

Legislative Brief

The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019

The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 was promulgated on September 18, 2019.

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Highlights of the Ordinance

- ◆ Electronic cigarettes are electronic devices that heat a substance (natural or artificial) to create vapour for inhalation. These e-cigarettes may contain nicotine and flavours, and include all forms of electronic nicotine delivery systems, heat-not-burn products, and e-hookahs.
- ◆ The Ordinance prohibits the manufacture, trade, and advertisement of e-cigarettes in India. Any person who contravenes these provisions will be punishable with imprisonment of up to one year, or a fine of up to one lakh rupees, or both.
- ◆ No person is allowed to use any place for the storage of any stock of e-cigarettes. If any person stores any stock of e-cigarettes, he will be punishable with an imprisonment of up to six months, or a fine of up to Rs 50,000, or both.

Key Issues and Analysis

- ◆ The Ordinance prohibits the trade, advertisement, storage, and transport of e-cigarettes as studies indicate that they may attract new users of nicotine. However, some other studies have argued that e-cigarettes are substantially less harmful than traditional cigarettes and could aid smokers give up the habit.

PART A: HIGHLIGHTS OF THE ORDINANCE

Context

E-cigarettes are battery-operated devices that heat a substance, which may contain nicotine and other chemicals, to create vapour for inhalation. Usually, e-cigarettes are shaped like conventional tobacco products (such as cigarettes, cigars, or hookahs), but they also take the form of everyday items such as pens and USB memory sticks. Unlike traditional cigarettes, e-cigarettes do not contain tobacco. Note that, as of 2015, the global market for the e-cigarettes industry was estimated at USD 10 billion.³

India is a signatory to the WHO Framework Convention on Tobacco Control which was developed in response to the globalisation of the tobacco epidemic.¹ In 2014, the WHO Framework Convention on Tobacco Control invited all its signatories to consider prohibiting or regulating the use of e-cigarettes in their countries.² This was suggested due to emerging evidence on the negative health impact of e-cigarettes which could result in lung cancer, cardiovascular diseases, and other illnesses associated with smoking traditional cigarettes.³ Since then, over 30 countries including Brazil, Mexico, Singapore, and Thailand have banned the production, trade, and advertisement of e-cigarettes.⁵ Some other countries such as the United Kingdom, Canada and France have brought out laws to regulate the manufacture, sale, advertisement, and use of e-cigarettes.

As per the Global Adult Tobacco Survey 2016-17, approximately 3% of adults (aged 15 years and above) in India were aware of e-cigarettes and there were 0.02% e-cigarette users.⁴ In August 2018, the Ministry of Health and Family Welfare issued an advisory to all states recommending that they should not approve any new e-cigarettes and restrict the sale and advertisements of existing e-cigarettes.⁵ Based on this advisory, 16 states including Delhi, Maharashtra, and Uttar Pradesh have since banned e-cigarettes.⁶ In May 2019, the Indian Council of Medical Research recommended a complete prohibition of e-cigarettes in India.⁷ In this context, the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 was promulgated.

Key Features

- **Electronic cigarettes:** The Ordinance defines electronic cigarettes (e-cigarettes) as electronic devices that heat a substance (natural or artificial) to create aerosol for inhalation. These e-cigarettes may contain nicotine and flavours, and include all forms of electronic nicotine delivery systems, heat-not-burn products, e-hookahs, and other similar devices. Note that, the definition of e-cigarettes does not include any medical product licensed under the Drugs and Cosmetics Act, 1940.
- **Banning of e-cigarettes:** The Ordinance prohibits the production, manufacture, import, export, transport, sale, distribution and advertisement of e-cigarettes in India. Any person who contravenes these provisions will be punishable with imprisonment of up to one year, or a fine of up to one lakh rupees, or both. For any subsequent offence, the person will be punishable with imprisonment of up to three years, along with a fine of up to five lakh rupees.
- **Storage of e-cigarettes:** No person is allowed to use any place for the storage of any stock of e-cigarettes. If a person stores any stock of e-cigarettes, he will be punishable with an imprisonment of up to six months, or a fine of up to Rs 50,000, or both.
- From the date on which the Ordinance came into force (i.e., September 18, 2019), the owners of existing stocks of e-cigarettes are required to declare and deposit these stocks at the nearest office of an authorised officer. Such an authorised officer may be a police officer (at least at the level of a sub-inspector), or any other officer as notified by the central or state government.
- **Powers of authorised officers:** If an authorised officer believes that any provision of the Ordinance has been contravened, he may search any place where trade, production, storage, or advertising of e-cigarettes is being undertaken. The authorised officer can seize any record or property connected to e-cigarettes found during the search. Further, he may take the person connected to the offence into custody. However, if the property or records found during the search cannot be seized, the authorised officer may make an order to attach such property, stocks or records.

PART B: KEY ISSUES AND ANALYSIS

Rationale for banning of e-cigarettes

Ordinance:
Clause 3(d),
4, and 5

The Ordinance prohibits the manufacture, trade, and advertisement of e-cigarettes. E-cigarettes are electronic devices that heat a substance, which may contain nicotine and other chemicals, to create vapour for inhalation. Both the WHO and the Indian Council of Medical Research (ICMR) have highlighted the negative health impact of using e-cigarettes which could result in cardiovascular and respiratory diseases.^{3,7} On the other hand, some studies have argued that e-cigarettes are less harmful than traditional cigarettes and could aid existing smokers quit.^{8,9}

As per the Public Health England (2018) and the United States National Academies of Sciences, Engineering and Medicine (2018), e-cigarettes are substantially less harmful than traditional cigarettes.^{8,9} They lack the tar and carbon monoxide of traditional cigarettes because combustion, which produces significant toxic substances, does not occur. Therefore, substituting e-cigarettes for traditional cigarettes may reduce the smokers' exposure to numerous toxic substances and carcinogens (substances capable of causing cancer).⁹ A clinical trial in the United Kingdom found that people who used e-cigarettes to quit smoking were twice as likely to succeed as people who used other nicotine replacement products such as patches or gum.¹⁰ However, there is still insufficient evidence to quantify the health risks and long term effects of e-cigarettes.^{5,7,11}

On the other hand, experts have noted that the use of e-cigarettes containing nicotine and other chemicals can adversely affect the human body.⁷ Nicotine is the addictive component of tobacco products.^{7,11} In addition to dependence, nicotine can have adverse effects on the development of the foetus during pregnancy, and contribute to cardiovascular diseases. The WHO has observed that e-cigarettes are heavily marketed towards youth through the use of flavourings and promotional strategies. This has resulted in a rapid increase in the use of e-cigarettes amongst youth. For instance, the percentage of youth using e-cigarettes in USA has increased from 1.5% in 2011 to 20.8% in 2018.¹² Several experts have highlighted that nicotine exposure amongst youth can have long-term consequences for brain development, potentially leading to learning and anxiety disorders.^{3,7,11} In addition to nicotine, the cartridges of e-cigarettes are filled with chemicals, flavourings, and metals that have been demonstrated to be responsible for causing cancers and diseases of the heart, lungs, and brain.⁷ While e-cigarettes may be seen as a substitute to traditional cigarettes, they may also serve as a gateway for young people to take up more harmful forms of nicotine or start smoking traditional cigarettes.¹¹

Note that, as per the Global Adult Tobacco Survey 2016-17, the tobacco consumption in India declined by 6% from 2009-10. The ICMR states that the introduction of an unproven product like e-cigarettes is unwarranted, in the context of a declining trend in tobacco consumption and multiple measures being taken to achieve tobacco control.⁷

Approaches to regulation of e-cigarettes in other countries

In 2014, the WHO Framework Convention on Tobacco Control invited all its signatories to consider prohibiting or regulating e-cigarettes, in order to minimise the potential health risks associated with them.¹³ While India has prohibited the manufacture, trade, and advertisement of e-cigarettes with this Ordinance, there is a wide variation in the approaches taken by different countries to the regulation of e-cigarettes. At present, over 30 countries including Brazil, Mexico, and Thailand have banned the manufacture, trade, and advertisement of e-cigarettes.⁵ In addition to this, Singapore and Cambodia have explicitly banned the possession of e-cigarettes.

On the other hand, over 98 other countries such as the United Kingdom, Canada, and France that decided against banning e-cigarettes, were recommended by the WHO to take the following measures: (i) prevent the initiation of e-cigarettes by non-smokers, and youth, (ii) minimise the potential health risks to e-cigarettes users and non-users from exposure, (iii) prevent unproven health claims about e-cigarettes, and (iv) protect tobacco control activities from all commercial interests related to e-cigarettes.¹³

To implement these measures, countries have used a range of regulatory mechanisms such as classifying e-cigarettes as tobacco products, prohibiting sale to minors, prohibiting use in public places, and regulating the amount of nicotine allowed in e-cigarettes. For instance, the European Union's Tobacco Products Directive requires e-cigarettes manufacturers to restrict the nicotine concentration at 20 mg/ml.¹⁴ Further, health warnings for e-cigarettes advising consumers that they contain nicotine and should not be used by non-smokers, are mandatory. Similarly, in the United Kingdom, packaging must include a list of ingredients contained in the product, information on the product's nicotine content, and information on adverse effects, addictiveness and toxicity.¹⁵ In the United States, several states such as New York, Michigan, and Massachusetts have prohibited flavoured e-cigarettes. Table 1 on the next page provides a comparison of international regulations with the Ordinance.

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6. Lok Sabha, Unstarred Question No. 5550, 'Sale of e-Cigarettes', Ministry of Health and Family Welfare, July 26, 2019.
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13. Report of the sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control Moscow, Russian Federation, October 2014, https://www.who.int/fctc/cop/sessions/COP6_report_FINAL_04122014.pdf?ua=1.
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15. The Tobacco and Related Products Regulations 2016, Government of United Kingdom, <http://www.legislation.gov.uk/uksi/2016/507/contents/made>.

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Annexure: Comparison of international laws with the proposed framework

Table 1 below compares the provisions of the Ordinance with the laws and regulations of other countries.

Table 1: Comparison with international regulations

Parameter	United States of America	United Kingdom	Canada	Singapore	France	India (Ordinance)
Extent of regulation	<ul style="list-style-type: none"> Regulates manufacture, trade, advertisement, and packaging. Prohibition of flavoured e-cigarettes in states such as New York, Michigan, Massachusetts, Oregon, and Montana. 	<ul style="list-style-type: none"> Regulates manufacture, trade, advertisement, packaging, and ingredients. Can license e-cigarettes as medical products. 	<ul style="list-style-type: none"> Regulates manufacture, trade, advertising, and packaging. Can license e-cigarettes as therapeutic products. 	<ul style="list-style-type: none"> Prohibits import, advertisement, sale, purchase, and possession. 	<ul style="list-style-type: none"> Regulates manufacture, trade, advertisement, packaging, and ingredients. Can license e-cigarettes as medical products. 	<ul style="list-style-type: none"> Prohibits manufacture, trade, and advertisement.
Ban of sale to minor	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Yes.
Restriction on use	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> Prohibited in public places and workplaces. 	<ul style="list-style-type: none"> Not applicable. 	<ul style="list-style-type: none"> Prohibited in public transport, workplaces, and areas with minors. 	<ul style="list-style-type: none"> Not applicable.
Product regulation	<ul style="list-style-type: none"> Review and regulate the ingredients, content of nicotine, and potential dangers. 	<ul style="list-style-type: none"> Limit on nicotine content is 20 mg per ml. Prohibition on certain additives and ingredients that pose a health risk. 	<ul style="list-style-type: none"> Prohibition on specified additives and ingredients such as amino acids, caffeine, and coloring agents. Only specified flavours can be used. 	<ul style="list-style-type: none"> Not applicable. 	<ul style="list-style-type: none"> Limit on nicotine content is 20 mg per ml. Prohibition on certain additives and ingredients that pose a health risk. Must comply with safety requirements under the Consumer Code. 	<ul style="list-style-type: none"> Not applicable.
Advertising	<ul style="list-style-type: none"> Prohibition of false, and misleading advertising. No free samples can be given. 	<ul style="list-style-type: none"> Prohibited. 	<ul style="list-style-type: none"> None. 	<ul style="list-style-type: none"> Prohibited. 	<ul style="list-style-type: none"> Prohibited. 	<ul style="list-style-type: none"> Prohibited.
Packaging restrictions	<ul style="list-style-type: none"> Mandatory warning statement disclosing that product contains nicotine. 	<ul style="list-style-type: none"> Mandatory warning statement disclosing that product contains nicotine. Requirement to disclose information on adverse health impacts, ingredients, and list of addictive substances. 	<ul style="list-style-type: none"> Mandatory warning statement. Requirement to disclose information on health impacts of the e-cigarette and its vapour. 	<ul style="list-style-type: none"> Not applicable. 	<ul style="list-style-type: none"> Mandatory warning statement disclosing that product contains nicotine. Requirement to disclose information on adverse health impacts, ingredients, and list of addictive substances. 	<ul style="list-style-type: none"> Not applicable.
Ban on possession	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> No. 	<ul style="list-style-type: none"> No.

Sources: Canada: The Tobacco and Vaping Products Act, 1997; UK: The Tobacco and Related Products Regulations 2016; EU: Directive 2014/40/EU of the European Parliament and of the Council; Singapore: Tobacco (Control of Advertisements and Sale) Act, 2011; France: Administrative Order of March 21, 2016 to Code of Public Health.; Administrative Order of May 19, 2016 to Code of Public Health; EU: Directive 2014/40/EU of the European Parliament and of the Council India: The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019