Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS)

Report by the Convention Secretariat

Purpose of the document

This report provides an update for the Conference of the Parties (COP) on the progress reported by the Parties on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS). It was prepared in response to a request from the Bureau to include an item on this topic on agenda of the Eighth session of the Conference of the Parties (COP8) to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC).

Action by the Conference of the Parties

The COP is invited to note this report and to provide further guidance.

Contribute to the Sustainable Development Goals (SDGs), if applicable: SDG 3 and SDG Target 3.a
Link to the workplan and budget item: N/A.
Additional financial implications if not included in the workplan and budget: None.
Author team(s): Office of the Head of the Secretariat.
Related document(s): Previous COP decisions regarding ENDS/ENNDS.
BACKGROUND

1. Ten years ago, as electronic nicotine delivery systems (ENDS) were being rapidly introduced into the market, the Parties to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) became concerned about the potential impact of these new products on individual and public health. In 2008, the Working Group on Articles 9 and 10 of the WHO FCTC made a recommendation through its report to the Third session of the Conference of the Parties (COP3) to request WHO to identify best practices in reporting to regulators on the contents, emissions and the characteristics of products, including electronic systems. This recommendation is reflected in decision FCTC/COP3(9).

2. The Convention Secretariat in 2010 presented a report to the Fourth session of the Conference of the Parties (COP4) 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 the World Health Organization (WHO). The report noted that there was a growing global concern about the quality, safety and “regulatory gap” of these emerging products, broadly called ENDS, as they continued to penetrate new markets.

3. Furthermore, the Working Group on Articles 9 and 10 requested the COP to indicate whether it agreed that ENDS are to be considered “tobacco products” and should be part of future work of the working group. There was, however, no decision made on whether ENDS should be considered tobacco products.

4. COP4 requested in decision FCTC/COP4(14) that the Convention Secretariat prepare jointly with WHO a comprehensive report based on the experience of the Parties on the matter of smokeless tobacco products and nicotine delivery systems, including electronic cigarettes, for consideration at the Fifth session of the Conference of the Parties (COP5).

5. At COP5 in 2012, the Convention Secretariat presented document FCTC/COP/5/13, in which it presented 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.

6. COP5 decision FCTC/COP/5/13 requested the Convention Secretariat to identify options for the prevention and control of ENDS and to examine emerging evidence on the health impacts of ENDS use.

7. WHO presented a report on ENDS to the Sixth session of the Conference of the Parties (COP6) in 2014 (FCTC/COP/6/10 Rev.1), which included the deliberations and scientific recommendations on ENDS made by TobReg and on the analysis from a WHO survey on tobacco products in 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.

8. COP6 decision FCTC/COP6(9) requested the Convention Secretariat to invite WHO to prepare a report on ENDS and electronic non-nicotine delivery systems (ENNDS) for the Seventh session of the Conference of the Parties (COP7). This decision also invited Parties to take measures to address the challenges posed by END/ENNDS and consider prohibiting or regulating them, including as tobacco products, medicinal products, consumer products or other categories, as appropriate, taking into account a high level of protection for human health.
9. In 2016 WHO presented a report (FCTC/COP/7/11) to COP7 updating the evidence of the health impact of ENDS/ENNDS, their potential role in tobacco cessation and their impact on tobacco control efforts, as well as an assessment on regulatory options.

10. COP7 adopted decision FCTC/COP/7(9) inviting the Parties to consider applying some regulatory measures suggested in the report prepared by WHO in document FCTC/COP/7/11. Measures included prohibition or restriction of the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to the Parties’ national laws and public health objectives. It also requested the Convention Secretariat to invite the Parties to monitor and report on scientific, regulatory and market developments such as initiation, cessation, advertising and promotion, and requested 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. A report will be prepared and presented at the ninth session.

11. Upon the request of the Parties, the COP7 Bureau asked the Convention Secretariat to include one agenda item in COP8 on the progress of ENDS and ENNDS regulatory measures undertaken by the Parties and on the current situation.

12. The Convention Secretariat has prepared the present report that describes the ENDS and ENNDS situation based on information from the Parties and other sources.

**USE OF ENDS GLOBALLY**

13. ENDS sales worldwide are increasing. ENDS reached US$ 2.76 billion in sales globally in 2014,\(^1\) US$ 8.61 billion in 2016 and is expected to garner US$ 26.84 billion by 2023.\(^7\) As there is very limited information on ENNDS, this report will concentrate on ENDS.

14. The use of ENDS varies greatly among different countries and regions. According to Eurobarometer 2017,\(^3\) only 2% of respondents from the European Union currently use ENDS, which include electronic cigarettes or similar devices (e.g. e-shisha, e-pipes). However, according to surveys conducted by the European Commission between 2010 and 2017, the share of adult smokers in the United Kingdom of Great Britain and Northern Ireland that has tried ENDS has more than tripled since 2012, reaching 60% by 2017.\(^4\) In terms of those who currently use ENDS, the share has also drastically increased from only 2.7% in 2010 to 17.95% in 2017.\(^5\) The current use of e-cigarettes in 2017 in the United Kingdom of Great Britain and Northern Ireland in all people (male and female) 16 years and over was 5.5%.\(^5\)

15. In other parts of the world, ENDS is becoming more popular, including in the United States of America, where data from the 2016 National Health Interview Survey showed that 3.7% of the population used ENDS.\(^6\) In Russia, according to the 2016 Global Adult Tobacco Survey (GATS), 3.5% of the adult population used ENDS. According to the 2015 GATS, 3.2% of the population used ENDS.

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\(^3\) Special Eurobarometer Attitudes of Europeans towards tobacco and electronic cigarettes, March 2017.


ENDS in Canada, and 3.2% of the population were ENDS users in Malaysia, 0.8% in New Zealand and 0.8% in the Philippines.

16. There is considerable heterogeneity in ENDS use among youth globally, across countries, and also between current smokers and non-smokers. A meta-analysis conducted with data from 27 publications (36 surveys) from 13 countries from 2013 to 2015 showed that among the youth, “ever-use” of ENDS was highest in Poland (62.1%; 95% CI: 59.9–64.2%), and lowest in Italy (5.9%; 95% CI: 3.3–9.2%). Among non-smoking youth, the prevalence of ENDS ever-use in 2013–2015 varied, ranging from 4.2% (95% CI: 3.8–4.6%) in the United States of America to 14.0% in New Zealand (95% CI: 12.7–15.4%). The prevalence of ENDS ever-use among current tobacco smoking youth was the highest in Canada (71.9%, 95% CI: 70.9–72.8%) and lowest in Italy (29.9%, 95% CI: 18.5–42.5%). Between 2008 and 2015, ENDS ever-use among youth increased in Poland, New Zealand, the Republic of Korea and the United States of America; decreased in Italy and Canada; and remained stable in the United Kingdom of Great Britain and Northern Ireland.

**APPROACHES TO REGULATE ENDS**

17. It has been 10 years since the Parties to the WHO FCTC have expressed concern with regard to the rapid expansion of ENDS use. In parallel and/or in reaction to COP discussions and decisions, governments have progressively engaged in regulating the ENDS market. This approach has included decisions on product classification, identification of related policy domains and choices of more adequate regulatory mechanisms.

18. **Product** classification. The first action many countries took was to develop a clear definition and classification of ENDS within existing laws and regulations. Countries have so far reported classifying ENDS in seven categories: 1) tobacco products; 2) products imitating tobacco; 3) medicinal products; 4) pharmaceutical products; 5) consumer products; 6) poison; or 7) ENDS.

19. **Policy domains.** When regulating ENDS, a number of policy domains may be considered, which will depend on product classification. A study conducted in 2016 identified the following domains of regulation including product prohibitions or restrictions related to e-cigarettes: manufacturing; distribution; importation; sales including where sales are allowed and minimum age of purchase; use restrictions including vape-free public places; the regulation of advertising, promotion and sponsorship; taxation; trademarks; health warning labelling; ingredients/flavours; safety/hygiene, reporting/notification; nicotine volume/concentration; and child-safety packaging. The 2014 European Union (EU) Tobacco Product Directive (TPD) both mandates and suggests a range of policy domains for regulating nicotine-containing e-cigarettes. The nine mandated provisions include reporting and notification, safety and quality (five provisions), packaging and labelling (two provisions) and advertising/promotion/sponsorship; suggested provisions include regulations around importation and cross-border sales, application of taxes, vape-free laws and minimum age of purchase.

20. **Regulatory** mechanisms. When regulating ENDS, countries have reported to have followed different approaches: 1) some have established a specific new law, decree, resolution or some other legal mechanism for regulating ENDS; 2) others are using existing legislation that can be applied if the

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10. 2018 global progress report on implementation of the WHO. See : http://www.who.int/fctc/reporting/summary_analysis/
classification of ENDS falls within the existing legal framework; 3) other countries have amended existing laws to address ENDS; and 4) some countries have a combination of these measures.

PARTIES’ REPORTING ON REGULATORY AND MARKET DEVELOPMENTS

21. In order to assist Parties in reporting on regulatory and market developments, the Convention Secretariat included two questions related to ENDS in its core questionnaire. These are: 5.5. Do you have any of the following products available on your national tobacco market – smokeless tobacco products, water-pipe tobacco, ENDS/ENNDS or others?; and 5.6. Have you adopted and implemented any policy or regulation that is specific to the following tobacco products – smokeless tobacco products, water-pipe tobacco, ENDS/ENNDS or others?

22. More detailed ENDS-related questions were introduced in the Additional Questions on the Use of Implementation Guidelines by the Parties in the Parties Reporting Instrument. This part of the questionnaire is voluntary for the Parties, and only six Parties responded to it. Nevertheless, these additional responses were included in this document. Questions regarding ENDS were introduced and include those on: tax measures; types of ENDS available in the market; flavours in ENDS; where ENDS are sold; how are they being regulated; if regulations for ENDS and ENNDS are different; what kind of policies are in place; whether marketed as harm reduction or smoking cessation aids; and whether the analyses of the contents and emissions of ENDS have been carried out.

SUMMARY OF RESULTS ACCORDING TO PARTIES’ REPORTS

23. The table below summarizes Parties’ responses to questions 5.5 and 5.6 in the core questionnaire for the 2018 reporting cycle.

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of Parties per Region</th>
<th>ENDS available in national market</th>
<th>Parties that responded where ENDS are available</th>
<th>Parties where ENDS are available but do not have regulations</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number</td>
<td>Percentage</td>
</tr>
<tr>
<td>Africa</td>
<td>44</td>
<td>21</td>
<td>12</td>
<td>57%</td>
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<tr>
<td>Americas</td>
<td>30</td>
<td>17</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>19</td>
<td>8</td>
<td>4</td>
<td>50%</td>
</tr>
<tr>
<td>Europe</td>
<td>51</td>
<td>38</td>
<td>7</td>
<td>18%</td>
</tr>
<tr>
<td>South-East Asia</td>
<td>10</td>
<td>5</td>
<td>4</td>
<td>80%</td>
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<tr>
<td>Western Pacific</td>
<td>27</td>
<td>13</td>
<td>6</td>
<td>46%</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>181</strong></td>
<td><strong>102</strong></td>
<td><strong>39</strong></td>
<td><strong>38%</strong></td>
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24. ENDS have reported availability in 102 of the 181 Parties to the WHO FCTC. However, in 39 of the 102 Parties where ENDS are reported to be available there is no reference to regulations regarding any policy domain. Furthermore, in the 79 Parties where ENDS are reported as not available, 65 do not make reference to having regulations. This leaves a total of 104 Parties with no regulations reported regarding ENDS.

25. Data gathered by WHO for the WHO Report on the Global Tobacco Epidemic 2017 using legislation in place by December 2016 illustrate that ENDS were banned in 30 of the 195 WHO Member States globally (about 15%). In the remaining Member States where ENDS were not banned, only about 65 had regulations. In 29 countries ENDS were regulated as therapeutic products, dependent or independent of the nicotine level. In 20 of those countries they were regulated as therapeutic or consumer products depending on the level of nicotine. In 18 countries they were regulated as tobacco products, and in 31 as consumer products – in some cases a combination of these regulatory treatments. In the last two years, since COP7, an increasing number of academic studies on the impact of ENDS on the tobacco epidemic and an initial evaluation of experiences with a number of policies implemented by the Parties have been published. While international scientific consensus was not yet reached on potential negative and/or positive impacts of ENDS, possible mechanisms for
reviewing the evidence that was published by an independent body might help future decisions by governments in approaching ENDS, its regulation, and its place, if any, in smoking cessation. In this regard, the Convention Secretariat is exploring with the International Agency for Research on Cancer (IARC) the possibility, if funding is available, to prepare a monograph that studies the evidence around the health effects and policy impact of ENDS and to agree on a research agenda on ENDS and on the vast array of new tobacco and nicotine delivery products and systems that are taking hold in the global market.

**Parties where ENDS are banned per Region**

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<tbody>
<tr>
<td>Parties where ENDS are banned</td>
<td>Turkmenistan</td>
<td>Ethiopia</td>
<td>Australia</td>
<td>Korea</td>
<td>Brazil</td>
<td>Bahrain, Egypt, Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, United Arab Emirates</td>
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<td></td>
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<td>Mauritius</td>
<td>Brunei</td>
<td>Brunei</td>
<td>Panama</td>
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<td>Cambodia</td>
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<td>Singapore</td>
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<td>Thailand</td>
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<td>Timor-Leste</td>
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26. In conclusion, according to various projections, the trend in ENDS sales worldwide is increasing. The use of these products varies greatly from one country to the other, although comparable data are not available for a great number of countries.

27. Despite ongoing discussions in the COP over the last 10 years with regard to potential approaches to regulate ENDS, there are still a large number of the Parties that are not yet regulating these products, with potential consequences with regard to increasing uptake by young people, the impact on existing tobacco control measures, misleading health claims and deceptive marketing strategies, and ultimately the lack of proper information to consumers.

28. It seems necessary and timely that Parties develop regulations covering the various policy domains contained in decisions FCTC/COP6(9) and FCTC/COP7(9) by using proper regulatory mechanisms adjusted for the legal framework of every Party.

29. Finally, Parties should make an effort to monitor and report on the use of these products in a uniform manner, as well as the regulatory measures in place.

30. The COP might consider mandating the Convention Secretariat to explore with IARC the possibility, pending funds, to prepare a monograph on ENDS and on the vast array of new tobacco and nicotine delivery products and related systems.

**ACTION BY THE COP**

31. The COP is invited to note the present report and provide further guidance.

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