



# **REGULATING NOVEL AND EMERGING NICOTINE AND TOBACCO PRODUCTS**

EUROPEAN CANCER LEAGUES' RECOMMENDATIONS FOR  
TOBACCO CONTROL AND PUBLIC HEALTH

**MAY 2024**

# ABOUT THE ECL PREVENTION AND EARLY DETECTION WORKING GROUP

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Established in 2020, the ECL Prevention and Early Detection Working Group connects cancer control experts from cancer leagues across Europe. These experts work together on various primary and secondary prevention issues, with a focus on tobacco control, early detection and obesity.

The working group contributes towards achieving ECL's mission statement: "to advocate for improved cancer control and care in Europe through facilitating collaboration between cancer leagues and influencing EU and pan-European policies".

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## Endorsements

The following organisation has reviewed and contributed to this publication:

Smoke Free Partnership (SFP)



Opinions expressed in this paper reflect the position of the ECL Prevention and Early Detection Working Group collectively. Some opinions may not reflect the views of the individual Working Group's members, nor the views of their respective organisations.

# RECOMMENDATIONS

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*These recommendations are intended for policymakers, regulatory bodies, public health authorities, healthcare professionals, advocacy organisations and other stakeholders involved in tobacco control and public health initiatives at both national and European Union levels.*

## **Policy**

- **Strengthen enforcement of strict regulations at the European level for Novel and Emerging Nicotine and Tobacco Products (NENTPs), ensuring alignment with existing tobacco product standards and adherence to FCTC's Article 5.2.** When considering the entry of Novel and Emerging Nicotine and Tobacco Products (NENTPs), strict regulation is essential and should be in full alignment with tobacco product regulations. It is crucial to recognise that the 'harm reduction' narrative surrounding NENTPs stems from the tobacco industry, as highlighted by the FCTC's Article 5.2, which emphasises action to prevent and reduce nicotine addiction.
- **Prevent high-nicotine content products from entering the EU market.** Products with a high nicotine content, such as snus and nicotine pouches, should [continue to] be banned from entering the EU market.
- **Encourage the integration of a One Health perspective into tobacco and nicotine regulations.** This approach broadens the research scope beyond individual health to consider environmental and social impacts. This will align regulatory efforts with environmental sustainability and equity goals, and is particularly relevant for products such as NENTPs, whose production and disposal often carries a high environmental burden.

- **Mandate the development of long-term stringent medicinal product regulatory pathways for NENTPs to follow in order to safeguard public health.** The Association of European Cancer Leagues (ECL) advocates for stringent regulatory measures, particularly for Member States contemplating non-medicinal NENTPs as nicotine replacement therapies. If electronic cigarettes remain on the market, they should be regulated as tobacco products in order to reduce the risk of uptake and use by non-smokers and youth. This approach guarantees a high standard of safety, efficacy and accuracy in marketing claims.
- **Prioritise the commitment to the FCTC Article 5.3 principle of non-interference across all EU regulatory processes concerning tobacco and nicotine products.** ECL emphasises the importance of consistent adherence to the FCTC non-interference stance throughout all EU regulatory processes concerning all tobacco and nicotine products, including NENTPs. Industry interference should be countered with actions, from EU and national decision-makers, to consistently enable and prioritise the active involvement of independent stakeholders, such as public health and healthcare professionals, in the development and update of regulatory frameworks for tobacco and nicotine products. Actively involve independent, impartial stakeholders to counterbalance the influence of commercial entities, in order to ensure regulatory decisions remain unaffected by commercial industry interests. This principle will safeguard public health, and will counteract the influence of commercial actors with vested interests on the policymaking process and its outcomes.
- **Continue prioritising traditional smoking cessation methods as a precautionary measure until independent research results become available.** Smokers should be informed about the evidence of electronic cigarettes, including their efficacy in randomised controlled trials, but also their lower safety profile as a smoking cessation tool compared with nicotine replacement therapies (NRT). This approach ensures that public health interventions align with evidence-based practices, ultimately safeguarding the well-being of those seeking to quit smoking.

## **Research**

- **Strategically invest in robust, evidence-based communication surrounding NENTPs to ensure accurate and reliable information reaches the public, fostering a well-informed, health-literate society.** The effective regulation of flavours in NENTPs entering the EU market is pivotal due to their key role in increasing the appeal, especially among youth. Therefore, further research must be implemented at EU and national level into the relative harms and benefits of using flavours in electronic cigarettes for smoking cessation, as opposed to the risk of enticing non-smokers, particularly youth, into nicotine addiction.
- **Direct EU funding towards independent and systematic research on the impact of NENTPs in Member States in which NENTPs are being recommended for smoking cessation.** ECL stresses the importance of independence and transparency in scientific research to ensure the credibility and reliability of research outcomes. It is essential that the EU relies solely on data from impartial scientific institutions, to uphold the integrity of the research findings that are key to inform evidence-based policymaking. ECL advocates for rigorous and systematic research focused on several key areas, including the efficacy of NENTPs in smoking cessation, youth uptake, smoking cessation, health impacts, carcinogenic potential and the accessibility of these products, especially among youth. Research initiatives should also investigate the environmental consequences of NENTPs, including the production, usage patterns, health impacts and disposal aspects. Additionally, the social impact on communities, particularly vulnerable populations, requires thorough exploration to inform relevant regulatory policies effectively. This research should be undertaken in countries in which these products are already on the market.



## **Communication**

- **Strategically invest in robust, evidence-based communication strategies concerning NENTPs.** This approach ensures that the public is equipped with accurate, reliable information, fostering a well-informed, fully health-literate society. The forthcoming fifth edition of the European Code of Code Against Cancer (ECAC), expected to be released in 2025, will play a pivotal role in disseminating evidence-based communication regarding the risks associated with various smoking devices, tobacco, and nicotine products.
- **All stakeholders acting in the interest of the public, from EU institutions to public health professionals in tobacco control policy, advocacy and research, must use accurate, neutral and encompassing terms for tobacco and nicotine products.** “Novel and Emerging Nicotine and Tobacco Products” is put forward as a suitable term, accurately reflecting the nature of these products.
- **Agreements must be found on product definitions within the policy and legal framework.** This is essential for ensuring adequate regulation of tobacco and nicotine products at the EU level, enabling timely responses to market developments, and limiting the industry’s ability to circumvent regulations.
- **Call for the relaunch of the EU Commission “*Ex-Smokers are Unstoppable*” campaign to motivate EU citizens to quit smoking and educate them about the risks of tobacco and nicotine consumption.** Advocate for a youth-led campaign to amplify awareness among younger demographics, driving momentum towards a tobacco-free generation.

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# TOBACCO AND NICOTINE: THE LINK TO CANCER

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Tobacco consumption is the single largest avoidable health risk, with the World Health Organization (WHO) estimating that tobacco kills more than 8 million people each year, with a further 1.3 million non-smokers dying annually from second-hand tobacco smoke [1, 2, 3]. The use of tobacco products accounts for a quarter of all cancer deaths globally. In 2020, 22.3% of the global population were current users of some form of tobacco, with over a quarter of the WHO European region population using some form of tobacco [3, 4]. There are more than 7,000 chemical components found in the smoke of tobacco, with the WHO finding that at least 69 of these are known to cause cancer [5, 6].

Nicotine, a profoundly addictive chemical found in tobacco, poses serious health risks. It serves as a potential gateway to cigarette smoking and the use of other harmful substances. Additionally, nicotine adversely affects brain development, dangers during pregnancy and foetal development, and has been linked to the promotion of tumour growth [7].

This paper focuses on 'novel and emerging nicotine and tobacco products' (NENTPs) [8, 9], which refer to various nicotine and tobacco products that have emerged in recent years as alternatives to conventional cigarettes, and have become especially popular among youth [8]. NENTPs refer to products that entered the market after 19 May 2014,

the day on which the Directive 2014/40/EU of the European Parliament and of the Council (Tobacco Products Directive – TPD) was formally adopted [10]. Examples of NENTPs include electronic cigarettes, heated tobacco products and nicotine pouches [9]. While extensive research on the long-term health consequences of NENTPs is underway, the products are still considered to be harmful, and there is already sufficient evidence that their use can lead to the use of other tobacco products through what is known as the 'gateway effect' [11, 12, 13, 14, 15].

Electronic cigarettes, also referred to as e-cigarettes or vapes, refer to electronic nicotine and non-nicotine delivery systems (ENDS and ENNDS) that heat a liquid to produce an aerosol to be inhaled by the user [16]. Electronic cigarettes pose significant health risks, especially for vulnerable populations such as young people and pregnant women, as well as non-smoking adults [12]. The surge in electronic cigarette usage, particularly among youth, is fuelled by enticing flavours, often marketed targeting children and young people, raising serious concerns about public health [17, 18].

The WHO define heated tobacco products (HTPs) as tobacco products that produce aerosols containing nicotine and toxic chemicals when tobacco is heated or when a device containing tobacco is activated [19].



These aerosols are inhaled by users during a process of sucking or smoking involving a device. They differ from electronic cigarettes in that they heat tobacco presented in a stick, as opposed to the e-liquid used in electronic cigarettes that generally does not contain tobacco [20]. Similar to other NENTPs, there remains a lack of evidence to suggest that HTPs are less harmful than conventional cigarettes. As tobacco products, HTPs are currently regulated under the Tobacco Products Directive (TPD) [21].

Nicotine is also being increasingly consumed through the use of nicotine pouches, which are placed under the upper lip to release nicotine [22]. While they closely resemble the tobacco pouches originating in Scandinavia, which are more commonly referred to as snus, nicotine pouches contain nicotine-containing powder as opposed to the cut tobacco leaves found in snus [23]. Nicotine pouches provide the opportunity for discreet usage and

offer a way to bypass smoke-free regulations [24]. The TPD currently prohibits snus from entering the EU market under the classification of tobacco for oral use, with the exemption of Sweden due to the country's long tradition of using the product [25]. However, nicotine pouches are not included in the TPD, and thus are not currently regulated products.

'Medicinal nicotine products', including nicotine replacement therapies (NRTs) like nicotine gum or patches, undergo rigorous medicinal regulatory procedures to gain approval as smoking cessation aides [26]. They come with clear instructions aimed at helping individuals quit smoking. In contrast, non-medicinal and recreational nicotine products often contain significantly higher nicotine levels, heightening the risk of addiction. The disparity underscores potential future public health concerns regarding the addictive nature of such products [27].

# TOBACCO AND NICOTINE EU REGULATORY LANDSCAPE

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The current legal and policy landscape surrounding tobacco falls substantially short of addressing the pressing challenges posed by the tobacco epidemic. There exists an urgent need to overhaul the existing regulatory framework, which is currently remains inadequate in sufficiently safeguarding public health.

To address the tobacco epidemic, WHO Member States adopted the WHO Framework Convention on Tobacco Control (WHO FCTC) in 2003. The European Union (EU) and several Member States are parties of the FCTC. The WHO FCTC Article 5.2 binds Parties to *“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”* [28].

At the European level, the EU and national governments have implemented various tobacco control (TC) measures in the form of legislation and recommendations. In 2003, the Tobacco Advertising Directive (TAD) [29] introduced an EU wide ban on cross-border tobacco advertising and sponsorship in media other than television, where advertisement was banned back in 1989. The EU has also been regulating

the taxation of manufactured tobacco products, with the most recent legislation being the Tobacco Taxation Directive in 2011 [30]. In addition, on 19 May 2014, the Directive 2014/40/EU of the European Parliament and of the Council (Tobacco Products Directive – TPD) [21] officially entered into force after its adoption by the EU, after being described as the most lobbied dossier in the history of the EU Institutions. The TPD regulates the manufacture, display and sale of tobacco and related products to reduce the morbidity and mortality associated with tobacco consumption. Over this period, several successful legislative actions in TC have been implemented across Member States, such as the tighter regulation of additives, the banning of menthol cigarettes and more dominant visual health warnings on packaging [1]. In 2022, the European Commission issued the Commission Delegated Directive (EU) 2022/2100 amending The TPD to withdraw certain exemptions of heated tobacco products [31].

However, several factors, including market developments and the emergence of NENTPs that fall beyond the definition of NRTs, have shown the urgency of a revision of the EU legislative framework for TC. An evaluation of the framework, funded by the European Commission and focusing primarily on the TPD and TAD, is currently ongoing. The

evaluation is now anticipated to conclude in late 2024, and its results will support the decision on the next steps regarding the TPD. Moreover, the revision of the Tobacco Taxation Directive, initially planned for December 2022, is still being finalised. The revision was initiated by the Commission at the end of 2020, with the aim of achieving greater tax convergence within the EU, including for NENTPs. Inconsistencies in the classification and regulation of combustion and non-combustion products such as electronic cigarettes, heated tobacco products, nicotine pouches and other non-medicinal nicotine products have led to the industry exploiting tax and advertisement regulatory loopholes. Additionally, interpretations of EU regulations differ across Member States, leading to inconsistent measures such as on packaging, and providing the industry with an opportunity to circumvent the regulations through creative interpretation. The inconsistencies are exacerbated by continued lobbying from the tobacco industry, with a new

report finding investment of almost €20 million from the industry to influence EU policymakers [32].

In February 2024, the Tenth Session of the Conference of the Parties (COP10) to the FCTC took place in Panama. COP10 concluded with the Decision to adopt specific guidelines to address cross-border tobacco advertising promotion and sponsorship, reaffirming that these measures must also be applied to NENTPs, a decision taken at COP8 in 2018 [33]. The Panama Declaration was adopted, which urges Parties to the FCTC to increase public awareness to the dangers of nicotine addiction and health risks, and the consequences of using NENTPs, particularly among children and youth [34]. It also urged the uptake and continuation of monitoring technological developments in relation to these products, as well as to monitor marketing strategies used for NENTPs, particularly in the entertainment media and in digital communication platforms.

## EMERGING INDUSTRY NARRATIVES

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Influence from the tobacco industry is considered to be the main obstacle to efforts to reduce the public health burden of NENTPs [35]. Over the last decade, the debate on the so-called 'harm reduction' approach to tobacco and nicotine consumption has been gaining traction among the public. The tobacco industry has been scaling up its efforts to push for governmental support of 'smoke-free alternatives' to traditional combustion tobacco products, dividing policymakers and public health experts [9]. NENTPs fall beyond the definition of nicotine-replacement therapies, but have been increasingly singled out as a potential tool to reduce the harms associated with the consumption of combustion tobacco products, with some studies claiming that these products are less harmful than cigarettes [36, 37].

Recent emerging evidence highlights the adoption and subsequent use of the 'harm reduction' narrative by the tobacco industry, occurring in direct response to the strengthening of the public health agenda, and therefore,

of tobacco control policies [38]. This move has increased the access and involvement of scientists, public health experts and policy makers, in an attempt to manage the reputation of the industry.

The EU and much of the scientific community have expressed concern, emphasising the lack of clear evidence regarding the long-term effects of these combustion-free tobacco and nicotine products. This underscores the need to apply the precautionary principle, and emphasises the dangers of dual use and of uptake among non-smokers. The WHO underscores the challenges regarding the scientific assessment of these products (e.g., wide variation of emissions, devices-content interactions, and specific features resulting in different levels of nicotine and toxicants) [39]. Consequently, both the WHO and the EU have supported the increase of regulation and taxation of all tobacco and related products.

# NATIONAL NENTP REGULATION

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The question persists as to whether NENTPs, which lack comprehensive research on their health impacts and their effectiveness in smoking cessation, can represent a valid alternative to existing nicotine replacement therapies, as well as to conventional products for heavy smokers who cannot or do not want to quit. In its 2021 report, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) highlighted limited evidence supporting the effectiveness of electronic cigarettes in assisting smokers to quit traditional tobacco smoking [40]. Additionally, the available evidence regarding smoking reduction is deemed to be weak to moderate in its assessment.

## **United Kingdom**

Nonetheless, the United Kingdom (UK) has recently started to recommend electronic cigarettes, while acknowledging that the long-term effects of e-cigarette use remain unknown [41]. Simultaneously, the UK have recently unveiled plans to ban the use of disposable electronic cigarettes, restrict flavouring and introduce plain packaging in an effort to reduce the rise in youth vaping that has been experienced as a result of their policies [42].

## **Belgium**

In Belgium, the government has taken a clear position regarding NENTPs. There is no advertisement of the products permitted. Furthermore, on 1 October 2023, the country banned the sale of nicotine pouches, with a similar ban on disposable electronic cigarettes from 2025 [43]. For electronic cigarettes, Belgium has a sales ban for minors (younger than 18 years old) and a ban on online sales. Heated Tobacco Products are treated in the same way as regular cigarettes.

## **Sweden**

In Sweden, electronic cigarettes and flavoured nicotine pouches are legally available for sale, with an age restriction of 18 years. However, there has been a notable increase in their use among young individuals in recent years. Rather than using them as smoking cessation aids, many young people are drawn to these products due to their easy accessibility, affordability and appealing flavours. This trend is concerning as the developing brain of young individuals is particularly vulnerable to addiction, with the human brain found to continue to develop until the age of 25. Consequently, a significant proportion of this demographic becomes dependent on nicotine [44].

## **Italy**

In 2020, a cohort study carried out in Italy provided insights into the impact of electronic cigarettes and heated tobacco products [45]. The findings reveal a concerning trend where non-smokers are more likely to initiate traditional cigarette smoking, ex-smokers face an increased risk of relapsing into nicotine addiction, and overall, these alternative products pose a hindrance to smoking cessation efforts among current smokers. This evidence underscores the potential risks associated with the growing use of such products, particularly in the context of the rising popularity among young people. The

combination of easy access, affordability and appealing flavours may foster an environment where nicotine dependency becomes more prevalent, especially among the youth. Furthermore, in Italy alone, over 31.9 million millilitres of e-liquid in disposable electronic cigarettes were sold between January and April 2023, equal to approximately 16 million devices sold in just four months [46]. This represents serious environmental concerns: if disposed of in general waste, they end up in landfills, introducing dangerous substances into the environment. If mistakenly discarded in the plastic recycling bin, they can contaminate the plastic recycling process, causing a serious environmental problem.



## RECOMMENDATIONS

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### **Policy**

- **Strengthen enforcement of strict regulations at the European level for Novel and Emerging Nicotine and Tobacco Products (NENTPs), ensuring alignment with existing tobacco product standards and adherence to FCTC's Article 5.2.** When considering the entry of Novel and Emerging Nicotine and Tobacco Products (NENTPs), strict regulation is essential and should be in full alignment with tobacco product regulations. It is crucial to recognise that the 'harm reduction' narrative surrounding NENTPs stems from the tobacco industry, as highlighted by the FCTC's Article 5.2, which emphasises action to prevent and reduce nicotine addiction.
- **Prevent high-nicotine content products from entering the EU market.** Products with a high nicotine content, such as snus and nicotine pouches, should [continue to] be banned from entering the EU market.
- **Encourage the integration of a One Health perspective into tobacco and nicotine regulations.** This approach broadens the research scope beyond individual health to consider environmental and social impacts. This will align regulatory efforts with environmental sustainability and equity goals, and is particularly relevant for products such as NENTPs, whose production and disposal often carries a high environmental burden.

- **Mandate the development of long-term stringent medicinal product regulatory pathways for NENTPs to follow in order to safeguard public health.** The Association of European Cancer Leagues (ECL) advocates for stringent regulatory measures, particularly for Member States contemplating non-medicinal NENTPs as nicotine replacement therapies. If electronic cigarettes remain on the market, they should be regulated as tobacco products in order to reduce the risk of uptake and use by non-smokers and youth. This approach guarantees a high standard of safety, efficacy and accuracy in marketing claims.
- **Prioritise the commitment to the FCTC Article 5.3 principle of non-interference across all EU regulatory processes concerning tobacco and nicotine products.** ECL emphasises the importance of consistent adherence to the FCTC non-interference stance throughout all EU regulatory processes concerning all tobacco and nicotine products, including NENTPs. Industry interference should be countered with actions, from EU and national decision-makers, to consistently enable and prioritise the active involvement of independent stakeholders, such as public health and healthcare professionals, in the development and update of regulatory frameworks for tobacco and nicotine products. Actively involve independent, impartial stakeholders to counterbalance the influence of commercial entities, in order to ensure regulatory decisions remain unaffected by commercial industry interests. This principle will safeguard public health, and will counteract the influence of commercial actors with vested interests on the policymaking process and its outcomes.
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## **Research**

- **Strategically invest in robust, evidence-based communication surrounding NENTPs to ensure accurate and reliable information reaches the public, fostering a well-informed, health-literate society.** The effective regulation of flavours in NENTPs entering the EU market is pivotal due to their key role in increasing the appeal, especially among youth. Therefore, further research must be implemented at EU and national level into the relative harms and benefits of using flavours in electronic cigarettes for smoking cessation, as opposed to the risk of enticing non-smokers, particularly youth, into nicotine addiction.
- **Direct EU funding towards independent and systematic research on the impact of NENTPs in Member States in which NENTPs are being recommended for smoking cessation.** ECL stresses the importance of independence and transparency in scientific research to ensure the credibility and reliability of research outcomes. It is essential that the EU relies solely on data from impartial scientific institutions, to uphold the integrity of the research findings that are key to inform evidence-based policymaking. ECL advocates for rigorous and systematic research focused on several key areas, including the efficacy of NENTPs in smoking cessation, youth uptake, smoking cessation, health impacts, carcinogenic potential and the accessibility of these products, especially among youth. Research initiatives should also investigate the environmental consequences of NENTPs, including the production, usage patterns, health impacts and disposal aspects. Additionally, the social impact on communities, particularly vulnerable populations, requires thorough exploration to inform relevant regulatory policies effectively. This research should be undertaken in countries in which these products are already on the market.

## **Communication**

- **Strategically invest in robust, evidence-based communication strategies concerning NENTPs.** This approach ensures that the public is equipped with accurate, reliable information, fostering a well-informed, fully health-literate society. The forthcoming fifth edition of the European Code of Code Against Cancer (ECAC), expected to be released in 2025, will play a pivotal role in disseminating evidence-based communication regarding the risks associated with various smoking devices, tobacco, and nicotine products.
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- **Agreements must be found on product definitions within the policy and legal framework.** This is essential for ensuring adequate regulation of tobacco and nicotine products at the EU level, enabling timely responses to market developments, and limiting the industry’s ability to circumvent regulations.
- **Call for the relaunch of the EU Commission “*Ex-Smokers are Unstoppable*” campaign to motivate EU citizens to quit smoking and educate them about the risks of tobacco and nicotine consumption.** Advocate for a youth-led campaign to amplify awareness among younger demographics, driving momentum towards a tobacco-free generation.

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