkey  
    In the USA  
    ENDS/ENNDS are considered tobacco products under the FDA deeming rule, although the FDA has not yet required ENDS/ENNDS companies to submit their products or modified risk claims for FDA evaluation |
substitutes” and liquids for e-cigarettes (regardless of nicotine content) as "tobacco extracts and essences”. ¹

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-cigarettes). ²

| 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. |

¹ WORKING NOTE; E-CIGARETTES: USE AND TAXATION. WBG Global Tobacco Control Program Team
² 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 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 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.”
   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.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 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 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:**

³ 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
     o Develop a clear definition of the tax base, detectable upon importation. This may be volume of liquid, or nicotine concentration.
     o 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
     o 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
     o 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:
     o Establish a list of prices of comparable products on the market and actively correct prices
     o Apply a specific excise duty or establish a minimum value (minimum tax base)
     o 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
     o Only allowing manufacturing of devices to licensed operators.
| Article 8 : Protection from exposure to tobacco smoke | 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) Emission of ENDS and ENNDS shall be considered as tobacco smoke alike and therefore included in work to comprehensively implement article 8 in line with the guidelines for implementation. b) A sign for ENDS/ENNDS (e-cigarettes) should be developed and then all no smoking signs should carry the signs of ENDS/ENNDS (e-cigarettes) to alert the public to them. 4 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 d) A comprehensive implementation plan should be drafted and enforced | Fifty-one member states prohibit or restrict the use of e-cigarettes in public places. USA does not allow ENDS on airplanes Use is prohibited in vehicles with minors in Austria (18 years), 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. |
| Article 9 : Regulation of the contents of tobacco products & Article 10 : Regulation of tobacco product disclosures | 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) in line with the guidelines for the implementation of Articles 9 and 10 and with the following additional considerations **Disclosures from industry to government** | Thirty-two EU Member States regulate the amount (concentration/volume) of nicotine in e-liquids — in the EU the threshold concentration is |

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4 COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO
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<td><strong>a)</strong></td>
<td>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.</td>
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<td><strong>b)</strong></td>
<td>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.</td>
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<td><strong>c)</strong></td>
<td>Require manufacturers to monitor and report adverse effects</td>
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<td><strong>d)</strong></td>
<td>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).</td>
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<td><strong>e)</strong></td>
<td>Information on nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;</td>
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<td><strong>f)</strong></td>
<td>Description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;</td>
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<td><strong>g)</strong></td>
<td>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.</td>
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<td><strong>h)</strong></td>
<td>Development of a reporting template for product information and requiring electronic reporting of such information</td>
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**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.\(^5\)
- **b)** Information must be comprehensible and descriptive

**Monitoring and regulating contents of products**

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\(^5\) 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 substances associated with ENDS/ENNDS (e-cigarettes) products which pose serious toxicological concern, such as diacetyl, acetyl propionyl, cinnamaldehydes or benzaldehyde.
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.6

Sanctions
a) Providing for the removal of products that do not comply with regulations

| Article 11: Packaging and labelling of tobacco products | Member States can consider regulatory options such as
1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) OR
| | Georgia
| | South Korea

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6 COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO
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<th>Article 12: Education, communication, training and public awareness</th>
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<td>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:</td>
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2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions:

   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
   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.
   c) Health warnings should be in line with proven health risks\(^7\)
   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.
   e) Member States applying plain packaging for tobacco products should apply the 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\(^8\)
   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

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\(^7\) FCTC/COP/6/10 Rev.1 Electronic nicotine delivery systems Report by WHO

\(^8\) COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO
| Article 13 : Tobacco advertising, promotion and sponsorship | 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 Article 13 comprehensively by applying a comprehensive ban on all forms of TAPS: direct or indirect.  
      • Direct advertising bans:  
        o National television and radio;  
        o Local magazines and newspapers;  
        o Billboards and outdoor advertising;  
        o Point of sale- internet  
        o Social media and mobile apps  
      • Indirect advertising bans: | UK  
Canada  
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9 COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO  
10 COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO
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<th>Demand reduction measures concerning tobacco dependence and cessation</th>
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<td>1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) OR</td>
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<tr>
<td>2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions:</td>
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<td>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.</td>
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b) Ban should include medical society and medical events; social media and mobile apps; internet videos and internet streaming adverts.

c) 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.\(^{11}\)

Several states in the USA have educational programs on ENDS: [https://flavorshookkids.org](https://flavorshookkids.org) and the FDA-Real Cost campaign is an educational programme for children.

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<th>Article 15</th>
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<td>1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) OR</td>
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<td>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,</td>
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\(^{11}\) 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 by minors | 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 Article 16 comprehensively to ENDS/ENNDS (e-cigarettes), including  
- Clear and prominent indicator at the point of sale about the prohibition of tobacco sales to minors  
- Ban point of sale advertising  
- Prohibit the manufacture of any object in the form of a tobacco products which appeals to minors  
- Ban tobacco vending machines.  
- Prohibit the distribution of free tobacco products to the public, especially minors.  
- Prohibit sales of ENDS/ENNDS in small packets as these increase the affordability of the products to minors.  
b) Banning the sale or distribution of ENDS/ENNDS (e-cigarettes) near/within educational facilities;  
c) Banning the sale and distribution of ENDS/ENNDS (e-cigarettes) by minors;  
d) Regulating places, density and channels of sales.  
e) Set the age limit for ENDS/ENNDS (e-cigarettes) use to 21.  
f) Establish an implementation and enforcement plan including penalties and confiscation of ENDS/ENNDS (e-cigarettes) devices. |
| Article 20: Research, surveillance and exchange of information | 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 years and be representative of the national population. |

South Africa  
Canada  
Estonia, Germany and Lithuania prohibit use by minors under 18 years.  
USA prohibits sales to anyone under 18. Several states and over 300 localities have sales limits of 21.  

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12 COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO  
13 [https://tobacco21.org](https://tobacco21.org)  
14 FCTC/COP/6/10 Rev.1 Electronic nicotine delivery systems Report by WHO
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 socio-demographic groups.\(^{15}\)

c) Ensure that the right questions are included to capture these products in order for the results to accurately reflect country situation.

\(^{15}\) DECISION: FCTC/COP7/9 Electronic nicotine delivery systems and electronic non-nicotine delivery systems