



To
The Under Secretary
Tobacco Control Department of Health and Family Welfare,
Room No - 414 'D', Nirman Bhawan,
New Delhi.

November 8, 2019

Dear Sir/Madam,

Re: "Public comments/views on Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Bill, 2019"

We are a registered consumer rights organisation that advocates for tobacco harm reduction as a public health strategy to combat the alarmingly high tobacco health burden of our country. We are a grassroots body that works with tobacco users from across the nation to disseminate information on risk reduction and to help them make an informed choice of transitioning to less harmful alternatives. This non-judgmental harm reduction approach is a well-accepted and proven intervention in treatment of opioid and other addictions, but has found stiff resistance in tobacco use due to vested interests despite affecting a lot more people and causing far greater population-level harm – there are 1.1 billion current smokers, 7 million of whom die prematurely every year.

AVI is globally recognised for its work and is part of international consumer advocacy efforts to cut tobacco death and disease. Following is our considered response to the proposed bill – specifically paras 1-6, sections 3(d) and 5, and missing provisions for consumer protection – which we believe will be highly detrimental to public health.

Background (India's tobacco problem)

As you are aware, India is reeling under a tobacco epidemic – 26.7 crore Indians (42.4% of men, 14.2% of women and 28.6% of all adults) use tobacco in some form, of whom 10.6 crore smoke, according to GATS-2 survey. Nearly a million Indians die every year from tobacco-related illnesses, with annual economic loss of over Rs 1 lakh crore, according to the Ministry of Health & Family Welfare.(1)

Though there was a 6% decline in tobacco use from 2010 to 2017 (GATS-1/2), at this rate it will be decades before use of tobacco is eliminated, during which time millions more Indians will die. India had the lowest quit rates among the countries surveyed in GATS-2 and despite the decline in use, the disease demography shows tobacco is becoming a bigger killer. Ischemic heart disease and chronic obstructive lung disease, both attributable to tobacco, ranked in positions 1 and 2 among causes of death in India in 2016, having ranked 6 and 8 respectively in the 1990s.(2) It should be noted that the disease burden associated with smoking is predicted to rise further in low- and middle-income countries (LMICs), which includes India.(3) This clearly shows that smoking and tobacco use is a public health priority in India, with urgent and effective measures needed to reduce the burden to society and the healthcare system.



The three state-sanctioned interventions – encouraging cold-turkey quit attempts, cessation services and counselling, and nicotine replacement therapy (NRT) – are not enough. Quit lines and media outreach have done little to change the overall 95% failure rate of willpower-led cessation. Tobacco cessation clinics remain woefully inadequate, with just 19 functional for a 27 crore user population.(4) The effectiveness of NRTs is also limited, hovering near 7%.(5)

Further, a recent study showed that a large majority of medical professionals in India have reported having insufficient experience to offer cessation assistance.(6) Additional barriers for smoking cessation include deeply ingrained cultural habits, tobacco use by healthcare professionals and limited motivation of physicians to document tobacco use and provide appropriate consultation.(7) Crucially, in 2018 a secondary analysis of cross-sectional data from nationally representative Household Consumer Expenditure Surveys (1999–2000; 2004–2005 and 2011–2012) found that India's National Tobacco Control Programme (NTPC) may not have produced reductions in tobacco use.(8)

Raising taxes also has limitations since cost increases above a certain threshold forces smokers to shift to cheaper, more harmful variants, thus causing more harm than good. High taxes also do little to limit uptake when the average cost of loose cigarettes (sold across the country despite bans in a few states) is extremely low.

Risk mitigation

It is hence imperative that we expand and intensify our tobacco control efforts. While continuing the interventions aimed at elimination of tobacco use, adequate focus has also to be laid on reduction in harm from tobacco by switching current users to lower-risk alternatives, including technology-driven e-cigarettes or Electronic Nicotine Delivery Systems (ENDS). This approach has been adopted by 65 nations worldwide (9), many of whom have since witnessed historic decline in smoking prevalence, including the US.(10)

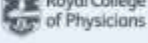
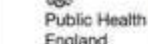
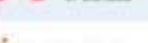
E-cigarettes are now the most popular method of assisted quit attempts in the United States, used in 35% of smokers' most recent quit attempts.(11) In the UK, where physicians prescribe ENDS to heavy smokers, there has been a sharp reduction in smoking prevalence.(12, 13) Along with the 9 million Americans who have quit smoking with ENDS, so have 2.9 million in the UK, 1.2 million in France, 1.5 million in Russia, 1.38 million in Italy, a million in Malaysia, 711,000 in Indonesia, 308,000 in Canada, and many more millions across the world.(14) According to Euromonitor, there are now over 40 million people have transitioned from smoking to e-cigarettes in a short span of under a decade, which is a tremendous public health gain.(15)

ENDS have also been found by credible institutions – Public Health England, Royal College of Physicians (UK), American Cancer Society, National Academies of Science Engineering & Medicine, US FDA, Health Canada, New Zealand Ministry of Health and many others – to be up to 95% less harmful than smoking as they eliminate combustion, which is recognised by WHO to be the main cause of harm as it produces tar and releases over 70 known carcinogens into the cigarette smoke. Following are some of their recommendations.



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Health organizations, agencies and governments that have reviewed the evidence on tobacco harm reduction	
	US National Academies of Sciences, Engineering and Medicine (NASEM): While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.
	US Food & Drug Administration: Make no mistake, We see the possibility for ENDS products like e-cigarettes to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that came with the combustion of tobacco.
	American Cancer Society: Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes.
	American Association of Public Health Physicians: Smokers unable or uninterested in quitting should consider switching to a less hazardous smoke-free tobacco/nicotine product [including] nicotine replacement therapy; electronic cigarettes; snus; other forms of moist snuff, and chewing tobacco.
	Royal College of Physicians: Available data suggest that e-cigarette health risks are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower. In the UK, harm reduction is a recognised element of comprehensive tobacco control. E-cigarettes are effective in helping people to stop smoking. There are as yet no identified health risks from second hand vapour.
	British Medical Association: There are clear potential benefits to e-cigarette use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use.
	British Lung Foundation: There's more evidence than ever that e-cigarettes are safer than smoking, and a way to give up altogether. Swapping cigarettes for an e-cig can improve your symptoms of lung conditions like asthma and COPD.
	Public Health England: Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, & of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know.
	Cancer Research UK: Evidence so far indicates e-cigarettes are far less harmful than tobacco and may help smokers to cut down or quit. We do not believe there is justification for an indoor ban, either on the basis of potential harm to bystanders from 2nd-hand vapour or that they renormalize smoking.
	Royal Society for Public Health: Endorses new Public Health England (PHE) report reflecting up-to-date evidence that is increasingly pointing in the same direction: not only is vaping at least 95% less harmful than smoking, but it is also helping increasing numbers of smokers to quit.
	Royal College of General Practitioners: The evidence so far shows that e-cigarettes have significantly reduced levels of key toxicants compared to cigarettes, with average levels of exposure falling well below the thresholds for concern.
	Cochrane Tobacco Addiction Group (Cochrane TAG): Electronic cigarettes may increase the chance of quitting smoking long term (and) no serious side effects were associated with their use (up to two years).
	Government of Canada: Vaping is less harmful than smoking. Adults can now legally get vaping products with nicotine as a less harmful option than smoking. Switching from tobacco cigarettes to vaping products will reduce a person's exposure to many toxic and cancer-causing chemicals.
	Truth Initiative: Some smokers may be unable or unwilling to quit using nicotine and would benefit by completely switching to a much lower harm nicotine delivery mechanism (including potentially a well-regulated e-cigarette).
	New Zealand Ministry of Health: The evidence on vaping products indicates they carry much less risk than smoking cigarettes. Vaping products could disrupt inequities and contribute to Smokefree 2025.
	Royal Australian & New Zealand College of Psychiatrists: Research shows that 70% of people with schizophrenia and 61% of people with bipolar disorder smoke compared to 16% of those without mental illness. E-cigarettes and vaporizers provide a safer way to deliver nicotine to those who are unable to stop smoking, thereby minimizing the harms associated with smoking tobacco and reducing some of the health disparities experienced by people with mental illness.
	Philippines House of Representatives: Voted unanimously to adopt a resolution promoting harm-reduction as part of its National Tobacco Control Strategy, particularly the use of electronic cigarettes as a less harmful alternative for smokers (August 2018).
	Drug and Alcohol Nurses of Australasia: E-cigarettes are a much safer alternative to smoking for those who are unable to quit with conventional therapies. DANA supports the use of e-cigarettes as a harm replacement tool or cessation aid for smokers who cannot quit with approved therapies, and supports low or no taxation on vaping products to maintain a price advantage to encourage smokers to switch.
	National Health Service Scotland consensus statement on e-cigarettes: Smoking kills. Helping people to stop smoking completely is our priority. There is now agreement based on the current evidence that vaping e-cigarettes is definitely less harmful than smoking tobacco. It would be a good thing if smokers used them instead of tobacco. <i>Created and endorsed by:</i> Action on Smoking & Health Scotland • Health Scotland • Cancer Research UK • Chest Heart & Stroke Scotland • Chief Medical Officer for Scotland • Directors of Public Health • Faculty of Public Health • NHS Ayrshire and Arran • NHS Greater Glasgow and Clyde • NHS Lathian • NHS Tayside • Royal Castle Lung Cancer Foundation • Royal College of General Practitioners • Royal College of Physicians of Edinburgh • Royal College of Physicians and Surgeons of Glasgow • Royal Environmental Health Institute of Scotland • Scottish Collaboration for Public Health Research and Policy • Scottish Consultants in Dental Health • Scottish Thoracic Society • UK Centre for Tobacco and Alcohol Studies • University of Edinburgh • University of Stirling



Moreover, the first major clinical trial into the effectiveness of ENDS as a smoking cessation method found them to be almost twice as effective as nicotine replacement therapies (NRTs) such as gums, lozenges and patches.(16)

Right to harm reduction

The concept of harm reduction is well-established and a proven intervention measure in substance abuse treatment. As Harm Reduction International notes, “The defining features are the focus on the prevention of harm, rather than on the prevention of drug use itself, and the focus on people who continue to use drugs.” This approach recognises that “people unable or unwilling to abstain from drug use can still make positive choices to protect their own health in addition to the health of their families and communities.” Harm reduction thus seeks to create an enabling environment for people who use drugs to protect their health and other human rights by providing them with evidence-based information, services, and resources.(17)

In India too, the harm reduction approach in drugs treatment is well-integrated into intervention policies, with free methadone distribution to opioid addicts and even through mobile clinics to make it easier for addicts to access harm reduction treatment.(18) On the other hand, while there is wide recognition that tobacco use also causes high level of dependence – in 1988, the US surgeon general's report on nicotine addiction declared nicotine to be as addictive as cocaine or heroin – tobacco intervention policies rely solely on willpower backed quit attempts, with NRT support unaffordable for most users, and little or no recognition for harm reduction strategies.

India's over 10 crore smokers therefore have an unalienable right to access accurate information on ENDS as well as the devices, which can mean the difference between life and certain death to them as smoking statistically kills over half of all users, and passive smoking causes 800,000 deaths worldwide every year.(19) ENDS have also been found to produce negligible second-hand harm.(20)

No Indian should be denied information or access to technology that can save their lives since the right to lead a healthier life, as well as the right to choice and life with dignity, are enshrined in our Constitution through Article 21. Banning ENDS thus violates the fundamental rights of citizens. It is also a serious case of spreading misinformation, and gravely detrimental to public health that a proven and globally adopted risk-mitigation tool is being denied to 11 crore Indian citizens.

Addressing teen use

It is unfortunate and irresponsible that despite clear empirical evidence that e-cigarettes are leading to rapid decline in smoking, their use is being framed in emotive terms and unsubstantiated fear is sought to be created about teen use. The claim that e-cigarettes will lead to smoking among teens is unfounded and there is little research to show ENDS act as gateway to smoking. A large study of 60,000 teen respondents in the UK found no evidence of the gateway theory.(21)

Indian courts have consistently taken a view against ENDS prohibition. First, the central advisory on ENDS was ruled to be nonbinding by Delhi high court.(23) Thereafter both the Delhi and Bombay high courts shot down ENDS bans, thus clearly indicating the wisdom of the courts against prohibiting a less harmful alternative to smoking.(24, 25) Recently, relief has also been granted by the Calcutta high court on the ordinance promulgated by the central government, and the matter is subjudice.(26) In view of accumulating legal precedence against prohibition of e-cigarettes, caution ought to have been exercised in banning the category.



Research ban

Despite the courts consistently taking a view against e-cigarette prohibition, despite available and mounting evidence on the harm reduction potential of e-cigarettes, and despite there being no primary research on e-cigarettes conducted in India to evaluate their relative risk compared to smoking, the health ministry has continued on the path of bans. Infact, an RTI-accessed file noting shows that Vikas Sheel, joint secretary, MOHFW, himself stated in June 2018, barely months before the health ministry advisory on banning ENDS, that: “The issue does not appear to have proceeded in a scientific and objective manner. We should arrive at a decision after thorough consideration, especially of the contrarian view”.(27)

A reasonable response to the absence of Indian research on e-cigarettes would have been to commission their scientific evaluation through local studies, especially in light of India’s burgeoning tobacco problem, low access to public healthcare among tobacco users, and e-cigarettes becoming the most popular means worldwide to quit smoking. Instead, the health ministry vide two circulars in May and August 2019 imposed a gag on ENDS research in centrally funded and National Board of Examinations (NBE)-accredited medical institutions and barred even consultations on the subject.(28, 29) This has created a fear among researchers of engaging in ENDS evaluation and has led to vacuum of information on the category.

The white paper on ENDS by Indian Council of Medical Research (ICMR) which proposes a ban has to be viewed in the context of this research gag as it was released a few weeks after the first circular and is indicative of the undue pressure being borne on state institutions. The paper relies on selective research to make a case against ENDS, without referring to any of the voluminous research available that shows the significant harm reduction potential of e-cigarettes, and even the research cited is from countries which have themselves not banned e-cigarettes. A detailed scientific critique of the ICMR paper has been published by international and Indian scientists.(30)

Therefore, in absence of and bar on hard scientific data, imposing a ban on life-saving technology goes against the goals of public health.

Benefit to tobacco companies

Soon after the health policy decision to ban e-cigarettes was announced by finance minister Nirmala Sitharaman, a surge was seen in the share prices of tobacco companies, clearly indicating whom the measure has actually benefited.(31) As a result of the ban, sale of the far more deadlier cigarettes is expected to rise thereby putting more lives in danger.

This protection given to tobacco companies at the cost of human health has also led to the questioning of state participation in tobacco trade. The Indian government’s significant 28% stake in the country’s largest cigarette maker, ITC, which makes 80% of the cigarettes sold in the country, and also another cigarette company VST, runs counter to its principle of protecting public health and puts into doubt its oft-stated goal of tobacco elimination – how is the state expected to end tobacco use when it itself participates in its trade?



The Indian government's participation in tobacco trade also violates Article 5.3 of WHO's Framework Convention for Tobacco Control (FCTC) treaty, to which India became a signatory in 2003. It is the same treaty which India is in direct violation of that it is now relying on to ban e-cigarettes thereby directly benefiting the tobacco companies it owns major stakes in.

In light of these circumstances, a ban on e-cigarettes which have led to accelerated decline in use of combustible cigarettes worldwide is not justified. Instead of the e-cigarette ban, the government should be expected to bear pressure on its tobacco trade partners to make a responsible shift towards risk-reduced alternatives to smoking, and incentivize such efforts in interest of public health to reduce the nearly 10 lakh annual deaths caused by smoking.

Paras 1-6 of proposed bill

The first six paragraphs lay out the reasoning for the bill. Following are our responses to each of these causes of action.

- 1) **Para 1 states the bill has been drafted "in the interest of public health and to protect people from harm":** This is an erroneous, misleading and unsubstantiated claim. No position has been staked by the Indian government or any other administration elsewhere that e-cigarettes are more harmful than traditional cigarettes, and even if the risk reduction was only 5%, there would have been no reasoning to ban them while allowing cigarettes on the market. Hence, harm reduction is well within the definition of public interest. Further, the prohibition of e-cigarettes cannot be categorized under "protecting people from harm" when an overwhelming number of its users are former smokers which has led to accelerated decline in smoking prevalence in nations where their use is permitted.

If the reference is specifically to protecting teens, the policy is discriminatory as it weighs the interests of one section of the population over another, especially when the user population numbers 11 crore and is highly vulnerable to death and disease caused by tobacco use.

In light of the available scientific evidence on e-cigarettes and cigarettes, it is also a slight to claim e-cigarettes are being banned because of their harm while allowing cigarettes to be sold, since it creates the impression that e-cigarettes are more harmful than smoking, which is entirely not the case.

- 2) **Paras 3-4 refer to the 2014 decision of the Conference of Parties (COP) on prohibiting or regulating e-cigarettes:** A COP is held every two years, with the 2014 one (COP6) held in Moscow. At the time, evidence available on ENDS was scant and hence a cautionary approach was proposed, which along with banning also included regulation. Since then, COP7 has been held in New Delhi and COP8 was held last year in Geneva which was chaired by India. Renewed position papers on ENDS based on updated scientific and empirical evidence have been presented at each of these COPs, with the latest one in 2018 focusing heavily on regulation.(9)



This is because a majority of FCTC member nations, 65, have since chosen to adopt the regulatory approach to ENDS instead of bans. It is therefore unjustified to rely on a 2014 FCTC decision when more updated decisions and policy recommendations, including one from a COP chaired by our country, are available.

Further, jurisprudence states that unless there is immediate and demonstrable harm, regulation is to be preferred over prohibition. E-cigarettes provide a risk-reduced alternative to smokers and have led to accelerated smoking declines in many nations. The bill itself recognizes there is no immediate and demonstrable harm to users since it does not ban the use of e-cigarettes. Further, the more harmful alternative, cigarettes, are regulated and not banned. There is hence a clear case for prudent regulation of e-cigarettes which ensures prevention of teen use while not denying adult smokers access to less harmful alternatives to smoking.

Moreover, harm reduction is a stated policy goal of the FCTC, enshrined in Article 1(d) in the very definition of tobacco control.(32)

- 3) **Para 5, referring to article 47 of Constitution, states e-cigarettes are injurious to health and have negative impact on public health:** Article 47 states “the state shall endeavor to prohibit the use of intoxicating substances, except for medical purpose, which are injurious to health.” While a simple reading of the provision may lead one to conclude it promotes prohibition, a careful assessment shows the provision is concerned largely with health damage and harms, and not taking a moralistic stance.

In the case of e-cigarettes, the health impact is far lower than from cigarettes and if all current smokers in India can be switched to noncombustible methods of getting their nicotine, the public health impact will be tremendously positive.

References have been made by health and ICMR officials to the vaping linked deaths in the US, and thereby stating that vaping can cause serious injury. This is a disingenuous claim. The cases have all occurred during a short span in 2019 and are localized to the US, while e-cigarettes have been around for over a decade and used by over 40 million people with no such cases reported earlier. The CDC has also since confirmed that over 77% of all reported cases are linked to the use of cannabis, or THC oil, and that too from the illegal market, while the US FDA has issued specific warning against the use of THC and illegal products.(33)

An e-cigarette ban will also lead to a black market in India, which while defeating the policy goal of preventing teen use, will put users of these devices further at risk in the absence of any quality control or product standards.

The current policy on smoking cessation, which in the absence of any quitting aid other than willpower-backed cold turkey attempts despite recognition that nicotine causes strong dependence, amounts to a moralistic ‘quit or die’ approach. There is inadequate appreciation that smokers need more than encouragement to wean off.



Providing them access to less harmful alternatives and encouraging a switch, as is being done by the National Health Service (NHS) in the UK, is a far more pragmatic intervention.

However, much worse is banning these alternatives and creating a false impression in the minds of smokers that they are more harmful since smoking is not banned while e-cigarettes are. The impact of such misleading policy will be felt for long as public impressions, once formed, take decades to reverse.

- 4) **Para 6 refers to respect for international treaty obligations:** The FCTC treaty, in its latest 2018 position on ENDS, imposes no obligation on the Indian government to ban e-cigarettes and infact lays emphasis on their regulation instead of prohibition. Further, it is rich on part of the government claim obligation to a treaty it is violating – through direct participation in tobacco trade despite strict prohibition on it vide Article 5.3 of the FCTC.

Section 3(d) of proposed bill

This section creates an unnecessarily wide and vague definition of electronic cigarette, including any “device that heats a substance to create an aerosol for inhalation”. This definition can include commonly available water heaters for nasal inhalation of local remedies for cold and cough. Are these also sought to be banned? Is any device that creates vapour, even water vapour, for inhalation also prohibited? Are wearable electronic air purifiers which process the polluted air for inhalation also banned? There is no justification for such an arbitrary ban and it is imperative that e-cigarettes be properly defined to defend against harassment of citizens.

Further, if the stated action is against nicotine inhalation, there is no justification to ban non-nicotine devices as there is no negative impact on public health or demonstrable injury. Prohibiting all forms of non-medical inhalation under an e-cigarette bill will create confusion and arbitrarily limit public choice.

No provision for consumer protection

The bill does not ban personal use of e-cigarettes but there is no indication to this effect in the bill. The only assurance given to public has been through a tweet by MOHFW.(34) A tweet is not adequate protection for consumers who are facing harassment by police and custom officials since the passing of the ordinance. It is therefore imperative that the bill clearly mention the provision on personal use of e-cigarettes.

Further, section 5 and others, while outlining the specific restrictions on e-cigarettes, including on storage, do not define what constitutes personal use. There is no mention in the bill on the quantities of e-liquids or the number of devices a person can possess without being categorized as a seller. These consumer protections are necessary to safeguard the public that have transitioned from smoking to e-cigarettes and wish to continue their use to protect their health.



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Additionally, while personal use has not been banned, no mechanism has been created for current users of e-cigarettes to avail these devices and components. We propose that a carveout be created in the bill for adult e-cigarette users to continue using these devices and not be forced back into smoking which has taken them a long struggle to quit.

We sincerely hope the above concerns, observations and recommendations will be considered by the ministry before taking any action on the proposed bill since the decision impacts the wellbeing of crores of Indian citizens.

Kind Regards

Samrat Chowdhery
Director
Association of Vapers India



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