

EFA's response to the call for evidence for the evaluation of the EU legislative framework for tobacco control (Directorate General for Health and Food Safety)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of over 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 45 national associations from 26 countries and channel their knowledge and patients' needs to the European institutions. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care, and a safe environment.

EFA warmly welcomes the European Commission's intention to step-up work on the legislative framework on tobacco. The current evaluation, based on a thorough assessment of the current product regulation, advertising, promotion and sponsorship, paves the way to the revision of the legislation next year that we, as patient representatives, hope will be bold and forward-looking. This is an absolute necessity, if the EU wishes to achieve its ambition for a 'tobacco-free generation' by 2040. Therefore, we hope that it will lead to more policies to reduce the uptake of the habit of tobacco, as well as programmes to help smokers quit efficiently.

Contents

Tobacco smoking: a heavy toll on respiratory diseases	2
Electronic cigarettes and novel tobacco products	2
Impact on respiratory disease	2
Tobacco harm reduction strategies: let's not be fooled	4
Exposure to smoke: patients find themselves unprotected.....	4
Packaging and labelling aspects: imbalances leading to health harms.....	5
Smoke-free environments: legislation still elusive	5

Tobacco is one of the most serious epidemics of our times, associated with enormous health burden across all societies. According to the Global Burden of Disease (GBD) study, in 2019 alone tobacco use was responsible for over 907,000 premature deaths and over 22,150,000 Disability-Adjusted Life Years (DALYs) in the EU. Moreover, exposure to second-hand smoke accounted for over 73,000 deaths and almost 1,760,000 DALYs¹. These grim figures make tobacco the single largest preventable cause of disease, disability and death in Europe, and a major public health threat.

The main tool of the EU to address the tobacco epidemic is the Tobacco Products Directive (TPD)², the latest revision of which became applicable in May 2016, containing rules on aspects such as product ingredients, labelling and packaging, novel tobacco products and electronic cigarettes. In its

¹ European Commission Health Promotion and Disease Prevention Knowledge Gateway, *Global Burden of Disease Study, 2019* https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/tobacco-smoking_en#health

² Directive 2014/40/EU 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 Text with EEA relevance https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2014_127_R_0001

implementation report published in May 2021, the Commission takes note of the TPD's contribution in enhancing tobacco control and improving public health overall, while identifying gaps and shortcomings, especially around market developments on novel tobacco products and electronic cigarettes, as well as enforcement capacities³.

Tobacco smoking: a heavy toll on respiratory diseases

Respiratory diseases are among the conditions that are heavily affected by smoking. Smoking is the primary cause of COPD, **the third leading cause of mortality worldwide**, affecting more than 36 million people in the European region as of 2020⁴. Globally, 65% of all deaths from COPD are attributed to tobacco use⁵. In asthma patients, smoking is linked with more severe disease symptoms, declined lung function, and higher mortality as compared to former smokers and non-smokers⁶. Finally, while still inconclusive, evidence shows that smoking is responsible for decreased lung function also in allergic rhinitis patients⁷.

Electronic cigarettes and novel tobacco products

Electronic cigarettes (e-cigarettes) and novel tobacco products, such as those based on heated tobacco (HTPs), are addressed by Articles 19 and 20 of the TPD. Today, they represent an increasingly prominent type of smoking products, with a rapidly emerging share in the EU market. E-cigarette users, for example, have more than doubled in the EU in recent years (from 7,2% in 2012 to 14,6% in 2017)⁸. HTPs, on the other hand, had almost 3 billion in sales in 2019⁹. The targeted consumers both product categories have been the young people.

Importantly, both product categories are currently exempted from the ban on characterising flavours such as candy or menthol, contrary to the regulation in place for conventional tobacco. There is strong evidence suggesting that these characteristics are a key factor of their increasing popularity among the youth, as flavours tend to make the products more attractive and reduce the perception of harm¹⁰.

Impact on respiratory disease

While the novel nature of these products means that research on their health effects is still emerging, there is near total scientific consensus that they too have negative effects on human

³ European Commission Report on the application of Directive 2014/40/EU

https://ec.europa.eu/health/publications/commission-report-application-directive-201440eu_en

⁴ A. Benjafeld, D. Tellez et al., 'An estimate of the European prevalence of COPD in 2050', 2021 https://erj.ersjournals.com/content/58/suppl_65/OA2866

⁵ J. Drope, S. Hamill, F. Chaloupka, C. Guerrero, H. M. Lee, M. Mirza, A. Mouton, N. Murukutla, A. Ngo, R. Perl, G. Rodriguez-Iglesias, N. Schluger, E. Siu, V. Vulovic, *The Tobacco Atlas*, 2022 <https://tobaccoatlas.org/challenges/health-effects/>

⁶ A. Tiotiu, I. Ioan et al., 'The Impact of Tobacco Smoking on Adult Asthma Outcomes', *International Journal of Environmental Research and Health*, 2021 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7908240/>

⁷ C. Grillo, I. La Mantia et al., 'Influence of cigarette smoking on allergic rhinitis: a comparative study on smokers and non-smokers', *Acta Biomedica*, 2019 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6776172/>

⁸ European Commission, Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), Opinion on Electronic Cigarettes, 2021 https://ec.europa.eu/health/system/files/2021-04/scheer_o_017_0.pdf

⁹ European Commission Report on the application of Directive 2014/40/EU

https://ec.europa.eu/health/publications/commission-report-application-directive-201440eu_en

¹⁰ Special Eurobarometer 506 Report, *Attitudes of Europeans towards tobacco and electronic cigarettes*, 2021 <https://europa.eu/eurobarometer/surveys/detail/2240>

health^{11,12,13}. For example, **e-cigarettes** contain harmful chemicals such as formaldehyde and volatile organic compounds, as well as nicotine, which we know from conventional tobacco as a highly addictive substance. Their use has been linked with increased symptoms, more exacerbations, and a more rapid decline in pulmonary function in asthma and COPD patients^{14,15}. With regards to smoke from e-cigarettes, they are linked with increased risk for respiratory health, including in certain inflammatory biomarkers and alterations in respiratory mechanics^{16,17}.

Meanwhile, HTPs have been found to contain various **toxic and irritant substances**, including nicotine and tar levels that are almost identical to a conventional cigarette^{18,19}. Use of HTPs is associated with an increase in the occurrence of respiratory diseases such as asthma and allergic rhinitis, as well as a higher inflammation risk²⁰. A study among Korean adolescents has demonstrated that the use of e-cigarettes and/or HTPs might enhance the adverse effect of conventional smoking on allergic rhinitis and asthma²¹.

In addition, there is emerging evidence on the **respiratory health effects of hookah**, another smoking tool that has risen in popularity in Europe. Despite much lower public awareness about it, smoking hookah has been shown to have negative effect on lung function, and regular users often face pulmonary complications and a higher risk for the development of COPD²².

¹¹ J. Drope, S. Hamill, F. Chaloupka, C. Guerrero, H. M. Lee, M. Mirza, A. Mouton, N. Murukutla, A. Ngo, R. Perl, G. Rodriguez-Iglesias, N. Schluger, E. Siu, V. Vulovic, *The Tobacco Atlas*, 2022

<https://tobaccoatlas.org/challenges/health-effects/>

¹² C. Girvalaki, M. Tzatzarakis et al., 'Composition and chemical health hazards of the most common electronic cigarette liquids in nine European countries', *Inhalation Toxicology*, 2018

<https://pubmed.ncbi.nlm.nih.gov/30369275/>

¹³ European Respiratory Society, *ERS Position Paper on Heated Tobacco Products*, 2019

<https://www.ersnet.org/news-and-features/news/ers-position-paper-on-heated-tobacco-products/>

¹⁴ S. C. Kotoulas, P. Katsaounou et al., 'Electronic Cigarettes and Asthma: What Do We Know So Far?', *Journal of Personalized Medicine*, 2021 <https://www.mdpi.com/2075-4426/11/8/723>

¹⁵ I. Thiri6n-Romero, R. P6rez-Padilla et al., 'Respiratory Impact of Electronic Cigarettes and "Low-Risk" Tobacco', *Revista de Investigaci6n Cl6nica*, 2018

https://clinicalandtranslationalinvestigation.com/frame_esp.php?id=199

¹⁶ TackSHS Project https://www.tackshs.eu/wp-content/uploads/2019/10/8-October_TackSHS_ICO_EN.pdf

¹⁷ A. Tzortzi, S. I. Teloniatis et al., 'Passive exposure to e-cigarette emissions: Immediate respiratory effects', *Tobacco Prevention & Cessation*, 2018 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7205134/pdf/TPC-4-18.pdf>

¹⁸ European Respiratory Society, *ERS Position Paper on Heated Tobacco Products*, 2019

<https://www.ersnet.org/news-and-features/news/ers-position-paper-on-heated-tobacco-products/>

¹⁹ X. Li, Y. Luo et al., 'Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes', *Nicotine & Tobacco Research*, 2019 <https://pubmed.ncbi.nlm.nih.gov/29319815/>

²⁰ M. Znyk, J. Jurewicz & D. Kaleta, 'Exposure to Heated Tobacco Products and Adverse Health Effects, a Systematic Review', *International Journal of Environmental Research and Public Health*, 2021 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8296358/>

²¹ S. J. Chung, B.-K. Kim et al. 'Novel tobacco products including electronic cigarette and heated tobacco products increase risk of allergic rhinitis and asthma in adolescents: Analysis of Korean youth survey', *Allergy*, 2019, <https://pubmed.ncbi.nlm.nih.gov/32003899/>

²² M. P. Patel, V. S. Khangoora, P. E. Marik, 'A Review of the Pulmonary and Health Impacts of Hookah Use', *Annals of the American Thoracic Society*, 2019 <https://www.atsjournals.org/doi/10.1513/AnnalsATS.201902-129CME>

Tobacco harm reduction strategies: let's not be fooled

Typically, novel tobacco and non-tobacco-based products are promoted by the industry as 'reduced-risk products' compared to conventional tobacco, often portrayed as a step towards quitting smoking. However, preliminary data show that, in many cases, **e-cigarettes use actually serve as an initiation to smoking** ('gateway effect'), with users moving on to other types of smoking products soon after^{23,24,25}. Even worse, almost 60% of e-cigarette users and 80% of HTP users end up being dual users i.e. smoking these products on top of conventional tobacco product consumption²⁶.

Besides, as described above, industry practices such as flavouring are widely used to increase the attractiveness of the products, **decreasing the users' harm perception** and increasing the will to try^{27,28}. Furthermore, a crucial by-product of the use of these products is the broader re-normalisation of smoking, especially among the youth.

In this regard, the **European Respiratory Society (ERS) adopted in 2019 a firm position** debunking several claims from the tobacco industry on the benefits of e-cigarettes and novel tobacco products and advising that a tobacco harm reduction strategy should not be used as a population-based strategy in tobacco control²⁹.

Exposure to smoke: patients find themselves unprotected

Passive exposure to second-hand smoke (SHS) is another factor of growing concern, especially for vulnerable groups such as children, pregnant women and people with chronic respiratory conditions. Today, beyond any doubt, research findings prove a **strong association between exposure to SHS and an increase in respiratory symptoms**. Even more alarming evidence shows that exposure to SHS is accountable for up to 4,3% of asthma cases and 2,9% of COPD cases, pointing towards a significant role of SHS exposure even in the onset of diseases among adult population³⁰.

Studies conducted in the context of the **EU-funded TackSHS project** concluded that the burden attributable to SHS is still substantial in the EU, mainly due to exposure at home. During 2017, SHS

²³ S. Soneji, J. L. Barrington-Trimis et al., 'Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis', *JAMA Pediatrics*, 2017 <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2634377>

²⁴ A. Glasser, H. Abudayyeh et al., 'Patterns of E-Cigarette Use Among Youth and Young Adults: Review of the Impact of E-Cigarettes on Cigarette Smoking', *Nicotine & Tobacco Research*, 2019

<https://academic.oup.com/ntr/article-abstract/21/10/1320/4998820?redirectedFrom=fulltext&login=false#no-access-message>

²⁵ D. Hammond, J. L. Reid et al., 'Electronic cigarette use and smoking initiation among youth: a longitudinal cohort study', *Canadian Medical Association Journal*, 2017 <https://www.cmaj.ca/content/189/43/E1328.long>

²⁶ Special Eurobarometer 506 Report, *Attitudes of Europeans towards tobacco and electronic cigarettes*, 2021 <https://europa.eu/eurobarometer/surveys/detail/2240>

²⁷ C. Meernik, H. N. Baker et al., 'Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review', *BMJ Open*, 2019 <https://bmjopen.bmj.com/content/9/10/e031598>

²⁸ European Commission, Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), Opinion on Electronic Cigarettes, 2021 https://ec.europa.eu/health/system/files/2021-04/scheer_o_017_0.pdf

²⁹ European Respiratory Society Tobacco Control Committee, *ERS Position Paper on Tobacco Harm Reduction*, 2019: <https://ers.app.box.com/v/ERSTCC-Harm-Reduction-Position>

³⁰ N. Korsbæk, E. M. Landt, M. Dahl, 'Second-Hand Smoke Exposure Associated with Risk of Respiratory Symptoms, Asthma, and COPD in 20,421 Adults from the General Population', *Journal of Asthma and Allergy* 2021 <https://www.dovepress.com/second-hand-smoke-exposure-associated-with-risk-of-respiratory-symptom-peer-reviewed-fulltext-article-JAA>

has been responsible for 344 deaths of children between 0 and 14 years old, as well as 30,000 premature deaths among the adult population³¹.

In addition, there are interesting findings emerging straight from patients: according to the EFA 'Active Patients' report of 2019, **tobacco smoke is patients' biggest concern**, with 9 in 10 asthma and COPD patients considering it as the main indoor pollutant that triggers most of their symptoms. While patients hold that authorities have done positive steps in establishing smoke-free environments, 1 in 3 thinks that more should be done to protect citizens in this respect, as exposure to second-hand smoke indoors is still too high.³²

Packaging and labelling aspects: imbalances leading to health harms

Articles 8 until 14 of the TPD provide the basis of the packaging and labelling requirements for tobacco and related products. These provisions are of paramount importance, as they include aspects such as health-related information and the product presentation, that can influence the attractiveness of products and therefore the number of smokers.

Article 11 grants the freedom to Member States to exempt e-cigarettes and novel tobacco products from featuring health warnings and information messages. As the study accompanying the Commission's implementation report describes, some Member States and stakeholders do not agree with the exemption measures, as these products may now be perceived as more attractive or less harmful by consumers³³.

Interestingly, the eight Member States that have gone beyond the TPD labelling provisions and have implemented a **mandatory plain packaging for tobacco products, report increased awareness of tobacco related-diseases** and associated illnesses, the motivation to quit, and help to reduce smoking, including among young people³⁴. Independent scientific evidence has also demonstrated that plain packaging works: it reduces smoking prevalence, increases thoughts about quitting and calls to quit lines, reduces brand awareness, attractiveness and appeal of the package, and increases the salience and effectiveness of health warnings among adolescents³⁵.

Smoke-free environments: legislation still elusive

Smoke-free environments are slowly gaining traction in recent years. According to the WHO, the European region has seen an increase in the number of countries applying a ban in all public places, from 4 countries in 2007 to 13 countries in 2017³⁶. While the TPD explicitly leaves the establishment of smoke-free environments at the discretion of the national governments, Member States have taken up action in various parts of the public domain. A key milestone in this respect has been the

³¹ TackSHS Project https://www.tackshs.eu/wp-content/uploads/2019/10/8-October_TackSHS_ICO_EN.pdf

³² European Federation of Allergy and Airways Diseases Patients' Associations (EFA), *Active Patients-ACCESS report*, 2019, https://www.efanet.org/images/Active_Patients_ACCESS_Care_EFA_Report_2019.pdf

³³ European Commission, *Support study to the report on the application of Directive 2014/40/EU*, 2021 <https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1/language-en>

³⁴ European Commission Report on the application of Directive 2014/40/EU

https://ec.europa.eu/health/publications/commission-report-application-directive-201440eu_en

³⁵ C. Vardavas, F. T. Filippidis et al., 'Plain packaging of tobacco products in the European Union: an EU success story?', *European Respiratory Journal*, 2017 <https://erj.ersjournals.com/content/50/5/1701232>

³⁶ World Health Organisation Regional Office for Europe, *European Tobacco Use – Trends Report 2019*, 2019 https://www.euro.who.int/_data/assets/pdf_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf

Council recommendation on Smoke-Free Environments of 2009, which in turn draws inspiration from the provisions in Article 8 of the Framework Convention on Tobacco Control (FCTC)³⁷.

Despite the progress being made, there are considerable gaps that remain in order to make the EU a truly smoke-free region, and ensure the full protection of people from exposure to SHS, in line with the recommendations in Article 8 of the FCTC guidelines³⁸.

As a recent study of the Commission demonstrated, compliance diverges among countries, with many Member States implementing only partial bans even in enclosed spaces such as libraries, hospitals, and restaurants/bars. **Partial bans are also observed in certain outdoor settings frequented by highly sensitive groups, such as playgrounds and public parks.** Overall compliance appears to be looser for e-cigarettes and HTPs compared to conventional tobacco, where compliance is much higher³⁹.

The reason for this seems to be the big **differences in the interpretation of indoor spaces**, coupled with significant enforcement gaps and the hospitality sector in many countries strongly opposing 100% smoke-free environments⁴⁰.

These findings are confirmed by the WHO too. The *Trends Report 2019* of the WHO Regional Office for Europe notes that protection from exposure to second-hand smoke varies greatly depending on the type of public place, and remains insufficient in government facilities, indoor offices, restaurants, pubs and bars, and on public transport. Moreover, despite the overwhelming evidence for smoke-free legislation, reducing harm from SHS and supporting the social norms of not smoking tobacco, over three quarters of countries in the WHO European Region had not implemented the recommended smoke-free policies as of 2016⁴¹.

Typically, measures on smoke-free environments are key aspects of broader national frameworks aiming at smoke-free generations. From this perspective too, variations among EU Member States are significant, with some of them drawing up ambitious plans and others advancing in a slower pace⁴².

In light of the extensive harm on health caused by exposure to SHS outlined above, EFA considers the upcoming revision of the Tobacco Products Directive and the update of the 2009 Council recommendation on Smoke-Free Environments as key opportunities to #ShowLeadership and take bold action against exposure to SHS. Whether it is pollution from tobacco smoke or novel products such as e-cigarettes, they all affect the air we breathe and must be prevented by applying the 100% smoke free environments⁴³.

³⁷ Council recommendation on Smoke-Free Environments, 2009 [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009H1205\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009H1205(01)&from=EN)

³⁸ World Health Organisation, Framework Convention on Tobacco Control (FCTC), *Guidelines for implementation of Article 8*, 2017 <https://fctc.who.int/publications/m/item/protection-from-exposure-to-tobacco-smoke>

³⁹ European Commission Directorate-General for Health and Food Safety, *Study on Smoke-Free Environments and Advertising of Tobacco and Related Products*, 2021 <https://op.europa.eu/en/publication-detail/-/publication/66e35611-5d59-11ec-9c6c-01aa75ed71a1/language-en>

⁴⁰ Ibid

⁴¹ World Health Organisation Regional Office for Europe, *European Tobacco Use – Trends Report 2019*, 2019 https://www.euro.who.int/_data/assets/pdf_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf

⁴² J. V. Been, A. A. Lavery et al., 'European progress in working towards a tobacco-free generation', *European Journal of Pediatrics*, 2021 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8589739/pdf/431_2021_Article_4116.pdf

⁴³ L. Li, Y. Lin, Y. Zhu, 'Effects of Electronic Cigarettes on Indoor Air Quality and Health', *Annual Review of*