

E-CIGARETTES IN INDIA- REGULATION OR PROHIBITION?

Dr. Chaitra. V

Assistant Professor, School of Law, Christ (Deemed to be University),
Hosur Road, Bengaluru – 560029.

ABSTRACT

The promulgation of the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Ordinance, 2019 is a wise decision by the Government to combat the potential e-cigarette market in India which is likely to progress to strong addiction. However, the Government could have adopted appropriate regulatory controls on the approval, sale, supply, use and promotion of e-cigarette products making health claims rather than absolutely prohibiting them.

Keywords: E-Cigarettes, Public Health, Government, Tobacco Products

INTRODUCTION

The approach to e-cigarette regulation in India recently underwent a notable change. In the last week of September 2019, the Union Government approved an ordinance prohibiting the production, manufacture, import, export, transport, sale, distribution and advertisement of e-cigarettes. Electronic cigarettes, or e-cigarettes is a battery powered device which uses liquid propylene glycol and/or glycerine with or without nicotine to create an inhalable vapour.¹ The ordinance has been challenged in the Calcutta High Court contending the government's discriminatory decision to ban less harmful e-cigarettes while continuing with the use of more harmful conventional cigarettes. The inevitable question which arises is whether e-cigarettes are safer than the conventional cigarettes. Across the globe, various medical and health organisations, experts, regional and national government bodies, and the public at large hold differing views on the subject. Some perceive e-cigarettes as a safe substitute for tobacco cigarettes, as they rely on some promising research studies which indicates that e-cigarettes are less harmful, or lessen the cravings for tobacco thus aiding the smokers quit. Others are

¹ National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems; Eaton DL, Kwan LY, Stratton K, editors. Public Health Consequences of E-Cigarettes. Washington (DC): National Academies Press (US); 2018 Jan 23. 5, Toxicology of E-Cigarette Constituents. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507184/>

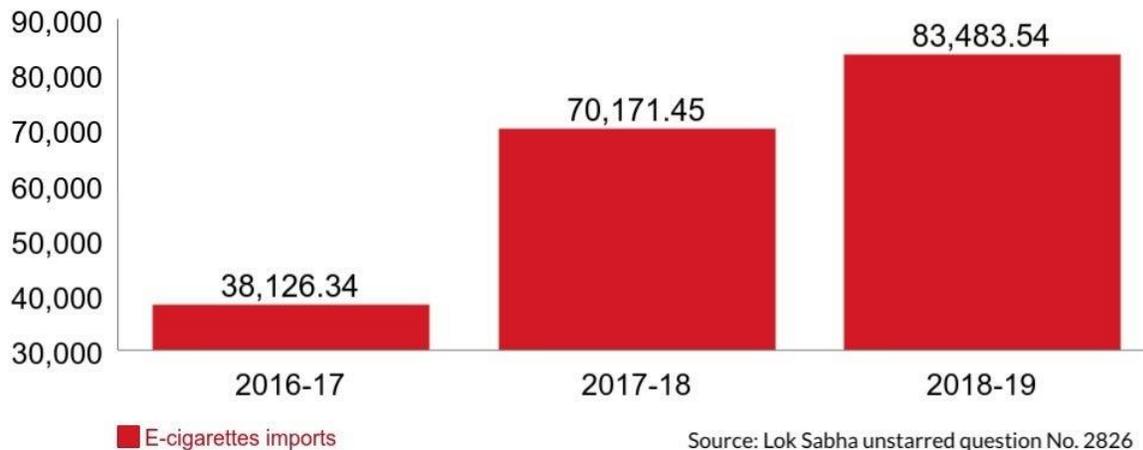
concerned that the nicotine in e-cigarettes may have diverse negative health effects which could lead to its addiction and elongate smoking behaviour.

The means to regulate e-cigarettes across the globe include prohibitions on the product/advertisements, regulation of e-cigarettes packaging designs including its constituents, pictorial health warnings, excise tax, smoking bans for minors. The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (hereinafter referred to as COTPA 2003) is the primary law governing tobacco control in India. Cigarettes, cigars, cheroots, beedis, cigarette tobacco, pipe tobacco and hookah tobacco, chewing tobacco, snuff, pan masala or any chewing material having tobacco as one of its ingredients (by whatever name called), guthka, tooth powder containing tobacco are listed as tobacco products in the Schedule of the COTPA 2003. E-cigarettes are not included in the Schedule and thus falls outside the purview of the COTPA 2003. India's progression in upholding the international standards governing tobacco control is consistent. India is a signatory to World Health Organisation Framework Convention on Tobacco Control since 2004. Conference of the parties to the aforesaid convention held in November 2012, invited the state parties to prohibit or regulate e-cigarettes including as tobacco products, medicinal products, consumer products or other categories. However, recently, India has chosen to prohibit the production, manufacture, import, export, transport, sale, distribution and advertisement of e-cigarettes by approving an ordinance to that effect. India's vaping market (e-cigarette market) is valued at around \$15.6 million, and is expected to grow at 60% annually until 2022, according to the market research firm Euromonitor International.²

² Niharika Sharma, *India's reason to ban vaping has little to do with its impact on health*, Quartz India (19/09/2019) available at <https://qz.com/india/1711740/indias-ban-on-vaping-has-little-to-do-with-health-impact/>

DKODING

E-cigarettes Imports in India (2016-2019)



Due to unclear regulations and import policies, the e-cigarette market in India is dominated by imported products, majorly from China with companies including JUUL Labs Inc., Joyetech Group, Shenzhen IVPS Technology Corporation Ltd., Shenzhen Eigate Technology Co., Ltd, and ITC Limited acting as key players in the market.³ In a biggest tobacco growing country like India which also produces tobacco products, the tobacco and cigarette sector industry, tobacco farmers have huge influence on government regulations in the name of loss of livelihood thus making stringent tobacco control measures difficult. In one sense, it is a wise move by the Government to stop the boom of potential e-cigarette market before it becomes an important source of livelihood and strong addiction in the country.

HEALTH EFFECTS OF E-CIGARETTES- AN UPDATE OF RESEARCH FINDINGS

There is no disagreement about the highly addictive and poisonous nature of nicotine. Most e-cigarettes contain nicotine which is also used in the conventional cigarettes. However, the levels of nicotine concentration in e-cigarettes may be slightly lesser than the conventional cigarettes. Plethora of studies find that e-cigarettes have toxicants which can have negative impact on

³ India E-Cigarette Market Research Report: By Product (Cig-a-like, Vaporizer, Vape Mod, T-Vapor), Gender, Age-Group, Distribution Channel (Vape Shops, Online, Hypermarket/Supermarket, Tobacconist) - Industry Size Analysis and Growth Forecast to 2024. The report is submitted by Prescient & Strategic (P&S) Intelligence Private Limited (formerly known as P&S Market Research Private Limited) which is available at <https://www.psmarketresearch.com/market-analysis/india-e-cigarette-market>

respiratory, cardiovascular, neurological and immune systems.⁴ In recent years, the trend in some developed countries is that the e-cigarettes making beneficial and therapeutic claims are classified as therapeutic goods and are subject to the approval of the appropriate regulatory authorities. On the other hand, the e-cigarettes without any therapeutic claims are classified as tobacco products, and are regulated in the same manner as conventional cigarettes. The report submitted by the Convention Secretariat on Electronic Nicotine delivery systems (ENDS), including e-cigarettes in the fifth session of Conference of the parties to the WHO framework convention on tobacco control held in 18 June 2012, pointed out that there is insufficient evidence currently to assess whether ENDS may be used to aid cessation, whether they create or sustain addiction, and whether they deliver constituents other than nicotine to smokers.⁵ It also urged the state parties to prohibit claims that these products have health benefits, reduce harm, or can be used to aid smoking cessation until they are scientifically proven.⁶ Thus the claim by many global tobacco control researchers and organisations that e-cigarettes is a safe substitute for conventional tobacco cigarettes is yet to be established.

E-CIGARETTE CONTROL MEASURES- WORLD HEALTH ORGANISATION

The Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control at its seventh session (Delhi, India, 7–12 November 2016) has provided with the following non-exhaustive list of regulatory options for the state parties that have not banned the importation, sale, and distribution of ENDS/ENNDS-

- “Banning the sale and distribution of Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) to minors/other vulnerable groups
- Testing heated and inhaled flavourants used in the e-liquids for safety, and banning or restricting the amount of those found to be of serious toxicological concern such as diacetyl, acetyl propionyl, cinnamaldehydes or benzaldehyde
- Regulating the need for manufacturers to disclose product content to government, appropriate labelling of devices and e-liquids
- Requiring manufacturers to monitor and report adverse effects

⁴ The Royal Australasian College of Physicians (RACP) in their document on Policy on Electronic Cigarettes, May 2018 have made an in-depth review of the available evidence on e-cigarettes and their health implications, available at <https://www.racp.edu.au/docs/default-source/advocacy-library/policy-on-electronic-cigarettes.pdf>

⁵This observation is made in the document by relying on the report on ENDS submitted by the WHO Study Group on Tobacco Product Regulation (TobReg)

⁶ They also recommended that in instances where health and/or therapeutic claims are being made or implied, quality, safety and efficacy data substantiating those claims should be presented to the appropriate national regulatory body.

- Prohibiting implicit or explicit claims about the effectiveness of ENDS/ENNDS as smoking cessation aids unless a specialized governmental agency has approved them
- Banning or restricting advertising, promotion and sponsorship of ENDS/ENNDS
- Combustible tobacco products should be taxed at a higher level than ENDS/ENNDS to deter initiation and reduce regression to smoking
- Banning or restricting the use of flavours that appeal to minors⁷

GLOBAL APPROACHES TO REGULATING E-CIGARETTES⁸

In recent years, e-cigarettes in higher-income countries are either regulated as tobacco products or as therapeutic products. On the other hand, there are also countries which have completely banned the use of e-cigarettes. In USA, from 2016 onwards, the Center for Tobacco Products established by the U.S. Food and Drug Administration (FDA) regulates the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of ENDS, including its components.⁹ E-cigarettes promoted as a therapeutic product are regulated by FDA Center for Drug Evaluation and Research (CDER). The regulation of non-nicotine e-cigarettes differ from state to state. However, FDA is currently in preparations to ban flavoured e-cigarettes which particularly targeted young children. In the United Kingdom, e-cigarettes containing nicotine are currently regulated under the EU Tobacco Products Directive (EU TPD) categorised as tobacco products. The regulatory measures include labelling requirements and warnings, restricting the volume of nicotine contents, ban on flavoured e-cigarettes etc.¹⁰ The products making a therapeutic claim are listed and regulated as medicines under the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).¹¹ In Canada, all category of E-cigarettes is regulated as vaping products under the Tobacco and Vaping Products Act (TVPA).¹² They are also regulated either by the Food and Drugs Act (FDA) or the Canada Consumer Products Safety Act, subject to the claims for therapeutic purposes. In France, E-cigarettes are sold either as medicines or consumer products. In Germany, nicotine-containing e-cigarettes are classified as tobacco related products. Non-nicotine e-cigarettes are considered as consumer products. In Japan non-nicotine

⁷ The document is available at https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1

⁸ Institute for Global Tobacco Control. Country Laws Regulation E-cigarettes: A policy Scan by the Global tobacco control Organization available at https://www.globaltobaccocontrol.org/e-cigarette/country-laws/view?field_policy_domains_tid%5B%5D=29&field_product_classifications_tid%5B%5D=45. The author has relied on the same to explore global regulatory approaches to e-cigarettes and used in this study.

⁹ *Ibid*

¹⁰ The UK Tobacco and Related Products Regulations 2016 implement the Tobacco Products Directive 2014/14/EU (TPD). The detailed procedure is provided at <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products>

¹¹ *Ibid*

¹² *Supra* note 9

e-cigarettes are currently unregulated. However, nicotine-containing e-cigarettes are classified and regulated as medicines under the Japanese Pharmaceutical Affairs Act and as of yet none have been approved.¹³ In Norway it is illegal to import and sell any product containing nicotine.

Parties where ENDS are banned per region

Region (Number of parties per region)	European (Total:50 parties)	African (Total: 44 parties)	Western Pacific (Total: 27 parties)	South East Asia (Total: 10 parties)	Americas (Total: 30 parties)	Eastern Mediterranean (Total: 19 parties)
Parties where ENDS are banned	Turkmenistan	Ethiopia Mauritius Uganda	Australia Brunei Cambodia Singapore	Korea (Democratic People’s Republic) Nepal Sri Lanka Thailand Timor-Leste	Brazil Mexico Panama Suriname Uruguay Venezuela	Bahrain Egypt Iran Jordan Kuwait Lebanon Oman Qatar Saudi Arabia Syria Unite Arab Emirates

Source-Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/8/10, 27 June 2018

As far as global approaches to regulating e-cigarettes is concerned, there is either absolute prohibition or stringent supervision of e-cigarettes.

¹³ The report is published by Knowledge-Action-Change, a company dedicated to the promotion of harm reduction to improve health, and funded through a grant from the Foundation for a Smoke-Free World. The report is available at <https://gsthr.org/countries/j-k/jp>

CONCLUDING REMARKS

In a biggest tobacco growing country like India which also produces tobacco products, the tobacco and cigarette sector industry, tobacco farmers have huge influence on government regulations in the name of loss of livelihood thus making stringent tobacco control measures difficult. The latest ordinance prohibiting e-cigarettes is a wise step taken by the Government of India to combat the potential e-cigarettes market before it becomes an important source of livelihood and its dangerous addiction. However, there is lack of evidence-based research and the long-term health effects of all types of e-cigarettes is not known. Given that the use of nicotine e-cigarettes has negative health effects, further studies on non-nicotine cigarettes making therapeutic claims are necessary to understand their public health implications better. In the absence of evidence, India could have adopted appropriate regulatory controls on the approval, sale, supply, use and promotion of e-cigarette devices making health claims rather than absolutely prohibiting them.