POLICY POSITION ON NON-MEDICINAL NICOTINE PRODUCTS



NCD Alliance

TIME TO LEAD
GLOBAL WEEK FOR ACTION ON NCDs

KEY TERMS

Tobacco products

Defined by the WHO Framework Convention on Tobacco Control (WHO FCTC) as "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing". These also include heated tobacco products (HTPs) per FCTC/COP8 [22].

Non-medicinal nicotine products

Nicotine products which do not contain tobacco and are used recreationally rather than as a medically licensed and regulated product to aid cessation. Nicotine in these products may be in any chemical form, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived, and includes alkaloids and analogues.

Electronic nicotine delivery systems (ENDS)

ENDS are the devices and/or the liquids that create a heated aerosol which the user then inhales, instead of burning or using tobacco leaves. The main components of the liquid are nicotine and propylene glycol, with or without glycerol and flavouring agents, in addition to other chemicals including some toxicants. "E-cigarettes" are the most common type of ENDS.

Electronic non-nicotine delivery systems (ENNDS)

ENNDS function in the same way as ENDS but do not contain nicotine.

Oral nicotine pouches (ONP)

ONP are smokeless products that typically consist of nicotine, plant-based fibres, flavourings, and other additives, placed between the gum and lip for nicotine absorption without inhalation or chewing.

NCD ALLIANCE'S POLICY POSITION ON NON-MEDICINAL NICOTINE PRODUCTS

Non-medicinal nicotine products, including electronic nicotine delivery systems (ENDS, also known as "e-cigarettes" or "vapes") and newer nicotine products such as oral nicotine pouches (ONP) are largely promoted by tobacco and related industries. These products have flooded the global market as an alternative for users of tobacco products in the past two decades, while also targeting their marketing to children, youth, and non-users [1].

These products do not contain tobacco leaf and therefore do not fall under the category of "tobacco products" as defined by the WHO Framework Convention on Tobacco Control (WHO FCTC). ENDS have commonly used tobacco-derived nicotine but more recently have also used synthetic nicotine and nicotine analogues due to decreasing production costs and in some cases to avoid regulation. The lack of explicit categorisation of these products under many domestic tobacco control laws has allowed them to enter some open markets under varying levels of regulation, including as aggressively marketed consumer products, raising public health concerns due to the addictive nature and other health risks of nicotine. In addition, the tobacco industry is using these products to undermine the effectiveness of tobacco control policies, impair tobacco denormalisation and maintain the next generation's tobacco market, underscoring the relevance these products have in the broader tobacco control response [2].

Non-medicinal nicotine products have been presented by the tobacco industry as less harmful than tobacco and as a tool for cessation [3] [4]. However, these products are not harm free and the evidence on their effectiveness for cessation is mostly limited to controlled settings and remains a topic of debate [5] [6] [7] [8] [9]. Moreover, the WHO and the Secretariat of the WHO FCTC recognise a "***fundamental and irreconcilable conflict between the tobacco industry's interest and public health policy interests***". As such, tobacco cessation solutions should not be led by the tobacco and non-medicinal nicotine industry due to the inherent conflict of interest, where decisions are driven by commercial motives rather than public health objectives.

Furthermore, **these products are aggressively targeted and marketed to children, youth, and non-users, including through product design, social media advertisements, paid product placement, and sponsorship of youth events, leading to increased uptake among young people** [1] [10]**. In countries where data exists, children are nine times more likely than adults to vape** [11]**. These products pose unique risks to youth and can harm their brain development** [12]**. They also present a risk of dual use alongside conventional tobacco products, as recognised in the COP7 report on ENDS/ENNDS** [13] [14]**.**

There is also a need for more independent research to fully understand the effectiveness of these products in tobacco cessation [15]. While some studies have shown ENDS to be more effective than traditional nicotine replacement therapies (NRT) for smoking cessation in controlled settings [16], other research suggests that their effectiveness is limited to such circumstances, particularly within controlled clinical settings [17] [18] [19] [20]. According to WHO, "e-cigarettes" as used in the real-world as consumer products have not been proven effective for smoking cessation at the population level and in fact may lead to prolonged nicotine dependence [20]. Moreover, it is important to note that these products are not without risks: they are not regulated and controlled like medicinal nicotine products; can contain high levels of nicotine and carcinogenic compounds; and their long-term health effects, particularly among children and youth, remain under investigation [21] [22] [23] [24] [25] .

Discussions on "novel and emerging tobacco products" at the WHO FCTC Conference of the Parties (COP) have primarily centred on heated tobacco products (HTPs), with decision **FCTC/COP8(22)** formally recognising HTPs as tobacco products, thus bringing them under WHO FCTC provisions. However, HTP regulation may differ across countries depending on how they are classified (as tobacco or "e-cigarettes"). Decision **FCTC/COP6(9)** recommends Parties to implement measures on ENDS/ENNDS to achieve four policy objectives: to prevent initiation by non-smokers and youth, minimise potential health risks, prevent unproven health claims from being made, and protect tobacco control activities from all commercial and vested interests. Decision **FCTC/COP7(9)** provides additional options on regulation for how to achieve this. Additionally, documents **FCTC/COP/7/11** and **FCTC/COP/8/10** report on the health impacts and progress of regulatory and market developments and may serve as useful references.



The case for action on non-medicinal nicotine products

1. Nicotine leads to addiction and harm, and non-medicinal nicotine products are far from being risk free

Nicotine is a highly addictive chemical widely recognised as the primary addictive substance leading to the continued use of tobacco products [2] [26] [27]. Nicotine exposure has been associated with cardiovascular health complications, insulin resistance, respiratory diseases, foetal and brain development issues, and DNA mutations leading to cancers [2] [27] [28] [29]. Moreover, nicotine products present a risk of nicotine addiction and tobacco uptake when promoted among non-users, and they also carry the risk of prolonged dual use [20] [30]. Furthermore, many ONP and some ENDS contain high nicotine concentrations, comparable to or even higher than those in tobacco cigarettes [9] [31] [32]. ENDS can deliver nicotine in concentrations and profiles capable of initiating and maintaining nicotine addiction and there are ENDS that also allow users to customise the amount of nicotine uptake [2] [33]. High nicotine levels can lead to short-term adverse effects such as nausea but also can cause long-term health risks, and have been linked to higher addiction potential [34] [35] [36].

Given their novelty, the long-term health effects of non-medicinal nicotine products are not yet fully understood [28] [37]**. Nevertheless, these products are not harm-free, and a growing body of evidence points to a range of health risks associated with their use** [38] [39] [40]. They deliver nicotine, a highly addictive substance that can adversely affect health and sustain nicotine addiction. These products, particularly ENDS, which are highly heterogenous and rapidly evolving, can contain other toxic substances which may not be well-known especially where they are subject to minimal or no regulation [41]. **Preventing people from using tobacco must remain a public health priority while also preventing people from becoming addicted to nicotine.** Article 5.2(b) of the WHO FCTC dictates that each Party shall "adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke."



2. Products used for tobacco cessation should be based on strong evidence about their effectiveness and safety

The tobacco and non-medicinal nicotine industry has marketed ENDS and other non-medicinal nicotine products with claims that they are less harmful, and therefore, they provide a solution for tobacco cessation, while also targeting non-users and youth. Non-medicinal nicotine products are far from being risk free, nevertheless this narrative has been leveraged by industry to promote its products and sustain its markets.

Parties of the WHO FCTC have the obligation to implement WHO FCTC Article 14 and its guidelines, that is, measures to motivate and assist existing tobacco users to quit tobacco using proven methods, including approved therapeutic products, advice from healthcare workers, toll-free quit lines, and mobile and digital cessation services. The 2022 updated NCD 'best buys' and other recommended interventions, include as an effective intervention with cost-effectiveness analysis use of the following pharmacological interventions for tobacco cessation: nicotine replacement therapy (NRT), bupropion and varenicline – which are part of WHO's Model List of Essential Medicines (EML) [42]. Cytisine was also added, as a drug to treat nicotine dependence, to WHO's EML in 2025 [43]. NRTs have indeed proved to be an effective and safe tool for tobacco cessation. They are designed to release nicotine in a slow and controlled manner which minimises risk of abuse, and the risk of nicotine poisoning through NRTs is minimal when used as advised or prescribed [9].

WHO's call to action on "e-cigarettes" also advises against the use of ENDS for tobacco cessation strategies, and if a government supports the use of "e-cigarettes" for tobacco cessation purposes as a last resort, it should "control the conditions under which the products are accessed to ensure appropriate clinical conditions and regulate the products as medicines (including requiring marketing authorisation as medicines)"[33].

It is critical that any consideration by governments of nicotine products as part of cessation strategies be in line with the implementation guidelines of WHO FCTC Article 14. Governments should prioritise interventions with the strongest independent evidence base, such as cost-covered pharmacological cessation treatments included in the WHO's EML, and ensure the involvement of independent cessation experts throughout strategy development.



3. Non-medicinal nicotine products pose serious risks to young people and non-users of tobacco

NCD Alliance's **Selling a Sick Future** report on marketing policy highlights how the industry aggressively targets children and youth with "e-cigarettes" through marketing tactics like flavours, colours, and other features that strongly appeal to young audiences; and similar marketing strategies are used for other non-medicinal nicotine products, such as ONP. WHO's technical note on "e-cigarettes" expresses concern over the rising use among young people, citing that the number of 16–19-year-olds currently using "e-cigarettes" in Canada doubled from 2017 to 2022 [20]. In Sweden, the national statistics on snus use (including tobacco snus and ONP) show a significant increase among young women since ONP were introduced in the market [44]. While data is lacking in many low- and middle-income countries (LMICs), the latest figures available from the Global Youth Tobacco Survey in 2016 also shows high rates of current e-cigarette use in many countries, including 20% of youth in Papua New Guinea, 17% in the Marshall Islands, and 12% in Fiji [45].

A joint report by WHO and STOP found that 85% of young people aged 15–30 were exposed to "e-cigarette" advertising across various media, with increased exposure linked to higher "e-cigarette" use [1]. However, as of 2024, 88 countries had no minimum age restriction for purchasing "e-cigarettes", and 74 countries did not have any regulations to control these products [46].

Concerns have been raised about ENDS having a "gateway effect" for smoking initiation including among young people [47] [48]. Observational studies indicate that non-smokers who use "e-cigarettes" are approximately three times more likely to become current smokers than those who do not use "e-cigarettes" [49]. In many LMICs, the potential for ENDS to act as a gateway for cigarette smoking is likely to be greater due to factors such as weak enforcement of sales bans to minors and affordability of cigarettes [45]. Aggressive marketing, combined with increasing inequalities, poverty and unemployment also makes youth in LMICs particularly vulnerable and they face heightened risks.

In addition, the growing use of disposable ENDS has raised significant environmental and public health concerns due to the substantial waste they generate, and the risks associated with improper disposal. Their plastic components, residual nicotine and other chemicals, and lithium-ion batteries can contaminate soil and waterways, harm wildlife, and pose additional risks to human health. In response to these concerns, countries such as Belgium and the United Kingdom have recently banned disposable "vapes" to reduce environmental damage and curb youth uptake [50] [51] [52].

Despite ongoing efforts to raise awareness among youth about the risks of using non-medicinal nicotine products, these products remain appealing in many countries due to their marketed features. Regulatory measures must aim at preventing initiation, reducing nicotine dependence, and avoiding the potential renormalisation of nicotine and tobacco product use. With continued investment in regulation and enforcement, countries can increasingly counter the marketing reach and tactics of companies selling these products. To reduce youth exposure and prevent uptake by non-users, such products should be subject to strict regulation, including at a minimum banning their advertising, promotion, and sponsorship. Strong enforcement of sales and marketing restrictions is essential to ensure the effectiveness of these measures[I,II].

I WHO recommends that countries "do not pursue a smoking cessation strategy that permits the commercialization of e-cigarettes as consumer products". Available **here**.

II **FCTC/COP/7/11** reports that *Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options: a. Prohibiting implicit or explicit claims about the effectiveness of ENDS/ENNDS as smoking cessation aids unless a specialized governmental agency has approved them.*

Policy recommendations

Regulating non-medicinal nicotine products is crucial to minimise nicotine addiction and tobacco use uptake. Such efforts should be seen as part of the tobacco control response given the impact these products have in undermining the effectiveness of tobacco control policies, perpetuating nicotine addiction, maintaining the tobacco market, and given the high degree of integration between tobacco and vaping companies.

Any consideration of non-medicinal nicotine products must rely solely on independent scientific evidence, be subject to stringent regulation, and fall under the oversight of public health authorities, not industry influence. WHO FCTC Parties have been invited by the COP, in accordance with national laws and public health objectives, to assess the risks and apply regulatory measures to ENDS/ENNDS[III]. All regulatory approaches should be grounded in obligations under the WHO FCTC, its guidelines for implementation, and decisions adopted by the COP, to ensure a comprehensive, evidence-based approach to tobacco control.

With this in mind, NCD Alliance urges the following policy considerations:

- Governments should ensure that any nicotine product regulation works hand-in-hand with comprehensive tobacco control regulation and in line with the WHO FCTC.
- Governments should protect public health policies, including those related to ENDS and other non-medicinal nicotine products such as ONP, from all commercial and other vested interests, including the tobacco industry, in line with their obligations under Article 5.3 of the WHO FCTC.
- Governments should reject industry-driven narratives that misuse the concept of harm reduction to promote non-medicinal nicotine products. The tobacco industry's appropriation of public health language undermines effective tobacco control and diverts attention from proven strategies. Harm reduction should be defined by the public health community, not revised by the industry, and grounded in the evidence-based measures outlined in the WHO FCTC to prevent tobacco use and nicotine addiction.
- When considering how best to regulate non-medicinal nicotine products, governments should assess the available evidence on the public health impact of non-medicinal nicotine products, including their potential effects on tobacco cessation, dual use, nicotine dependence, youth uptake, and initiation among non-tobacco users. They should also consider their regulatory and enforcement capacity.
- In complying with WHO FCTC Article 14 and its Guidelines for implementation, governments should ensure that the therapeutic products they support for tobacco cessation are based on the strongest independent evidence base available, **promoting the use of medically-licensed and regulated products, such as those included in the WHO's Model List of Essential Medicines and the NCD 'best buys', which do not include non-medicinal nicotine products**.
- Despite previously laid-out policy considerations, in the case that governments decide to support the use of ENDS or other nicotine products for tobacco cessation, these products should be strongly regulated, ideally as medicines. This includes requiring marketing authorisation, prohibiting features that allow user manipulation (e.g., adjustable nicotine delivery) or that appeal to young populations, and warning about potential health risks including respiratory disease. Countries should also ensure they are neither produced nor sold by entities with ties to the tobacco industry, given concerns around brand stretching and in light of Article 5.3 of the WHO FCTC and its guidelines for implementation. Countries can also consider limiting availability to regulated healthcare channels (e.g., by prescription).

III For more information, see Decision FCTC/COP8(22), Decision FCTC/COP7(9), and Decision FCTC/COP6(9).

- If available as consumer products, governments should strongly regulate these products to prevent uptake by young people and non-users of tobacco. Measures to consider could include the prohibition of sale and distribution to minors, marketing in all its forms and misleading claims, flavours and other appealing features, and features that enable user manipulation after purchase; banning or restricting the sale of single-use "vapes" to reduce both environmental damage and youth use; limiting the concentration and quantity of nicotine; the enforcement of health warnings and fiscal measures; expanding smoke-free spaces to include newer tobacco and nicotine products; applying other tobacco control measures for shaping the supply and demand of products in the WHO FCTC to non-medicinal nicotine products; and/or sharing information regarding the harmful effects of non-medicinal nicotine products with the public.
- If governments decide to prohibit the sale, import, manufacture and distribution of non-medicinal nicotine products, they should assess the existing legal measures in effect to ensure that their use in public places and their advertising, promotion and sponsorship is also prohibited.
- Governments must prioritise not only the adoption of such regulations but also the establishment of robust enforcement mechanisms, including sufficient funding for monitoring and ensuring compliance.
- Governments should ensure meaningful social participation of civil society, people with lived experience and youth, in the design, implementation and monitoring of these policies.
- Governments, in collaboration with academic institutions, should monitor use prevalence and support more research on the long-term health effects of non-medicinal nicotine products, including ENDS and ONP, and the impact of their use on tobacco use trends, with a focus on its impact on young people. This is particularly pertinent in LMICs as per the WHO Tobacco Epidemic Report 2023, no low-income countries and just 21 middle-income countries monitor e-cigarette use among both adults and adolescents, despite also having the least comprehensive regulations.
- Governments should monitor and enforce that products sold as ENNDS do not contain nicotine. Countries which lack the capacity to do so may consider applying ENDS regulations to ENNDS.



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