Response from the Association of European Cancer Leagues (ECL) to the public consultation of the Tobacco Products Directive and the Tobacco Advertising Directive

The Association of European Cancer Leagues (ECL), a non-profit umbrella organisation made up of 35 national and regional cancer leagues advocating for improved cancer control and care across Europe, welcomes the possibility to contribute to the public consultation of the Tobacco Products Directive and the Tobacco Advertising Directive, as well as the European Commission's willingness to review the tobacco framework and ensuring a high level of human health protection in all policies.

Tobacco control saves lives and remains indispensable to reducing Europe's cancer burden

ECL strongly believes that measures protecting people from tobacco and nicotine consumption and from exposure to second-hand tobacco smoke and aerosols are essential to public health and highly beneficial to society.

Tobacco remains the leading preventable cause of ill health and premature death in Europe. It causes more than 20 types or subtypes of cancer and accounts for 25% of cancer deaths globally. In the WHO European Region, approximately 64% of deaths from cancers of the trachea, bronchus and lung were attributable to tobacco in 2021 [1]. In the European Union (EU), tobacco use, including exposure to second-hand smoke, caused an estimated 520,000 deaths and 13.6 million disability-adjusted life years in 2021 [2].

This burden also has major economic consequences. The European Commission's Joint Research Centre estimates that first-hand use of traditional tobacco products costs the EU €80.7 billion annually, comprising €40.4 billion in direct healthcare costs and €40.2 billion in productivity losses and informal care. This is a conservative estimate, as it excludes exposure to second-hand smoke and novel tobacco and nicotine products, for which long-term cost data remain insufficient [3].

Cancer remains a profound and growing challenge. In 2024, approximately 2.7 million new cancer cases and 1.3 million cancer deaths were estimated in the EU. Lung cancer remained the leading cause of cancer death, accounting for almost 20% of the total [4]. Although these estimates represent a modest decrease compared with 2022, population ageing alone is projected to

Association of European Cancer Leagues (ECL)
Chaussée de Louvain, 479, B-1030 Brussels, Belgium
Tel: +32 2 256 2000 | Email: ecl@cancer.eu
https://www.cancer.eu/

increase cancer diagnoses by 19% and cancer deaths by 27% across EU and EFTA countries by 2040 [5]. Effective tobacco control is therefore indispensable to reducing the future cancer burden and protecting both the population and the sustainability of health systems.

The Tobacco Products Directive (TPD) and Tobacco Advertising Directive (TAD) have been instrumental in achieving progress. The Commission's evaluation concludes that the EU tobacco-control framework contributed to significant declines in smoking prevalence and tobacco-related mortality [6]. Smoking prevalence fell from 32% in 2007 to 24% in 2023 [7]. This represents a major public-health achievement. Product regulation, health warnings, ingredient controls—including restrictions on flavours—and advertising restrictions have helped to reduce uptake, inform consumers and denormalise smoking. Tobacco-control policies work and, ultimately, save lives.

However, this progress is at risk because the market has changed fundamentally. Products that were absent or marginal when the Directives were adopted now account for substantial sales. By 2023, the EU markets for heated tobacco products, e-cigarettes and nicotine pouches had reached approximately €12.5 billion, €5 billion and €1 billion, respectively [8]. Use of these products is concentrated among younger populations. More than one in five 15-year-olds reported using e-cigarettes during the previous 30 days in 2022, while approximately one in five tobacco or nicotine users aged 15–19 began regular use with e-cigarettes [7].

Achieving a Tobacco-Free Generation—with less than 5% of the population using tobacco by 2040—as set out in Europe's Beating Cancer Plan and reinforced by the Safe Hearts Plan, requires both Directives to be comprehensively updated and future-proofed [8]. Equivalent protections must apply across tobacco, nicotine and related products, while digital and emerging marketing practices must be fully addressed. Without decisive action, novel products and nicotine addiction risk reversing hard-won public-health gains.

Novel and emerging products already threaten public health and a Tobacco-Free Generation

Novel and emerging products—including e-cigarettes with or without nicotine, heated tobacco products, nicotine pouches and future products designed to deliver nicotine or imitate tobacco use—already pose a significant and growing public-health risk. "Novelty" is a regulatory or marketing characteristic, not evidence of safety.

E-cigarette aerosols can contain metals, ultrafine particles and potentially carcinogenic substances and are associated with adverse respiratory and cardiovascular effects [2]. A 2026 qualitative assessment integrating human, animal and mechanistic evidence concluded that

nicotine-containing e-cigarettes are likely to be carcinogenic to humans, potentially causing lung and oral cancers, although the magnitude of the risk cannot yet be quantified [10]. A large observational study also found that e-cigarette use after smoking cessation was associated with higher lung-cancer incidence and mortality than complete cessation, although causality could not yet be established [11].

Heated tobacco products expose users to nicotine and toxic substances and have been associated with adverse cardiovascular and respiratory outcomes. Nicotine pouches can deliver sufficient nicotine to induce and sustain dependence, and evidence raises concerns regarding cardiovascular and developmental effects and exposure to toxicants [2]. Although nicotine pouches may expose users to fewer toxicants than combustible tobacco products, this does not make them safe. Nor is there compelling evidence that they are effective smoking-cessation tools. Evidence regarding their long-term effects, including cancer outcomes, remains incomplete because these products have not been marketed for long enough—not because an absence of harm has been demonstrated [2].

These products are particularly concerning for children and young people. Flavours, discreet formats, colourful and playful designs and digital marketing reduce perceptions of harm, encourage experimentation and can establish lifelong nicotine addiction [6, 9]. The rapid evolution of this market demonstrates why the revised Directives must address both the products causing harm today and those that may threaten the health of future generations.

Future-proof Directives must close regulatory loopholes and cover all current and future products

The revised TPD and TAD must be comprehensive and future-proof. The current framework relies heavily on product-specific definitions that can rapidly become obsolete. This allows manufacturers to make minor changes to a product's composition, ingredients, flavours, technology, delivery mechanism or presentation and thereby avoid requirements intended to protect public health. The Commission's evaluation confirms that the legislation has not kept pace with market, consumption and technological developments [6].

Definitions should therefore be broad, technology-neutral and based on a product's function, contents, mode of use, emissions and potential to cause addiction or harm. They should cover all tobacco products, non-medicinal nicotine products, nicotine-free inhalation products, devices, components, accessories and nicotine analogues, allowing the inclusion of products not yet on the market. The framework should also include a mechanism enabling the Commission to respond rapidly to scientific, technical and market developments without awaiting a complete legislative revision.

Existing regulatory gaps must be closed. Nicotine pouches, nicotine-free e-cigarettes, heated herbal products and other emerging products are absent from, or insufficiently regulated by, the current framework. There is no public-health justification for applying weaker protections to a recreational product simply because it contains nicotine without tobacco. All tobacco, nicotine and related products should be subject to equivalent requirements concerning product standards, ingredients, packaging, health warnings, flavours, advertising, promotion, sponsorship, sales and reporting. Medicinal nicotine products authorised for smoking cessation should remain governed by the applicable medicinal-products framework.

Product design must also be regulated. Novel products are frequently made attractive to children and young people through bright colours, playful or high-tech formats, lights, screens, concealability, cartoons, cartoon-like characters and references to video and mobile games [6, 9]. The revised Directives should prohibit design features that increase youth appeal, disguise the nature of a product or facilitate concealed use.

A comprehensive prohibition of flavours is necessary across all tobacco, nicotine and related products. It must cover characterising flavours, flavour descriptors, additives, capsules, cards, filters and accessories, preventing manufacturers from reproducing the same sensory effects through technical modifications.

The TAD must also be modernised for the digital environment. Advertising, promotion and sponsorship should be comprehensively prohibited across social media, influencer content, online marketplaces, streaming services, gaming, entertainment media and other present or future digital channels. These restrictions should cover direct and indirect, paid and commercially coordinated promotion and apply across borders. This approach is consistent with the WHO FCTC Article 13 Guidelines, which call for the comprehensive elimination of tobacco advertising, promotion and sponsorship at domestic and international levels [12].

Without comprehensive, adaptable and enforceable rules, industry innovation will continue to outpace regulation. Young people will remain the principal target, jeopardising cancer-prevention gains and placing the objective of a Tobacco-Free Generation by 2040 at serious risk.

EU legislation must provide a strong common floor while empowering Member States to go further

The revised Directives must fully reflect the obligations of the EU and its Member States under the WHO Framework Convention on Tobacco Control (WHO FCTC). They should establish ambitious, harmonised minimum standards across the EU—a regulatory floor, not a ceiling.

Effective harmonisation is essential to ensure that everyone in the EU receives a high level of protection, irrespective of where they live. Current differences leave citizens unevenly protected and allow the industry to exploit regulatory gaps. The 2025 Tobacco Control Scale found that 23 of 37 European countries had lower scores than in 2021. Italy's score fell by 15 points, mainly because heated tobacco products were excluded from smoke-free and/or advertising regulations. This illustrates the consequences of failing to apply equivalent protections to all tobacco and nicotine products [13].

At the same time, harmonisation must not prevent Member States from responding more rapidly or ambitiously to national circumstances and emerging evidence. Article 2.1 of the WHO FCTC expressly encourages Parties to implement measures beyond those required by the Convention and permits stricter requirements consistent with international law [14]. The revised Directives should therefore preserve—and, where necessary, strengthen—the regulatory space available to Member States, including the possibilities currently provided under Article 24 of the TPD [15]. Member States should be explicitly encouraged to adopt stronger public-health measures rather than being required to demonstrate exceptional circumstances before protecting their populations, in alignment with the WHO FCTC.

This approach is consistent with Article 168 TFEU, which requires a high level of human-health protection across all EU policies while respecting Member States' responsibility for defining their health policies [16]. EU internal-market legislation should support national public-health leadership, not constrain proportionate measures that provide a higher level of protection.

Compliance with Article 5.3 of the WHO FCTC on good governance must be guaranteed throughout the entire policy cycle—not only during legislative drafting, but also during implementation, enforcement, infringement procedures, monitoring and evaluation. The EU institutions and Member States must protect tobacco-control policy from the commercial and other vested interests of the tobacco industry [14]. Any interaction with the industry or organisations acting on its behalf should occur only when strictly necessary for effective regulation and should be fully transparent, documented and publicly accessible. Industry partnerships, voluntary regulatory arrangements and privileged access to decision-makers must

be rejected in accordance with the Article 5.3 Guidelines [17]. Equivalent safeguards should apply to manufacturers and commercial actors operating in non-medicinal nicotine markets.

A strong common floor, combined with the freedom and encouragement for Member States to go further, is indispensable to protecting cancer-prevention gains and achieving a Tobacco-Free Generation by 2040.

Lack of long-term evidence is not evidence of safety: the case for precautionary principle

The revised Directives must explicitly apply the precautionary principle to all tobacco, nicotine and related products. Where scientific assessment identifies a plausible risk of serious harm, uncertainty—particularly regarding long-term effects—must not be used to delay protective action or be misrepresented as evidence of safety. This is especially important for novel products whose cancer and other chronic-disease consequences may take decades to become fully apparent, while addiction can begin in childhood. The EU should therefore adopt timely, proportionate and reviewable restrictions on products, ingredients, designs and promotional practices that may endanger health, with particular priority given to protecting children and non-users [18].

Conclusion

Cancer touches every family and remains one of the greatest burdens facing European society. Yet Europe can change this trajectory: around 40% of cancer cases are preventable, and tobacco remains the leading cause of preventable cancer [19].

Everyone has a role in cancer prevention, and policymakers have a unique responsibility to create environments that protect people—especially children—from harmful products and addiction. By adopting ambitious, comprehensive and future-proof legislation, the EU can preserve the progress already achieved and bring the Tobacco-Free Generation within reach.

We will not end preventable cancers without ending tobacco use and preventing a new generation of nicotine addiction. A Tobacco-Free Generation is achievable. This revision is the opportunity—and the responsibility—to make it a reality.

Association of European Cancer Leagues (ECL)
Chaussée de Louvain, 479, B-1030 Brussels, Belgium
Tel: +32 2 256 2000 | Email: ecl@cancer.eu
https://www.cancer.eu/

References

[1] WHO Regional Office for Europe. *Effects of tobacco on health*. 19 May 2025. WHO Europe.

[2] Perez-Cornago A, Sarasa-Renedo A, Jarach C, Wollgast J, Maragkoudakis P. *Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches*. Luxembourg: Publications Office of the European Union; 2026. JRC146139. JRC repository. https://doi.org/10.2760/0061469.

[3] Salari P, Maragkoudakis P-A, Wollgast J. *The health-related costs attributable to tobacco use in the EU*. Luxembourg: Publications Office of the European Union; 2026. JRC146176. JRC repository. https://doi.org/10.2760/5833286.

[4] European Cancer Information System. *2024 estimates of cancer cases and deaths in the EU*. Joint Research Centre; 2026. ECIS factsheet.

[5] European Cancer Information System. *Impact of population ageing on the burden of cancer by 2040 in EU/EFTA countries*. Joint Research Centre; 2024. ECIS factsheet.

[6] European Commission. *Evaluation of the legislative framework for tobacco control*. Commission Staff Working Document, SWD (2026) 111 final. Brussels: European Commission; 2026. EUR-Lex.

[7] Berlingieri F, Casabianca E, Vlachos S. *Trends and patterns of use of tobacco and nicotine products in the EU*. Luxembourg: Publications Office of the European Union; 2026. JRC143862. JRC repository. https://doi.org/10.2760/3233096.

[8] European Commission. *Public consultation questionnaire: Revision of the EU rules on tobacco products and tobacco advertising*. 2026. European Commission consultation page.

[9] World Health Organization. *Hooking the next generation: how the tobacco industry captures young customers*. Geneva: World Health Organization; 2024. ISBN 978-92-4-009464-2. WHO publication page and full report.

[10] Stewart BW, Marshall H, Bonevski B, et al. The carcinogenicity of e-cigarettes: a qualitative risk assessment. *Carcinogenesis*. 2026;47(1). https://doi.org/10.1093/carcin/bgag015. See also the UNSW summary of the findings.

[11] Kim YW, Park EJ, Kwak KI, et al. Electronic cigarette use after smoking cessation and lung cancer risk. *Nature Medicine*. 2026;32:2410–2419. https://doi.org/10.1038/s41591-026-04469-5.

[12] WHO Framework Convention on Tobacco Control. *Guidelines for implementation of Article 13 and specific guidelines to address cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in entertainment media*. Geneva: World Health Organization; 2024. ISBN 978-92-4-009565-6. WHO FCTC publication.

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Chaussée de Louvain, 479, B-1030 Brussels, Belgium
Tel: +32 2 256 2000 | Email: ecl@cancer.eu
https://www.cancer.eu/

[13] Joossens L, Abbink H, Roman E. *The Tobacco Control Scale 2025 in Europe*. Brussels: Smoke Free Partnership; 2026. Full report. See also the Tobacco Control Scale 2025 results page.

[14] World Health Organization Framework Convention on Tobacco Control. *WHO Framework Convention on Tobacco Control*, particularly Articles 2.1 and 5.3. Geneva: World Health Organization; 2003, updated reprint 2005. ISBN 92-4-159101-3. Official treaty text.

[15] European Parliament and Council of the European Union. Directive 2014/40/EU of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, particularly Article 24. *Official Journal of the European Union*. 2014;L127:1–38. EUR-Lex.

[16] European Union. *Consolidated version of the Treaty on the Functioning of the European Union*, particularly Article 168. *Official Journal of the European Union*. 2012;C326:47–390. EUR-Lex: Article 168.

[17] WHO Framework Convention on Tobacco Control. *Guidelines for implementation of Article 5.3: protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry*. Geneva: World Health Organization; 2013. WHO reference FCTC/16.1. WHO FCTC publication.

[18] European Commission. *Communication from the Commission on the precautionary principle*. COM(2000) 1 final. Brussels: European Commission; 2 February 2000. EUR-Lex.

[19] European Commission. *Europe's Beating Cancer Plan*. Communication from the Commission, COM(2021) 44 final. Brussels: European Commission; 3 February 2021. EUR-Lex. See also the current European Commission Cancer Plan page.