Regulating E-Cigarettes

The introduction of electronic cigarettes (or e-cigarettes) in countries around the world poses new challenges to governments wanting to protect youth and reduce tobacco use. Policies governing e-cigarettes must be guided by an assessment of the impact of these products on the pace of progress in reducing the death and disease caused by tobacco use.

The evidence around the health harms from e-cigarettes and their impact on young people is evolving. Any assessment of the evidence has to consider the impact on both individual smokers and the population as a whole. While e-cigarettes may have health benefits to individual smokers if they are proven to help smokers quit completely, they are nevertheless harmful to public health if they lead to more young people starting, if they renormalize tobacco use, and/or if they discourage smokers from quitting.

The World Health Organization has concluded that e-cigarettes are "undoubtedly harmful" and that countries "that have not banned [e-cigarettes] should consider regulating them as harmful products." [1] This is consistent with the general obligations of the WHO Framework Convention on Tobacco Control, which require Parties to the Convention to implement measures for preventing and reducing nicotine addiction. [2] In the absence of effective government regulation, e-cigarettes could create a new generation of nicotine and tobacco users and undermine the progress made in combatting the tobacco epidemic.

This policy brief uses a three-step process to assist government officials in determining how to regulate e-cigarettes to fit their country circumstances while balancing competing public health considerations:

GOALS

1. PURSUE PUBLIC HEALTH POLICY GOALS

The public health policy goals for any government regulating e-cigarettes should be to:

1.1 Prevent e-cigarette use by non-smokers, particularly youth

1.2 Minimize potential health risks to e-cigarette users and non-users

1.3 Prevent e-cigarettes from undermining progress in reducing tobacco consumption and nicotine addiction

1.4 Protect public health policy from the commercial interests of the tobacco and e-cigarette industries

1.5 Assist smokers to quit and avoid dual use

ASSESS

2. ASSESS COUNTRY CIRCUMSTANCES

2.1 Current status of tobacco control measures

2.2 Trends in smoking rates

2.3 Existing market for e-cigarettes

OPTIONS

3. SELECT REGULATORY OPTION

3.1 Complete ban

3.2 Regulate as medicinal product

3.3 Regulate strictly using tobacco control measures

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1   PURSUE PUBLIC HEALTH POLICY GOALS

The reasons and evidence supporting the public health policy goals are set out below.

1.1   Prevent E-Cigarette Use By Non-Smokers, Particularly Youth

Youth and young adult use of e-cigarettes

- The use of nicotine in any form by youth, including e-cigarettes, is unsafe, causes addiction and can cause harmful changes to the developing adolescent brain.[3]

- Many countries have experienced patterns of high e-cigarette use by young people including in the U.S. and some European countries.[4,5,6] In the U.S. one in four high school students is now an e-cigarette user.[7]

- According to the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM), there is substantial evidence that youth and young adults who initiate e-cigarette use are at greater risk of ever using conventional cigarettes.[8]

Marketing and sales practices target young people

- Youth use of e-cigarettes is impacted by several factors, including flavorings, nicotine delivery, industry marketing, and the nature and extent of government regulation.

- E-cigarette industry marketing follows the tobacco industry's playbook, including the use of social media, to reach young people.[3,9]

- Recent market trends show an increase in sales of e-cigarettes that deliver high levels of nicotine more efficiently and with less irritation, making it easier for young people to initiate use and develop addiction.[10]

- The industry targets youth with sweet and fruit flavored products. Research shows adolescents consider flavor as the most important factor when trying e-cigarettes and are more likely to initiate e-cigarette use with flavored products.[11]

1.2   Minimize Potential Health Risks To E-Cigarette Users And Non-Users

- E-cigarette emissions contain nicotine and other harmful constituents, including 80 compounds such as acetaldehyde (possible carcinogen), formaldehyde (known carcinogen), acrolein (toxin) and metals such as nickel, chromium and lead.[8]

- There is currently insufficient evidence to quantify the absolute risk of harm from e-cigarette use or the level of harm compared to conventional cigarettes.[8]

- The health impacts of long-term e-cigarette use are not yet clear.[8]

- Because more research is needed before potential harms to bystanders are known,[3] non-users should not be exposed to secondhand aerosol emissions.

- A wide variety of products are currently available with differing nicotine concentrations, e-liquid contents, and device features, which makes it difficult to ensure product safety.[3,12]

1.3   Prevent E-Cigarettes From Undermining Progress In Reducing Tobacco Consumption And Nicotine Addiction

- At a time when many countries are seeing significant reductions in youth tobacco use, e-cigarettes are creating a new generation of nicotine addicts. One example of this is the US, where there is a youth 'epidemic' of e-cigarette use.[13]

- According to the U.S. NASEM, there is substantial evidence that e-cigarette use increases the risk of smoking initiation among youth and young adults.[8]

- Public health organizations raise concerns that e-cigarette use will re-normalize smoking behaviors.[3,14]

- Industry marketing practices explicitly include re-normalizing nicotine consumption, depicting recreational use of e-cigarettes, including in indoor venues.[15]

1.4 Protect Public Health Policy From The Commercial Interests Of The Tobacco And E-Cigarette Industries

- E-cigarette manufacturers have a profit motive, not a public health motive. Their primary goal is to sell as many products as possible and maintain or grow their customer base.

- Tobacco companies have made significant investments in the global e-cigarette market,[1] raising serious concerns given their history of targeting youth, deceiving the public about the consequences of tobacco use and the nature of nicotine, and fighting against proven tobacco control measures.

- Tobacco companies' investments in the global e-cigarette market come at a time when global cigarette consumption has been steadily declining since 2012 and is forecasted to continue falling.[16]

- Industry investments in e-cigarettes can be interpreted as a strategic business decision to compensate for a shrinking customer base.

- The major tobacco companies all include e-cigarettes in revised marketing and lobbying strategies[17] in an attempt to increase their influence and credibility in policy and regulation decisions.[18]

- E-cigarette manufacturers, including the major tobacco companies, are spending millions of dollars on lobbying law makers in countries around the world, to seek favorable e-cigarette regulation.[19]

- Like research funded by cigarette companies, research funded by e-cigarette interests produced results that showed e-cigarettes as less harmful. Work not funded by industry showed higher dangers.[20]

1.5 Assist Smokers To Quit And Avoid Dual Use

- According to the U.S. NASEM, there is substantial evidence that completely switching from conventional cigarettes to e-cigarettes results in reduced short-term negative health outcomes, and conclusive evidence that completely switching reduces users' exposure to many toxicants and carcinogens present in conventional cigarettes.[8]

- Some smokers report using e-cigarettes to quit nicotine entirely. Other smokers have quit smoking but continue to use e-cigarettes.[21] However, several countries report a high level of dual use of e-cigarettes and conventional cigarettes.[22]

- Some governments and public health organizations have concluded that there is the potential for significant public health benefits if e-cigarettes can assist large numbers of smokers to stop using conventional cigarettes.[21] Those governments have sought to encourage existing smokers to switch to e-cigarettes through public messaging campaigns[23] or by lifting a previous ban to permit their sale.[24]

- However, many other governments and organizations have concluded there is insufficient evidence to support the use of e-cigarettes as a population-level tobacco cessation intervention, including when compared to medicinal nicotine therapy products.[1,8]

- Smokers who continue to smoke, even if they smoke fewer cigarettes per day, and also use e-cigarettes (dual use) will increase their individual risk if this delays or prevents cessation.[8]

- There is no e-cigarette on the market that has been medicinally licensed as a smoking cessation aid anywhere in the world.[25]

2   ASSESS COUNTRY-SPECIFIC CIRCUMSTANCES

In determining the best approach for e-cigarette regulation in a particular country, relevant country-specific circumstances include: tobacco control measures already in place, current smoking rates, and the scale of any existing market for e-cigarettes.

2.1   Current Status Of Tobacco Control Measures

Comprehensive tobacco control strategies in all WHO Framework Convention on Tobacco Control (FCTC) policy areas are proven to reduce tobacco use. These measures encourage and assist smokers to quit while also preventing young people from initiating tobacco use. Fully implementing WHO FCTC measures and giving them time to produce results is the most effective approach for reducing tobacco use and nicotine addiction.

Allowing the sale and marketing of e-cigarettes may undermine these proven strategies and in particular risks youth initiation of e-cigarettes and their transition to tobacco products, as well as dual use by existing smokers which could deter quit attempts.

If comprehensive WHO FCTC measures for tobacco products have not yet been fully implemented, governments should consider a ban on e-cigarettes. This would allow time to maximize the number of people who quit smoking completely while avoiding the risk of creating a new generation addicted to nicotine and the other risks associated with e-cigarettes.

2.2   Trends In Smoking Rates

If comprehensive tobacco control strategies have been or are being implemented and smoking rates are falling, allowing e-cigarettes onto the market may undermine that progress. Governments could consider a ban on e-cigarettes to allow as many people to quit as possible as a result of evidence-based tobacco control strategies.

If smoking rates have declined following the implementation of comprehensive strategies but the decline has stalled and if there are indications that e-cigarettes would assist the remaining smokers to quit, governments could consider allowing the sale of e-cigarettes, strictly regulated using tobacco control measures as described in the Annex. However, the benefit to smokers who may quit smoking using e-cigarettes would need to be weighed against concerns that young people may be attracted to and begin to use e-cigarettes, and that existing smokers may start to use e-cigarettes as well and delay quit attempts.

2.3   Existing Market For E-Cigarettes

If there is currently a limited market for e-cigarettes, governments could consider banning their sale before they become established in the population.

On the other hand, if there is already a well-established adult market for e-cigarettes a ban might be impractical and potentially raises concerns about creating a black market. Under these circumstances, governments would consider strict regulation using tobacco control measures (as outlined in the Annex) rather than a ban. This would require a government to assess what form of regulation it is best able to enforce.
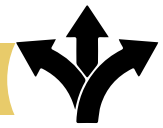
3   SELECT REGULATORY OPTION

Taking into account the policy goals and country-specific circumstances, we recommend policy makers consider the following three approaches:

3.1   Complete Ban

E-cigarettes may not be manufactured, imported, or sold.

Factors in favor of this option:

- There is a limited existing market in e-cigarettes.
- Strong WHO FCTC measures not yet in place for reducing and preventing tobacco use, or measures are in place but need more time to take effect.
- The precautionary principle: there is significant scientific uncertainty about the overall risks and potential benefits of e-cigarette use, although there is certainty that nicotine products are harmful to youth. Therefore, a ban could be justified until more research and information is available.

At least 24 countries/jurisdictions ban e-cigarettes: Argentina, Brazil, Brunei, Cambodia, Ethiopia, Gambia, India, Iran, Lebanon, Macau, Mauritius, Mexico, Oman, Panama, Qatar, Singapore, Sri Lanka, Suriname, Syria, Thailand, Timor-Leste, Turkmenistan, Uganda, and Uruguay.

3.2   Regulate As Medicinal / Therapeutic Products

Specific e-cigarettes are only allowed for sale if the individual product has been approved as a medicinal or therapeutic product under a country's established medical/drugs regime.

Factors in favor of this option:

- Limited existing market in e-cigarettes – regulating as medicinal products would remove all existing products from the market unless or until any were granted a medicinal license.
- Smoking rates are steadily declining as a result of implementing tobacco control measures.
- Robust medicinal/therapeutic approval process exists.
- The government has concluded that evidence shows e-cigarettes hold significant potential as smoking cessation aids.
- The government has sufficient resources to undertake case-by-case assessments taking into account the variety of e-liquids and devices and the different toxic emissions of e-cigarettes.

At least 7 countries/jurisdictions permit the sale of e-cigarettes <u>only</u> under a medicinal or therapeutic product license: Australia, Chile, Hong Kong, Japan, Malaysia, Taiwan, and Venezuela.

*In these countries, this amounts to a **de facto ban** on sales because there are currently no e-cigarettes being sold that have been medicinally licensed as a smoking cessation aid.*

3.3   Regulate Strictly Using Tobacco Control Measures

E-cigarettes are subject to requirements that align with the WHO FCTC.
The Annex sets out recommendations on how to apply these measures to e-cigarettes.

Factors in favor of this option:

- There is a well-established existing market in e-cigarettes.
- Strong WHO FCTC measures are in place for reducing and preventing tobacco use, have had time to take effect, and the effects are being monitored.
- Declines in smoking rates have stalled and prevalence remains at an unacceptable level.
- The government has concluded that evidence shows e-cigarettes hold significant potential as smoking cessation aids for their remaining smokers.
- The government has sufficient resources and a strong commitment to government messaging about the appropriate use of e-cigarettes, as well as the capacity for ongoing monitoring and enforcement, particularly with regard to youth uptake.

At least 47 countries regulate e-cigarettes using tobacco control measures: 28 countries of the European Union (EU), as well as Albania, Azerbaijan, Belarus, Canada, Cote D'Ivoire, Georgia, Guyana, Iceland, Israel, Moldova, Montenegro, New Zealand, Norway, Rep. of Korea, Saudi Arabia, Tajikistan, Tunisia, United Arab Emirates, and United States.

Not all of these countries apply the laws in the same way to e-cigarettes as they do to conventional tobacco products. There are variations among these countries as to the level and nature of the restrictions on public use, advertising, health warnings, content restrictions, sales and access, and taxation.

OPTIONAL. Some of these countries require manufacturers to apply for a license/approval to sell a particular e-cigarette as a medicinal/therapeutic product if:

- A manufacturer wants to make a claim that the e-cigarette could be used as a cessation or quit aid; or
- An e-cigarette or e-liquid has a nicotine concentration above a certain threshold.

This option should only be considered if a robust medicinal/therapeutic approval process exists. There are currently no e-cigarettes being sold that have been medicinally licensed as a smoking cessation aid.

Further details on countries' existing laws regulating e-cigarettes are available at www.tobaccocontrollaws.org.

ANNEX

Specific Recommendations for Regulating E-Cigarettes Using WHO FCTC Measures

If governments determine that the most appropriate way to regulate e-cigarettes is to use their tobacco control measures, the key WHO FCTC-based tobacco control measures should be applied to both e-cigarettes and tobacco products. WHO FCTC-based measures should be supplemented by clear government messages on the risks of e-cigarette use, that e-cigarettes should only be used by existing smokers, and that the best approach for smokers is to quit all tobacco and nicotine use or if that is not possible, to completely switch to using e-cigarettes.

WHO FCTC-based measures, as applied to e-cigarettes, include:

Restrictions On Public Use*

- Prohibit the use of e-cigarettes in all indoor public places, workplaces, public transport, and other smoke-free places.

Health Warnings And Packaging

- Require prominent, effective and scientifically accurate rotating health messages and warnings on all e-cigarette packaging.
- Apply plain packaging to e-cigarettes.
- Prohibit packaging and labeling that is false, misleading or likely to create erroneous impressions about health effects or toxicity.
- Prohibit health claims and cessation claims.

Prohibition On Advertising, Promotion And Sponsorship

- Apply a comprehensive ban on all e-cigarette advertising, promotion and sponsorship, including point of sale advertising and displays, cross border advertising, and internet promotion.

Content Restrictions

- Prohibit flavors other than tobacco flavor.
- Consider mandating a maximum nicotine concentration. All 28 EU countries, Albania, Iceland, Israel, Moldova, Montenegro, and Saudi Arabia set a maximum concentration of 20 mg/ml in e-liquids to prevent products with a higher addiction potential from being sold.
- Prohibit ingredients that make the products more attractive, such as caffeine and vitamins.

Sales And Access Restrictions

- Prohibit sales to persons below a specified minimum age, sales via vending machines, the internet or other remote means, and sales in or near schools and health facilities.

Taxation

- Tax e-cigarettes in the same way as tobacco products using ad-valorem tax (% of cost), specific tax (fixed amount per volume) or a combination of both.
- Tax at a rate that deters youth and non-smokers from using e-cigarettes.

*In countries that require manufacturers to apply for a license to sell a particular e-cigarette as a medicinal/therapeutic product under certain circumstances, those products would be regulated under the medicinal regime, not the tobacco control regime. However, the use of all e-cigarettes should be prohibited in indoor public places, workplaces, and public transport.

REFERENCES

1. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.
2. WHO Framework Convention on Tobacco Control, Article 5.2(b).
3. U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General–Executive Summary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
4. CDC. Global Youth Tobacco Survey (GYTS), various countries. More data available from: www.cdc.gov/tobacco/global/gtss/gtssdata/index.html.
5. Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2018;67:1276–1277. DOI: http://dx.doi.org/10.15585/mmwr.mm6745a5.
6. CDC. Global Youth Tobacco Survey (GYTS), Italy 2014 and 2018. Data available from: www.cdc.gov/tobacco/global/gtss/gtssdata/index.html.
7. Preliminary results from the 2019 National Youth Tobacco Survey (NYTS) show that 27.5% of high school students used an e-cigarette in the last 20 days. This is a substantial increase from 20.8% in 2018 and 11.7% in 2017. U.S. Food & Drug Administration News Release, September 11, 2019. Available at: www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.
8. National Academies of Sciences, Engineering, and Medicine. 2018. Public health consequences of e-cigarettes. Washington, DC: The National Academies Press. Available at: http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx.
9. U.S. Surgeon General, "Know the Risks: E-cigarettes & Young People". Available at: https://e-cigarettes.surgeongeneral.gov/.
10. Jackler RK, Ramamurthi D. Nicotine arms race: JUUL and the high-nicotine product market. Tobacco Control. Published Online First: 06 February 2019. doi: 10.1136/tobaccocontrol-2018-054796; and Goldenson NI, Leventhal AM, Stone MD, McConnell RS, Barrington-Trimis JL. Associations of Electronic Cigarette Nicotine Concentration With Subsequent Cigarette Smoking and Vaping Levels in Adolescents. JAMA Pediatr. 2017;171(12):1192–1199. doi:10.1001/jamapediatrics.2017.3209
11. Zare S, Nemati M, Zheng Y. A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type. PLoS One. 2018;13(3):e0194145. Published 2018 Mar 15.
12. Romberg AR et al. Patterns of nicotine concentrations in electronic cigarettes sold in the United States, 2013-2018. Drug and Alcohol Dependence. Vol 203 p 1-7. October 2019. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0376871619302571?via%3Dihub.
13. FDA News Release, September 11, 2019, Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products. Available at: www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.
14. Wilson N et al., Should e-cigarette use be included in indoor smoking bans?, Bulletin of the World Health Organization 2017, 95:540-541. doi: http://dx.doi.org/10.2471/BLT.16.186536
15. Stanwick R. E-cigarettes: Are we renormalizing public smoking? Reversing five decades of tobacco control and revitalizing nicotine dependency in children and youth in Canada. Pediatr Child Health. 2015 Mar; 20(2):101-105.
16. GlobalData market analyzers online database. Accessed August 2, 2019.
17. WHO FCTC Knowledge Hub on Article 5.3. "Dangers of the 'Unsmoke' Campaign: Frequently Asked Questions". Available at: https://untobaccocontrol.org/kh/article-53/dangers-un-smoke-campaign-frequently-asked-questions/.
18. Mathers et al., Transnational Tobacco Companies and New Nicotine Delivery Systems, February 2019, vol109, No. 2 AJPH.
19. Filings held on opensecrets.org show JUUL spend $1.6million on federal lobbying in 2018 www.opensecrets.org/lobby/clientsum.php?id=D000070920&year=2018; and reports indicate JUUL spent over $2million in the first half of 2019. Meyer, T, "Nickles will lobby for Juul," Politico, July 29, 2019, www.politico.com/newsletters/politico-influence/2019/07/29/nickles-will-lobby-for-juul-462611.
20. Pisinger, Charlotta & Godtfredsen, Nina & Bender, Anne. (2018). A conflict of interest is strongly associated with tobacco industry–favourable results, indicating no harm of e-cigarettes. Preventive Medicine. 119. 10.1016/j.ypmed.2018.12.011.
21. McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England.
22. For example: in the UK in 2018, 44.2% of current e-cigarette users were smokers, ASH Smokefree GB Survey 2018; In Canada in 2017, 64.5% of current e-cigarettes users were smokers. Reid JL, Hammond D, Tariq U, Burkhalter R, Rynard VL, Douglas O. Tobacco Use in Canada: Patterns and Trends, 2019 Edition; In the United States in 2015, 58% were current users of both products. Mirbolouk, M, et al., "Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016," Annals of Internal Medicine, published online August 28, 2018.
23. In 2018 in the UK, the National Health Service ran a public campaign "Stop Smoking with and E-Cigarette in 2018." The NHS Website gives e-cigarettes as one type of quit aid. Available at: https://www.nhs.uk/oneyou/for-your-body/quit-smoking/using-e-cigarettes-vapes-to-quit-smoking/.
24. In Canada, e-cigarettes containing nicotine were unlawful until May 2018 when a new law permitted their sale, along with advertising and promotion with some limited restrictions on advertising that would appeal to youth. The Tobacco and Vaping Products Act 2018.
25. McNeill A, Brose LS, Calder R, Bauld L & Robson D (2019). Vaping in England: an evidence update February 2019. A report commissioned by Public Health England. London: Public Health England.