Safeguarding Public Health: Strict Regulation of Electronic Smoking Devices

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About SEATCA
SEATCA is a multi-sectoral non-governmental alliance promoting health and saving lives by supporting ASEAN countries to accelerate and effectively implement the evidence-based tobacco control measures contained in the WHO Framework Convention on Tobacco Control. Acknowledged by governments, academic institutions, and civil society for its advancement of tobacco control in Southeast Asia, the WHO bestowed upon SEATCA the World No Tobacco Day Award in 2004 and the WHO Director-General’s Special Recognition Award in 2014. SEATCA is an official NGO Observer to the WHO FCTC Conference of Parties and a co-initiator of the Global Center for Good Governance in Tobacco Control (GGTC).

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Key Messages

• **Electronic Smoking Devices (ESDs) pose significant health risks**: exposure to harmful chemicals and their potential long-term consequences, maintenance of nicotine addiction, reduced smoking cessation, uptake among children and adolescents, risk of poisoning, and physical injuries from burns and explosions.

• **Product development and marketing strategies employed by the tobacco and nicotine industry**, including attractive design, flavors, and packaging, and the use of social media and influencer collaborations, along with social pressure and easy access, **have increased initiation and regular use of ESDs among the youth and never-smokers**.

• **The current regulatory landscape for ESDs varies globally**, with at least 40 countries **banning them** and others implementing restrictions, but challenges in enforcement, technological advancements, and regulatory gaps persist.

• **Effective regulation is essential to address the public health problem of ESDs**, including completely prohibiting these products or restricting them through measures such as flavor bans, tax and price measures, comprehensive marketing bans, pictorial health warnings, access restriction, and expansion of smoke-free restrictions to cover ESDs.
Introduction

This policy paper addresses the growing concerns surrounding Electronic Smoking Devices (ESDs) and advocates for their regulation by prohibition or restriction to protect public health. ESDs include a diverse array of products like e-cigarettes and heated tobacco products. Given their rapid proliferation and wide variety, there is an urgent need to regulate these devices to address the harms and risks associated with their use.

While manufacturers would like policymakers and the public to believe that ESDs are a 95% safer alternative to traditional cigarettes and can aid in smoking cessation, a large and growing body of evidence has challenged and disproven these claims. Public health experts also highlight the limitations in the available evidence used to arrive at this conclusion and the complexities of comparing ESDs to combustible tobacco in terms of relative harm, particularly for long-term daily use. A more crucial consideration are the added health risks of ESD use compared to non-use.

Studies have revealed that ESD aerosols contain, in addition to nicotine, harmful chemicals such as heavy metals, volatile organic compounds, and ultrafine particles, which can damage the lungs and heart. The detection of these substances in ESD emissions raises significant concerns about the acute and long-term impact of ESDs on health.

The industry’s false narrative of tobacco harm reduction, reinforced by enticing flavors (such as fruits and sweets), stylish product designs, and aggressive marketing, often targeting young people through social media platforms and other channels, has driven the rapid increase in prevalence of ESD use, particularly among youths. This has led to a surge in nicotine addiction among teens, who may not have otherwise started smoking, sparking concerns about the normalization of nicotine use and long-term consequences on their health and well-being. Studies have shown that young people, who use ESDs, are more likely to transition to conventional cigarette smoking and other addictive substances. To protect public health, it is vital to consider this potential gateway effect of ESDs, whereby non-smoking youth are introduced to nicotine addiction.

By taking decisive actions to regulate the manufacture, marketing, sale, and use of ESDs, policymakers can better prevent youth initiation to nicotine addiction and mitigate the risks posed by ESDs to public health.
Overview of Electronic Smoking Devices

Electronic smoking devices (ESDs) encompass a range of electronic products designed to deliver nicotine and other chemicals through aerosol inhalation. Electronic Nicotine Delivery Systems (ENDS), such as e-cigarettes or vapes, typically consist of a battery, a heating element, a cartridge/tank with e-liquid, and an atomizer that converts the e-liquid into an inhalable aerosol. Vape pens, pod systems, and mods are variations of ESDs that offer different features and customization options.¹

Vape pens, pod systems, and mods are variations of ESDs that offer different features and customization options. These devices have gained substantial popularity due to their perceived modernity, convenience, and the illusion of a safer alternative to traditional smoking. Heated tobacco products (HTPs), on the other hand, are another category of ESDs that use an electronic device to heat specially prepared tobacco sticks or loose tobacco leaf, sometimes in combination with e-liquid.² These products also release an aerosol that is closer to tobacco smoke, with a higher amount of fine and ultrafine particles than e-cigarettes.³

ESDs carry various risks and harms that necessitate strict regulation:

1. The health effects of ESD use and potential long-term consequences: ESD aerosols are not simply harmless water vapor; they contain fine and ultrafine particles and harmful chemicals including nicotine; cancer-causing, tobacco-specific nitrosamines; formaldehyde; acetaldehyde; acrolein; metals, such as lead, chromium, and nickel; and flavoring chemicals, sometimes with toxicant concentrations equal to or greater than traditional cigarettes under normal conditions of use.⁴

2. Maintenance of addiction and risks of dual use: The nicotine in ESDs is addictive and merely transitioning to these products does not address the addictive nature of nicotine. Studies show that a large proportion (often a majority) of smokers, who use ESDs to quit smoking become dual users or concurrently use ESDs and traditional cigarettes. Smokers end up continuing or even escalating their cigarette use with ESDs. Such dual use undermines quit attempts, increases risk of smoking relapse among former smokers, and increases health risks compared to smoking cigarettes only.⁵, ⁶, ⁷, ⁸, ⁹

3. Particular risks for youth and pregnant women: ESD use among youth has reached epidemic proportions in some jurisdictions where these are sold legally. Nicotine exposure before and during adolescence can have detrimental effects on brain development, affecting cognition, attention, and impulse control. Nicotine exposure during adolescent brain development can lead easily to addiction, disease, and disability in early adulthood.¹⁰ ESDs have also been shown to be a gateway for youths to conventional cigarette smoking and other addictive substances.¹¹, ¹² Pregnant women who use ESDs expose themselves and their unborn babies to potential risks, as nicotine and other chemicals can interfere with fetal development.¹³

4. Harms from secondhand smoke/aerosol: Secondhand exposure to ESD aerosol can result in the inhalation of nicotine, particulate matter, and other harmful chemicals. This poses risks to bystanders, particularly in indoor environments where ventilation is limited. Infants, children, and individuals with respiratory conditions may be more vulnerable to the effects of secondhand ESD aerosol.¹⁴, ¹⁵, ¹⁶

5. Risk of poisoning: Nicotine poisoning is another significant concern associated with ESDs, especially when e-liquids with high nicotine concentrations are mishandled or ingested. E-liquids typically come in sweet and fruity flavors/aromas and bright colors, and may even resemble candies or beverages, enticing young children to ingest them. Nicotine poisoning can cause nausea, vomiting, increased heart rate, and even seizures and death in severe cases.¹⁷, ¹⁸, ¹⁹, ²⁰, ²¹, ²²
6. **Physical injuries from burns and explosions**: E-liquids are flammable. When used in faulty ESDs or when ESDs are powered by faulty lithium-ion batteries, fires or explosions can occur. Serious physical injuries to users, such as burns and skull fractures, and at least two deaths have been reported in these instances.\(^{23, 24}\) A seventeen-year-old Filipino teen sustained severe facial and cranial injuries from an exploded e-cigarette.\(^{25}\)

### Marketing Tactics and Appeal to Youth

**a. Marketing strategies by the industry**

Marketing strategies of the tobacco and nicotine industry have profoundly increased the appeal of ESDs to the youth. Advertising techniques, including product placements and use of social media influencers, have successfully captured the attention of this target demographic. The design, flavors, packaging and accessibility of ESDs contribute to their appeal, and combined with peer pressure, social misperception of ESDs as relatively safe, resulted in increased experimentation and initiation among young individuals.

**Advertising techniques, promotional campaigns, product placements**

The tobacco and nicotine industry has utilized various marketing strategies to promote their products. One common technique is through advertising, where companies employ creative and persuasive tactics to attract potential consumers. Teens exposed to e-cigarette advertising are more likely to use e-cigarettes, cigarettes, and cigars just one year later.\(^{26}\)

Moreover, promotional campaigns are launched to associate ESDs with a certain lifestyle, targeting specific demographics, such as adolescents. Product placements in movies, TV shows, and music videos have also been used to increase visibility and desirability of ESDs among the youth.

**Use of social media, influencers**

The industry has effectively leveraged social media platforms to reach a wider audience, particularly the youth. Social media allows for targeted advertising and direct engagement with potential consumers. ESD manufacturers often collaborate with influencers to promote their products. These influencers create content showcasing ESDs in a positive light, associating them with a trendy and desirable lifestyle. By utilizing social media and influencers, ESD companies can effectively bypass traditional advertising regulations, maximize visibility, and reach a younger audience.
One of the reasons ESDs have gained popularity among the youth is their appealing design, flavors, and packaging. ESDs are often sleek, compact, and resemble everyday items like USB drives or pens, making them easily concealable and creates the perception of ESDs as fashionable or high-tech. Additionally, a wide range of flavors, such as fruit, candy, and sweets, are available, which can be enticing to the youth who may find these flavors more appealing than traditional tobacco products. The attractive packaging, resembling popular consumer products like candies or energy drinks, contributes to the overall appeal and may encourage experimentation and regular use among the youth.

Peer pressure and social norms have a profound impact on young people, who are more likely to try ESDs if they perceive ESD use as a common behavior in their social circles. The portrayal of ESDs as fashionable or socially acceptable contributes to the perception that their usage is widespread and desirable. Consequently, the desire to conform and be regarded as cool or stylish can drive young individuals to experiment with ESDs, regardless of their awareness of the associated health risks.
The easy access and affordability of ESDs have also contributed to their appeal among the youth and increased the likelihood of youths trying and initiating ESD use. ESDs are widely available in various retail locations, including convenience stores and online platforms, making them easily accessible to young individuals. Their relatively low cost compared to traditional tobacco products can make ESDs seem more affordable and attractive to the youth, who may have limited financial resources.

c. Impact of ESD marketing on youth initiation and addiction

Exposure to e-cigarette advertising and marketing has been found to be associated with subsequent e-cigarette use among youth and young adults in the US. Youths are constantly exposed to social media and one platform that has seen a surge in e-cigarette promotion is TikTok. Exposure to tobacco or nicotine posts on TikTok and other social media platforms has been associated with use of e-cigarettes among adolescents and young adults.

A recent study found that there is significant presence of pro-vaping content on TikTok and the current policies of the social media platform are not sufficient or properly enforced to restrict e-cigarette promotion. It further revealed that an overwhelming majority of e-cigarette related videos (97.7%) on TikTok portrays it positively. In the US, research showed that high school students in the US who use TikTok several times per day were more likely to initiate the use of e-cigarettes.

Current Regulatory Landscape

Most existing regulatory frameworks were developed for traditional tobacco products, before the rapid and massive proliferation of new technologies, product designs, and delivery systems in the ESD industry. These advancements have outpaced the ability of regulators to respond effectively, leaving gaps in regulations. For example, some manufacturers may alter product components or introduce newer ESD variants to circumvent specific restrictions, rendering existing regulations ineffective.

The industry has also marketed these products as being different from traditional tobacco products, leading to confusion about the best way to regulate these newer products. Globally, the various approaches to regulate ESDs range from outright bans to specific restrictions to no regulation.

Over 40 countries and jurisdictions have banned ESDs. In the ASEAN, ESDs are banned in Brunei, Cambodia, Lao PDR, Singapore, and Thailand. The challenge for these countries is to update and refine this policy continually and address enforcement issues, such as illicit trade and online promotion and sales.

Other countries regulate ESDs as tobacco products, pharmaceuticals, or poison, or have introduced ESD-specific regulations that encompass multiple aspects of ESD production and use, considering factors like nicotine content, product labeling, and manufacturing standards. These regulations often include age restrictions, mandatory health warnings on packages, restrictions on advertising and promotion, restrictions on public use, and prohibition on certain flavors.
a. Regulatory approaches from selected jurisdictions

**Singapore** has prohibited the importation and sale of imitation tobacco products since 2011; this applies to ESDs. In 2017, it extended the ban to cover purchase, distribution, use, possession, advertising, promotion, and sponsorship of ESDs.  

The government’s rationale behind this approach is to prevent the normalization and potential uptake of e-cigarettes among the youth. The government also considers these products as a potential gateway or “starter product“ that hooks the youth on nicotine and leads them to later cigarette use. The strict enforcement of these regulations has been successful in maintaining low smoking rates among the population, as well as preventing the emergence of a significant vaping culture.

**Thailand** banned the importation of e-cigarettes and e-liquids in 2104. The next year, it extended the ban to the sale of these products. HTPs are categorized as e-cigarettes; therefore, their sale and importation are also banned under existing regulations. The industry has been lobbying aggressively to overturn this ban.

**Hongkong** adopted a similar approach to Singapore out of growing concern of youth uptake. In 2019, the government proposed legislative amendments to prohibit the import, manufacture, sale, distribution, and advertisement of alternative smoking products (ASPs), including e-cigarettes, HTPs and herbal cigarettes. The new law came into effect on 30 April 2022. The regulations are aimed at protecting public health, preventing youth access to these devices, and reducing the potential harms associated with vaping.

The enforcement provisions in the Hong Kong law grant authority to inspectors from the Tobacco and Alcohol Control Office of the Department of Health and officers from the Customs and Excise Department to enforce the regulations. Users of ASPs in designated no-smoking areas face fines comparable to those imposed on individuals who illegally use conventional cigarettes. The penalties for importing, manufacturing, selling, and distributing these products are more severe, including a maximum fine of HKD 50,000 or USD 6,500 and prison terms of up to a maximum of six months.

In contrast to Singapore, Thailand, and Hong Kong, **India** first implemented an ESD ban in different states, before a nationwide ban was implemented in 2019. Around 15 state regulations are implemented, but the level of implementation differs. The national law bans the production, manufacture, import, export, transport, sale and distribution of e-cigarette components. The Indian government was particularly concerned about the increasing popularity of e-cigarettes among adolescents and the potential gateway effect to conventional tobacco.

**The United States** has implemented various regulations at the federal and state levels. The US Food and Drug Administration regulates ESDs as tobacco products under the Family Smoking Prevention and Tobacco Control Act. This includes age restrictions, health warning labels, ingredient disclosure, and marketing restrictions. Additionally, several states have implemented their own regulations, such as bans on flavors and online sales, while a few cities have banned the sale of all tobacco products, including ESDs.
The European Union implemented its revised Tobacco Products Directive (TPD) in 2014, laying down the minimum rules for regulation of e-cigarettes, novel tobacco products, and other tobacco-related products. The TPD imposes restrictions on advertising, packaging, and product ingredients, among others. It also sets limits on nicotine concentrations and requires health warnings on packaging. Furthermore, member states can introduce additional regulations, such as flavor bans and product notification requirements.

The United Kingdom has implemented the Tobacco and Related Products Regulations 2016 (TRPR), which applies to ESDs. Regulations for e-cigarettes include minimum standards for the safety and quality of all e-cigarettes and refill containers, which includes information to consumers through labelling and health warnings, restriction of volume of e-cigarette tanks, restriction of nicotine strength. HTPs are regulated as a novel tobacco product and are subject to requirements under tobacco laws, which includes a ban on advertising, access restrictions. TRPR outlines product standards for HTPs but does not currently require pictorial health warnings and allows flavors like menthol.

Since October 2021, a medical prescription is needed to legally access ENDS products in Australia; HTPs are banned. However, despite this requirement, ENDS were widely sold across the country, including to teens. In May 2023, the government announced new regulations – banning non-prescription ENDS, requiring pharmaceutical packaging, and banning brightly colored packs and disposable ENDS.

Malaysia previously regulated nicotine under its Poisons Act 1952, which classified nicotine as a controlled substance. However, in April 2023 the government exempted nicotine liquids and gels from the Poison Act, allowing them to be taxed and sold, including to minors, in the absence of any regulatory policy for ENDS. The tobacco control bill that includes ENDS regulation has been stalled in Parliament. Religious edicts in the states of Penang, Kedah, Johor, Kelantan, and Terengganu currently ban vaping.

The Philippines regulates ESDs under the Vaporized Nicotine and Non-Nicotine Products Regulation Act (RA 11900), which was passed in July 2022 despite strong opposition from public health advocates, including the Philippine Medical Association. Most regulations governing tobacco products, such as pictorial health warning requirements, apply to e-cigarettes. The previous regulation banning flavors, except for plain tobacco and menthol, was not expressly repealed in RA 11900, but RA 11900 lowered the minimum age of purchase from 21 to 18 years and allows online ESD sales and advertising. Subsequent enforcement of flavor restrictions and youth access restrictions has been poor.

b. Impact of certain regulatory policies on ESD use

A study in Southeast Asia found that the highest prevalence of e-cigarette use among adolescents was in Indonesia (11.8%), while the lowest was in Thailand (3.3%), while Malaysia’s prevalence rate ranged from 5.9% to 9.1%. The study discussed that the disparities may be linked to the differing e-cigarette regulations in these countries. This is consistent with an analysis of Global Youth Tobacco Surveys in 75 countries showing that countries that prohibit the sale of e-cigarettes have much lower levels of youth e-cigarette use than countries that allow them with age restrictions for youths.
Current evidence favors taxing e-cigarettes at parity with tobacco. A World Health Organization (WHO) report has raised concerns of product substitution between conventional cigarettes and ENDS and provided tax policy recommendations to ensure that ENDS are unaffordable to youths, while ensuring that prices of tobacco products are kept sufficiently high to discourage switching from ENDS to conventional tobacco products.\textsuperscript{48} As HTPs are technically tobacco products, they should be taxed similarly to other tobacco products.\textsuperscript{49}

Flavors are highly attractive to the youth and contribute to the initiation and continued use of ESDs. By prohibiting the sale of flavored ESDs, policymakers aim to reduce the appeal and accessibility of ESDs among young people. \textbf{Finland}, \textbf{Hungary}, \textbf{Netherlands}, \textbf{Ukraine}, \textbf{Lithuania}, and \textbf{China} have national-level bans on flavors other than tobacco flavor. \textbf{Denmark} and \textbf{Estonia} ban flavors other than tobacco and menthol, and \textbf{Canada} and the \textbf{United States} have sub-national restrictions in place.\textsuperscript{50}

A comprehensive ban in San Francisco, California on flavored tobacco products, including flavored e-cigarettes, was associated with a decrease in prevalence of flavored tobacco use and flavored e-cigarette use among young adults (18-24 and 25-34 years old).\textsuperscript{51} After implementation of a Massachusetts statewide flavor ban on all flavored tobacco product sales, there was a significant decline in overall cigarette and menthol cigarette sales in Massachusetts, without significantly impacting sales in neighboring states where such products were still sold.\textsuperscript{52}

c. Challenges in ESD regulation enforcement

Enforcing ESD regulations presents its own set of challenges:

- **Cross-border trade and online sales.** The global nature of the ESD market and the ease of online sales allows ESDs to be purchased easily from overseas suppliers or online platforms, often bypassing local regulations and age restrictions. Effective monitoring and control of cross-border trade and online sales require international cooperation, information sharing, and harmonization of regulations. Lack of uniformity of regulations across jurisdictions makes it challenging to address these issues effectively.

- **Lack of product standardization.** The absence of standardized testing protocols and uniform product standards hampers regulatory efforts. Different manufacturers use diverse ingredients, formulations, and production methods, making it difficult to compare and evaluate products consistently. The tobacco industry’s interference in national and international standard setting for ESDs has raised concerns about the impartiality and integrity of regulatory processes. By exerting influence on the development of testing protocols and product standards, the tobacco industry undermines effective regulation and promote its own interests. This interference impedes efforts to establish consistent and robust standards, compromising the ability to adequately assess and regulate the health risks associated with ESDs.

- **Limited government resources and expertise.** Regulatory bodies responsible for enforcing ESD regulations often face constraints in funding and expertise. These limitations can hinder their ability to conduct comprehensive inspections, perform product testing, and keep pace with industry developments. Insufficient resources for research and monitoring make it challenging to assess the long-term health effects of ESDs accurately. Additionally, limited expertise in emerging technologies can impede regulatory decision-making.
• **Market surveillance.** The vast number of ESD products available in the market makes it challenging to conduct effective market surveillance. Identifying non-compliant products, detecting unauthorized distribution channels, and enforcing penalties require comprehensive market surveillance strategies and strong collaboration between regulatory and law enforcement agencies.

Addressing these challenges within the ESD regulatory landscape is crucial to protect public health, ensure product safety, and mitigate the risks associated with ESDs.

**Conclusions and Policy Recommendations**

This policy paper highlights the need for urgent regulation of Electronic Smoking Devices (ESD) to safeguard public health, especially among vulnerable populations such as the youth. Despite claims by the tobacco and nicotine industry that ESDs are less harmful alternatives to conventional cigarettes, a large and growing body of evidence challenges this. ESD aerosols contain harmful chemicals that can harm respiratory and cardiovascular health, and their long-term impact remains uncertain. The paper emphasizes the risks of nicotine addiction, particularly among teenagers, and the potential gateway of ESDs leading to conventional cigarette smoking.

The marketing tactics employed by the tobacco and nicotine industry have greatly contributed to the appeal of ESDs to the youth. Aggressive promotion, social media influence, and attractive designs with enticing flavors have led to increased initiation and experimentation among young individuals. The accessibility and affordability of ESDs, coupled with peer pressure and the perception of ESDs as trendy, further contribute to the popularity among the youth.

While ESD regulatory experience is growing globally, current regulatory approaches vary widely, and existing regulations are often reactive and slow to keep pace with the rapid evolution of ESDs, allowing the industry to exploit policy gaps and weaknesses. Cross border trade and online sales pose challenges in enforcing regulations, and limited resources and expertise hinder comprehensive monitoring and standardization efforts.

**Regulate ESDs by prohibiting or restricting**

Given the clear and growing evidence on the harmful effects of ESDs and their appeal to the youth, it is imperative to implement stringent measures that prohibit or restrict their manufacture, sale, distribution, marketing, and use, in order to decrease the appeal of ESDs to young people and denormalize their use.

Regulation by prohibiting ESDs is driven by the obligation of governments to protect and promote public health, particularly by preventing youth access to harmful products, the subsequent nicotine addiction and other harms from such products, and the reversal of current tobacco control progress.

If society were to apply history’s lessons from the mistake of allowing cigarettes and other tobacco products to be made, marketed, and sold widely under certain restrictive conditions for more than a century now, a complete ban on ESDs is recommended as an effective public health policy that would significantly reduce, if not prevent, the risks associated with their use.
Implementing a ban as the preferred policy option may require immense political capital. Conversely, implementing robust restrictive regulations to mitigate the risks in allowing the manufacture, marketing, and sale of ESDs could impose heavier regulatory burdens on governments: tax and price measures, product standards control, prohibiting advertisement and marketing tactics, limiting access of the youth, imposing age restrictions, flavor bans, comprehensive smoke-free regulations, health warnings on packaging, and imposing strict penalties for non-compliance.

It is important to tailor regulations to the specific context and risks associated with ESD use in each country, with continuous evaluation and refinement of ESD regulations. As products evolve and new challenges emerge, it is crucial for countries with existing regulations to update their policies and address enforcement issues, such as illicit trade and online sales. This dynamic approach ensures that regulations remain relevant and effective in protecting public health.

**Collaboration among policymakers, NGOs, and public health experts**

Effectively addressing the risks associated with ESDs requires a multi-faceted approach involving collaboration among policymakers, public health experts, and non-governmental organizations. Policymakers play a vital role in developing regulations and policies based on scientific research and public health evidence. By actively engaging with researchers, public health experts, and advocacy groups, evidence-based regulations and policies can be developed. However, it is imperative that they do so while adhering to the principles enshrined in Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC), which seeks to protect public health policies from tobacco industry interference.

Collaboration with NGOs can provide valuable insights into the marketing tactics used by the tobacco industry and assist in implementing effective prevention strategies to counteract these tactics. NGOs work with affected communities and individuals and can provide inputs on marketing techniques on youth and vulnerable populations, thereby addressing another aspect emphasized in Article 5.3. These insights are instrumental in tailoring interventions that mitigate the impact of ESDs on the most susceptible segments of society.

The involvement of public health experts is crucial to assess the available evidence, analyze the emerging trends, and provide guidance to policymakers.
Endnotes


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