

## White Paper

Indian J Med Res, Epub ahead of print, pp 1-10  
DOI: 10.4103/ijmr.IJMR\_957\_19



# White Paper on Electronic Nicotine Delivery System

Indian Council of Medical Research\*

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Received May 29, 2019

### EXECUTIVE SUMMARY

Electronic nicotine delivery systems (ENDS) or e-cigarettes are battery-powered devices used to smoke or ‘vape’, a flavoured solution containing a varying concentration of nicotine, an addictive chemical found in cigarettes and other forms of tobacco products. There are various types of ENDS devices. The most common type is an e-cigarette that produces an aerosolized mixture of the flavoured liquids and nicotine, which is inhaled by the user. Nicotine is considered as one of the most addictive substances. The rapidity at which it is introduced into the body, age of first exposure and the dosage administered all add to determine the potential risk of a person being addicted to it throughout life. The various flavours and attractive designs also add to the allure of these products to the young population.

ENDS or e-cigarettes are manufactured in such a way to resemble conventional tobacco products such as cigarettes, pipes and cigars and common gadgets such as flash drives, flashlights or pens. Currently, there are more than 460 different e-cigarette brands with varied configuration of nicotine delivery available in the market, for example, cigar-likes (first generation), tank systems (second generation) and personal vaporizers (third generation) with over 7700 flavours. This makes collation of data on health effects more difficult for the generation of scientific evidence.

#### **Increasing use by youth and adolescents**

There is an increasing trend for the use of ENDS or e-cigarettes amongst the youth and adolescents in many countries where these products were introduced. E-cigarettes are the most commonly used nicotine products in the

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United States, and their use is reported to be rising at an alarming rate. A study suggests that about 21 per cent of high-school students and 5 per cent of middle-school students reported to have used e-cigarettes in the last 30 days in 2018, which represents an increase of 1.5 million youth from 2017 to 2018. A recent WHO report showed that use of ENDS amongst non-smoking youth has increased by a factor of five and eight, respectively, in three years in Florida, USA, and Poland, to reach a prevalence of 6.9 and 13 per cent. A rapid increase in the use of ENDS or e-cigarettes has also been reported amongst the youth and adolescents in some European Union countries and also in various other parts of the world. Data from longitudinal studies indicate that the use of ENDS by minors doubles their chances of starting to smoke. Thus, the increasing use of e-cigarettes by youth is a significant public health concern since the extent of potentially harmful effects, beyond the demonstrated nicotine addiction, is still to be fully revealed and remains a cause for concern.

### **Potential harmful health effects**

The use of ENDS or e-cigarettes adversely affects almost all the human body systems with impact across the life course, from the womb to tomb. The cartridges used in ENDS or e-cigarettes are filled with liquid nicotine, flavouring agents and other chemicals. A typical cartridge contains about as much nicotine as a pack of 20 regular cigarettes and can act as a potential source for nicotine addiction. Furthermore, the amount of nicotine and other chemicals in these products varies widely, and thus, the consumer remains unaware of the actual contents of the products they use. Studies on these nicotine solvents had shown a varied degree of release of potential carcinogens – which includes acetaldehyde, formaldehyde and acetone – depending on the battery output voltage. The liquid-vapourizing solutions also contain toxic chemicals and metals that have been demonstrated to be responsible for several adverse health effects, including cancers and diseases of the heart, lungs and brain.

E-cigarette use adversely affects the cardiovascular system, impairs respiratory, immune cell function and airways in a way similar to cigarette smoking and is responsible for severe respiratory disease. The particulate nature of vapour in e-cigarettes has been established by various studies. The number of particles delivered and the particle size distributed by these devices are similar to those of conventional cigarettes. Most of these particles are ultrafine in nature and can easily reach deep into the lungs and can cross into the systemic circulation. A study has reported that human bronchial cells grown in a medium-exposed to e-cigarette aerosol have shown a similar pattern of gene expression to those grown in a medium-exposed to tobacco smoke. Such exposure induces DNA damage and cell death independently of nicotine in cell lines. The flavouring agents used in e-cigarettes to attract consumers can adversely affect the health of the users due to their cytotoxic effect, which has been demonstrated by various studies. Studies indicate that ENDS can adversely affect pregnant women who are either users or exposed to passive aerosol. It also poses risks to foetal, infant and child brain development.

Tests by the US Food and Drug Administration (US-FDA) have demonstrated the presence of diethylene glycol on some ENDS, which can lead to mass poisonings and deaths if inadvertently substituted for propylene glycol in consumer products. There were additional presences of genotoxins and animal carcinogens (*e.g.* benzoic acid, diethyl carbonate, butyl acetate, quinoline and dioctyl phthalate 2,6-dimethyl phenol). This is a matter of great concern calling for further investigation.

### **Harm to non-users**

ENDS have adverse health impacts even when people are exposed to second-hand vapours. Passive exposure to vapours during pregnancy can severely affect the health of both the mother and foetus. There are reports of poisoning due to accidental swallowing by children. These devices also can cause fire and explosion.

### **Gateway to nicotine addiction and smoking**

Studies have found that youths using ENDS or e-cigarettes are more likely to use regular cigarettes later. E-cigarettes increase the likelihood to experiment with regular tobacco products and increase intention to indulge in cigarette smoking. They also increase the risk of dual use due to lack of awareness about the harmful effects of ENDS.

## **Electronic nicotine delivery systems (ENDS) as a tobacco cessation aid: Myths and reality**

ENDS or e-cigarettes are popularly perceived as a smoking cessation aid, but their efficacy and safety as a quitting aid have not yet been firmly established. Although some smokers claim to have cut down smoking while using ENDS, the total nicotine consumption seems to remain unchanged. E-cigarettes seem to have rather similar or even weaker efficacy as a cessation aid when compared to nicotine patches, due to different sizes of e-liquid vials, variable amount of nicotine in each vial, uncontrolled number of vapes and variable amount of nicotine in each vape puff. Moreover, a considerable number of ex-smokers who have reported stopping cigarette use with the aid of ENDS continue using the latter product, thus sustaining nicotine dependence. In a four-country survey carried out between July 2010 and June 2011 in the United States, the United Kingdom, Canada and Australia, 70.4 per cent of the study subjects reported to have used ENDS as a way to obtain nicotine in smoke-free spaces, indicating that ENDS were being used to satisfy nicotine addiction during periods of forced abstinence.

There is very limited evidence regarding the impact of ENDS on tobacco smoking cessation, reduction in cigarette use or adverse health effects. The International Association for the Study of Lung Cancer does not recommend the use of e-cigarettes for treating nicotine dependence even in cancer patients, due to the absence of sufficient evidence on their efficacy and safety. The Indian Medical Association considered ENDS as an unhealthy and disguised form of tobacco addiction, with serious long-term health effects and unfit to be used for tobacco cessation.

### **Marketing and promotion**

ENDS are advertised through various forms of media (print, television and internet), with youth being the target group. These products are advertised as a socially attractive trend for attracting young people and have already gained significant popularity over social media. They are being marketed as safer alternatives to conventional cigarettes or harm reduction products, in a glamorous manner, so as to make them attractive under the guise of being less harmful. These techniques are aimed at targeting the youth and children. Some of their advertisements also suggest that these products can be used for bypassing the smoke-free rules.

It is also noteworthy that major tobacco companies have purchased or developed ENDS products, with the dual-commercial intent of expanding their range of tobacco products while touting their ability to offer a product that they claim reduces harm from the cigarettes. Cigarette smokers who may have otherwise given up the habit are thereby retained as nicotine-addicted customers, while those who may have never attempted to experiment with cigarettes are drawn into the nicotine addiction web. This duality of product marketing is a business strategy adopted by tobacco companies who see conventional cigarette smoking diminishing in many countries.

What is alarming is that the market for ENDS continues to grow rapidly, supported by relatively low barriers to entry and thus allowed many businesses to bring a diverse set of products to consumers through a variety of channels.

### **Monitoring and regulation**

Monitoring of these products differs amongst various countries. For example, in the United Kingdom, these are regulated as medicines from 2016, for ensuring their quality and safety, but some countries have introduced restrictions on the sale and use of ENDS. The sale of e-cigarettes is completely banned in 25 countries, including Brazil, Norway and Singapore, while market authorization is required in 17 other countries. In the United States, ENDS that are marketed for therapeutic purposes are currently regulated by the US-FDA and Center for Drug Evaluation and Research.

### **Indian perspective**

In India, use of nicotine as an ingredient in any food item is prohibited under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 of the Food Safety and Standards Act, 2006. Nicotine and nicotine sulphate are listed as hazardous chemicals under the Environment (Protection) Act, 1986 and in the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989. There are other laws and regulations which are also applicable to ENDS.

Tobacco consumption, especially cigarette smoking, has shown a decline in India in recent years, in response to several tobacco control measures. The marketing of a product-like ENDS, with unproven benefit and high potential harm from addiction and health risks, is unwarranted as a tobacco control measure. The risk of youth addiction is high as borne out by international experience and in Indian media reports. The adverse population-level health impact will outweigh any presumed benefit to individual cigarette smokers.

## Conclusions

Based on the currently available scientific data from multiple streams of research, the Council recommends complete prohibition on ENDS or e-cigarettes in India in the greater interest of protecting public health, in accordance with the precautionary principle preventing public harm from a noxious agent, considering the following facts and circumstances:

- ENDS or e-cigarettes contain nicotine solution, which is highly addictive, and also contain other ingredients as flavouring agents and vaporizers, which are also harmful for health.
- Use of ENDS or e-cigarettes has documented adverse effects on humans which include DNA damage; carcinogenesis; cellular, molecular and immunological toxicity; respiratory, cardiovascular and neurological disorders and adverse impact on foetal development and pregnancy.
- The magnitude of potential short-term and long-term health risks to the users still remains undetermined at the population level since the products are recent and come in diverse forms.
- Whereas, the degree to which, if at all, the ENDS or e-cigarettes benefit as tobacco cessation aides is not firmly established, evidence suggests that there is a risk of dual use to some extent and initiation to tobacco addiction to non-smokers. Hence, on the balance these products have a net negative impact on public health.
- Use of ENDS can open a gateway for new tobacco addiction which is a potential threat to the country's tobacco control laws and on-going tobacco control programmes.
- The rapidly increasing trend of use of ENDS or e-cigarettes by young persons, in countries where it was introduced, underscores a potential threat to public health.

## MAIN PAPER

### Introduction

Electronic nicotine delivery systems (ENDS) or e-cigarettes or vape pens/vaping devices are battery-powered devices used to smoke or 'vape', a flavoured solution containing varying concentrations of nicotine, an addictive chemical found in cigarettes and other forms of tobacco products. Amongst these various types of ENDS devices, e-cigarettes are the most common type. They produce an aerosolized mixture of the flavoured liquids and nicotine, which is inhaled

by the user. Nicotine is considered as one of the most addictive substances. The rapidity at which it is introduced into the body, age of first exposure and the dosage administered all add to determine the potential risk of a person being addicted to it throughout life. Nicotine addiction is established more strongly when the exposure occurs in adolescence. The various



**Fig. 1.** Various types of electronic nicotine delivery systems devices.  
Source: Ref. 1



**Fig. 2.** Various prototype e-cigarettes.  
Source: Ref. 1

flavours and attractive designs also add to the allure of these products to the young population.

ENDS or e-cigarettes are manufactured in such a way to resemble conventional tobacco products such as cigarettes, pipes and cigars and common gadgets such as flash drives, flashlights or pens (Figs. 1 and 2)<sup>1</sup>. Structurally, most e-cigarettes contain four different components: a cartridge or reservoir, which holds a liquid solution containing varying amounts of nicotine with flavourings, and other chemicals (e-liquid or e-juice), namely a power source (usually a battery), a heating element (atomizer) and a mouthpiece that the person uses to inhale. They date back to 17<sup>th</sup> August 1965 when the first documented patent for this type of device was issued in Pennsylvania. Since then, it took several decades of additional propagation before mass production was initiated in 2003 in China and some other countries. Currently, there are more than 460 different e-cigarette brands with varied configuration of nicotine delivery available in the market, for example, cigar-likes (first generation), tank systems (second generation) and personal vaporizers (third generation) with over 7700 flavours<sup>2</sup>. This makes collation of data on health effects more difficult for generation of scientific evidence.

### **Increasing use of electronic nicotine delivery systems (ENDS) or e-cigarettes amongst the youth**

There is an increasing trend of use of ENDS or e-cigarettes amongst the youth and adolescents in many countries where these products were introduced. E-cigarettes are the most commonly used nicotine products in the United States, and their use is reported to be rising at an alarming rate. A study suggests that about 21 per cent of high-school students and 5 per cent of middle-school students reported to have used e-cigarettes in the last 30 days in 2018, which represents an increase of 1.5 million youth from 2017 to 2018<sup>3,4</sup>. A recent WHO report showed that the use of ENDS amongst non-smoking youth has increased by a factor of five and eight, respectively, in three years in Florida, USA, and Poland, to reach a prevalence of 6.9 and 13 per cent<sup>5</sup>. There is also an increasing trend of e-cigarettes use amongst youth in some of the European Union countries as evidenced by the Global Youth Tobacco Survey trends. A rapid increase in the use of ENDS has also been reported amongst adolescents in various other parts of the world<sup>6</sup>. Thus, the increasing use of e-cigarettes by youth is a significant public health concern since the extent of potential harmful effects, beyond the demonstrated

nicotine addiction of e-cigarettes, is still to be fully revealed and remains a cause for concern. Further, data from longitudinal studies indicate that the use of ENDS by minors doubles their chances of starting to smoke regular tobacco<sup>5-7</sup>.

### **Potential harmful health effects of electronic nicotine delivery systems (ENDS) or e-cigarettes**

The use of ENDS or e-cigarettes adversely affects almost all the human body system with impact across the life course, from the womb to tomb. The cartridges used in these ENDS or e-cigarettes are filled with liquid nicotine, flavourings agents and other chemicals<sup>8,9</sup>. A typical cartridge contains about as much nicotine as a pack of 20 regular cigarettes<sup>10</sup> and can act as a source for nicotine addiction. Furthermore, the amount of nicotine and other chemicals in these products varies widely, and thus, the consumer remains unaware of the actual contents of these products they use. Studies on these nicotine solvents had shown a varied degree of release of potential carcinogens – which includes acetaldehyde, formaldehyde and acetone – depending on battery output voltage<sup>11</sup>. The liquid-vapourizing solutions also contain toxic chemicals and metals that have been demonstrated to be responsible for several serious adverse health effects, including cancers and diseases of the heart, lungs and brain<sup>8,9</sup>. Moreover, the flavouring agents used in e-cigarettes to attract consumers can also adversely affect the health of users due to cytotoxic effect of the flavourings in refill fluids as has been demonstrated by various studies<sup>12,13</sup>. There are great apprehensions regarding safety in pregnant women who are either users or are exposed to the passive (second-hand) ENDS aerosol due to higher sensitivity of stem cells to cytotoxicity, as compared to differentiated adult pulmonary fibroblast cells<sup>14</sup>.

Contrary to the marketing claims which advertise ENDS aerosol as ‘water vapour’, particulate nature of the vapour in e-cigarettes has been established by various studies. The size and distribution of the particle and number of particles delivered by these devices are similar to those of conventional cigarettes. Most particles are ultrafine in nature and can easily reach deep into the lungs and can cross into the systemic circulation<sup>15,16</sup>. A study has reported that human bronchial cells grown in a medium-exposed to e-cigarette aerosol have shown a similar pattern of gene expression to those grown in a medium-exposed to tobacco smoke<sup>17</sup>. Moreover, e-cigarettes can also induce DNA damage and cell death demonstrated in the cell lines<sup>18</sup>.

E-cigarettes adversely affect the cardiovascular system<sup>19-21</sup>, contain known carcinogens<sup>22,23</sup>, impair respiratory, immune cell function<sup>13</sup>, affect airways in a similar way as cigarette smoking<sup>24</sup>, are responsible for severe respiratory diseases<sup>25</sup> and pose risks to foetal, infant and child brain development<sup>26,27</sup>.

Tests by the US-Food and Drug Administration (US-FDA) have demonstrated the presence of diethylene glycol on some ENDS, which can lead to mass poisonings and deaths if inadvertently substituted for propylene glycol in consumer products. There were additional presences of genotoxins and animal carcinogens such as benzoic acid, diethyl carbonate, butyl acetate, quinoline and dioctyl phthalate 2,6-dimethyl phenol<sup>28</sup>. This is a matter of great concern warranting further investigations.

### **Harmful effects and health risks to non-users**

ENDS have adverse health impacts even when non-users are exposed to second-hand vapours<sup>27,29,30</sup>. Passive exposure to vapours during pregnancy can adversely affect the health of both the mother and foetus<sup>14</sup>. ENDS have been reported to be responsible for poisoning due to accidental swallowing by children<sup>31</sup> and may cause fire and explosion<sup>32</sup>.

### **Gateway to nicotine addiction and tobacco smoking**

Young persons using ENDS are more likely to use regular cigarettes later<sup>26</sup>. ENDS use increases the likelihood to experiment with regular tobacco products<sup>33</sup>, increases intention to cigarette smoking<sup>34</sup> and also increases the risk of dual use<sup>35</sup>, due to lack of awareness about the harmful effects of ENDS<sup>26</sup>.

### **Electronic nicotine delivery systems (ENDS) as tobacco cessation aid: Myths and reality**

ENDS or e-cigarettes are popularly perceived as smoking cessation aid, but its efficacy and safety as a quitting aid have not yet been firmly established. Although some smokers claim to have cut down smoking while using ENDS, the total nicotine consumption seems to remain unchanged. E-cigarettes seem to have rather similar or even weaker efficacy as cessation aid, when compared to nicotine patches, due to different sizes of e-liquid vials, variable amount of nicotine in each vial, uncontrolled number of vapes and variable amount of nicotine in each vape puff. Moreover, a considerable number of ex-smokers who have stopped cigarette use with the aid of ENDS continue using the latter product, thus sustaining

nicotine dependence. In a four-country survey carried out between July 2010 and June 2011 in the United States, the United Kingdom, Canada and Australia, 70.4 per cent of the study subjects reported to have used ENDS as a way to obtain nicotine in smoke-free spaces, indicating that ENDS were being used to satisfy nicotine addiction during periods forced abstinence<sup>14</sup>. This may be responsible for reducing cessation rates<sup>28</sup>. There is very limited evidence on the impact of ENDS as tobacco smoking cessation and/or reduction in use and adverse health effects<sup>2,7,36,37</sup>. Systematic and meta-analysis of data from randomized controlled trials (RCTs), observational studies and cohort studies has reported low certainty of evidence and several limitations from which no credible inferences can be drawn<sup>7</sup>.

A recent RCT published on 30<sup>th</sup> January 2019 in 'The New England Journal of Medicine' reported 18.0 per cent one-year abstinence rate in the e-cigarette group compared to 9.9 per cent in the nicotine-replacement group. However, the trial had several limitations and the researchers indicated that it may not even be replicable in other settings. The safety evaluation of this trial reported two deaths, one in the e-cigarette group (due to ischemic heart disease) and other in the nicotine-replacement group (traumatic spine injury), and 27 serious adverse events have reported in the e-cigarette group compared to 22 in the nicotine-replacement group. This raises serious concerns regarding the long-term health risk<sup>38</sup>.

The International Association for the Study of Lung Cancer does not recommend the use of e-cigarettes for treating nicotine dependence even in cancer patients due to the absence of sufficient evidence on their efficacy and safety<sup>39</sup>. The Indian Medical Association considered ENDS as an unhealthy and disguised form of tobacco addiction, with serious long-term health effects and unfit to be used for tobacco cessation<sup>40</sup>.

### **Marketing and promotion**

In this new era of multimedia marketing, ENDS or e-cigarettes are advertised through all forms of media and internet, with youth being the main target group. These products are promoted in socially attractive trends through television commercials, celebrity and sports endorsement and social networking, with cultural sponsorship. The online advertising and displays and point-of-sale pricing strategies of these products claim these products to be safe and have positive role in cessation in innovative way as the main

marketing themes. These products are being marketed as safer alternatives or harm reduction products, in a glamorous manner, so as to make them attractive under the guise of being less harmful. These techniques are aimed at targeting youth and adolescents and have gained significant popularity over social media. Some of the advertisements also suggest that these products can be used for bypassing the smoke-free rules.

In 2013, major tobacco companies had purchased or developed ENDS products with the dual-commercial intent of expanding their range of tobacco products while touting their ability to offer a product that they claim reduces harm from the cigarettes<sup>14</sup>. The industry tactics of launching ENDS to attract as potential customers persons who may not have wished to experiment with conventional cigarettes, as well as hold captive people who are trying to quit smoking by trapping them in new web of nicotine addiction, are evident from the fact that the tobacco companies themselves have taken over the ownership of these products. This duality of marketed products is a business strategy adopted by tobacco companies which view the declining cigarette consumption in many countries as a threat to their conventional products.

What is alarming is that the market continues to grow rapidly, supported by relatively low barriers to entry and thus allowing many businesses to bring a diverse set of products to consumers through a variety of channels. A study has reported that at the end of 2016, sales of ENDS were expected to reach £6.1 bn globally from just £0.7 bn in 2010, with an increase of around 800 per cent. Moreover, by 2020, sales have been projected to rise just under £12 bn, increasing at a compound average growth rate of 17 per cent per year<sup>41</sup>.

### **Monitoring and regulation**

Monitoring of these products differs amongst countries to countries. For example, in the United Kingdom, these are regulated as medicines from 2016 to ensure their quality and safety, but in some countries, they have already introduced restrictions on the sale and use of ENDS. The sale of e-cigarettes has been completely banned in 25 countries, including Brazil, Norway and Singapore, while market authorization is required in 17 other countries<sup>42</sup>. In the United States, ENDS that are marketed for therapeutic purposes are currently regulated by the US-FDA and Center for Drug Evaluation and Research and from 2016<sup>14</sup>. The US-FDA has expanded its regulatory authority for all

tobacco products, including ENDS for manufacture, packaging, labelling, advertising, promotion, sale and distribution and import. Through this new law (often called the 'Deeming Rule'), the FDA has envisaged many strict provisions for regulation of ENDS. For example, there are requirements of health warnings on ENDS and other tobacco products, it prohibits the sales of ENDS to youth under the age of 18 yr, it prohibits and bans distribution of free samples and sale of ENDS in vending machines, it requires that ENDS manufacturers receive marketing authorization from the FDA and also require vape shops that mix e-liquids to comply with legal requirements for tobacco manufacturers.

### **Indian perspective**

As per the Global Adult Tobacco Survey (GATS), there is an overall 6 per cent decline in tobacco use, from GATS 1 to GATS 2 in India. This indicates a positive impact of the country's efforts towards tobacco control. Under the National Tobacco Control Programme (NTCP), the support for tobacco cessation is multipronged, ranging from brief advice to comprehensive counselling including support for nicotine-replacement therapy. Under the NTCP, one tobacco cessation centre (TCC) is being established in all the districts. The Dental Council of India has also mandated to establish one TCC in all the dental colleges. In addition, National Tobacco Quitline (1800 11 2356) and mCessation (011-22901702) are fully functional to provide cessation support to whoever wishes to quit tobacco.

In the context of a declining trend in cigarette consumption and multiple measures being taken to achieve tobacco control, both by preventing tobacco uptake in the first place and by promoting cessation of the tobacco habit, the introduction of an unproven product-like ENDS as a cessation aid is unwarranted. The claim of harm reduction has to be assessed by contrasting the uncertain long-term health effects on a small fraction of tobacco users with the potential harm, resulting from large-scale uptake of this novel form of nicotine addiction by a large fraction of the youth. That this danger is very real is evident from a news report in the Times of India, published on 26<sup>th</sup> May 2019. It reports the serious concerns expressed by school principals in Delhi regarding the increasing trend of vaping by young students. It quotes a seller as reporting that the sale of these devices has spiralled since they were introduced in 2007 and reports that many schools are surrounded by shops selling these devices<sup>43</sup>.

In India, the use of nicotine as an ingredient in any food item under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 of the Food Safety and Standards Act, 2006. Nicotine and nicotine sulphate are listed as hazardous chemicals under the Environment (Protection) Act, 1986 and in the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989. Other laws and regulations that are applicable to ENDS include as follows:

- (i). Advisory from the Ministry of Health and Family Welfare, Government of India, to all states and union territories to ensure that ENDS and similar devices are not sold (including online sale), manufactured, distributed, traded, imported and advertised in their jurisdictions.
- (ii). Ban on import by the Department of Revenue: The advisory is implemented by the Central Board of Indirect Taxes and Customs (Anti-Smuggling Unit). For all non-compliant consignments, action is taken under the Drugs and Cosmetics Act, 1940.
- (iii). Sale, Manufacture, Distribution, Trade, Import, Advertisement banned by the DCGI since no ENDS or like nicotine delivery devices are approved by the authority.
- (iv). Ban on e-cigarettes advertisements under The Ministry of Electronics and Information Technology.
- (v). The Poisons Act, 1919, the Chandigarh Poison (Possession and Sale) Rules of 2015, enacted under the said Act, lists 'nicotine in extracted form or nicotine in any form as an additive and/or its derivatives,' in the category of poison.
- (vi). Ban under the Poisons Act, 1919: States of Punjab and Haryana have banned the manufacturing, sale and distribution of e-cigarettes as it is in contravention with the Poison Rules read with the Poisons Act, 1919.
- (vii). The Environment (Protection) Act, 1986 listed nicotine as a hazardous chemical.
- (viii). The Insecticide Act, 1968 lists nicotine as an insecticide.
- (ix). The Food, Safety and Standards Act, 2006 and Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, prohibit the use of nicotine as an ingredient in any food item or article.

Since all the big brands of ENDS globally are owned by the tobacco industry, the marketing of these undermines all tobacco control norms. It violates the Provisions of Article 16 (1) (c) of the WHO FCTC

that mandates '*prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors*'. This is also against the National Tobacco Control Law, *i.e.* COTPA Section 6, the smoke-free laws, COTPA Section 4 and COTPA Section 5, as it promotes and entices youth into initiating conventional cigarette smoking and is a threat to the on-going tobacco control programmes in the country.

## Conclusions

Based on the currently available scientific and research data, the Council recommends complete prohibition on ENDS or e-cigarettes in India in the greater interest of protecting public health, in accordance with the precautionary principle of protecting the population from a noxious substance, after considering the following facts and circumstances:

- ENDS or e-cigarettes contain nicotine solution, which is highly addictive, and also other ingredients such as flavouring agents and vapourizer, rendering these products harmful for health.
- Uses of ENDS or e-cigarettes have documented adverse effects on humans which include DNA damage; carcinogenesis; cellular, molecular and immunological toxicity; respiratory, cardiovascular and neurological disorders and adverse impact on foetal development and pregnancy.
- The potential short-term and long-term health risks to the users still remain to be fully determined as the products are relatively recent and are marketed in diverse forms.
- Whereas, the degree to which, if at all, the ENDS or e-cigarettes benefit as tobacco cessation aides is not firmly established, evidence suggests that there is a risk of dual use to some extent and initiation to tobacco addiction to non-smokers. Hence, on the balance these products have a net negative impact on public health.
- The marketing of ENDS can open the gateway to a new form of tobacco addiction, which is a potential threat to the country's tobacco control laws and on-going tobacco control programmes.
- The documented trend of a rapid increase in the use of ENDS or e-cigarettes by young persons, in countries where it was introduced, portends a major potential threat to public health if the products are marketed in India.

**Financial support & sponsorship:** None.

**Conflicts of Interest:** None.



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