EFA's response to the preliminary opinion of the Scientific Committee on Health, Environmental and Emerging Risks on Electronic Cigarettes (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 39 national associations from 24 countries and channel their knowledge and demands 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 is full Member of the **European Network for Tobacco Control and Tobacco Control** (ENSP), and we fully support their contribution to this consultation.

We welcome the opportunity to comment on this preliminary opinion, as it aims to offer input to the Implementation Report of the Tobacco Products Directive 2014/40/EU[1], due for May next year. The report findings will in turn feed into further decisions on a possible revision of the legislation.

There is another key reason why such initiatives are necessary: as electronic cigarettes are relatively new in the market and their share is rapidly increasing, there is an emerging **need to better understand their impact on health**, both from the user's and the non-user's perspective. Such an understanding requires significant commitment to longitudinal research, as well as multi-disciplinary studies to grasp the full extent of its associations with the onset and worsening of diseases.

EFA fully relies on researchers and academics to provide input on the scientific and technical aspects of e-cigarettes. Using science as our basis, **our main role as patients' representatives is to provide the patients' perspective arising from people's experiences**. We firmly believe that both the scientific and the patient evidence are needed and complementary on issues affecting human health, and kindly invite SCHEER to review our contribution through this lens.

EFA's comments on the SCHEER preliminary opinion on e-cigarettes

EFA believes that the preliminary draft opinion covers very well the current reality of e-cigarettes in Europe: their use and adverse health effects in the short and long term; their role as a gateway to smoking/ the initiation of smoking; and their role in cessation of traditional tobacco smoking.

We however find the opinion incomplete from the following points affecting allergy, asthma and COPD patients.

6.5 Assessment of Health Risks

Regarding the assessment of scientific evidence linking e-cigarettes use and health effects, we are worried that **lung disease and respiratory health in general health have been side-lined** (page 49) as compared to the amount of evidence collected for other diseases such as cardiovascular (pages 47-48). There is solid evidence linking e-cigarettes use with negative respiratory health outcomes, including reduced lung function[2]. The evidence below responds to the Terms of reference of this

[1] European Commission, Tobacco Products Directive 2014/40/EU
https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

[2] G. M. Brozek, M. Jankowski, J. E. Zejda, ''Acute respiratory responses to the use of e-cigarette: an intervention study'', Sci Rep., 2019 https://pubmed.ncbi.nlm.nih.gov/31048778/

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SCHEER opinion: "human data on health impacts on users of electronic cigarettes from epidemiological studies or clinical 20 trials" (page 11, lines 29-31).

- short-term vapor inhalation from e-cigarettes is associated with a greater prevalence of inflammation among asthma patients[3]
- e-cigarettes trigger processes that drive the development of the disease among COPD patients[4]
- e-cigarette use increases the risk of allergic rhinitis and asthma[5]

Almost all studies mentioned above note the pressing need for research on the long-term use of e-cigarettes and its health outcomes, a call that EFA fully supports. While developing this body of evidence will take several years to be conclusive, we think that **the association of e-cigarettes with adverse effects on respiratory health in the short term is already robust enough and should be fully embedded into the decision-making of the EU institutions**, firstly in this SCHEER opinion, and secondly in the EU regulatory approach to smoking and tobacco control.

6.5.5.3 Risk assessment based on modelled topography of electronic cigarette 48 consumption and second-hand exposure scenarios

Given that everyone spends the vast majority of their time inside, second-hand smoke directly affects indoor air quality. Whether it is pollution from e-cigarettes or from tobacco smoke, they all affect the air we breathe in and should be prevented by applying the **100% smoke free environments**, agreed on Article 8 of the WHO Framework Convention on Tobacco Control.

Studies have shown that e-cigarettes have the ability to degrade indoor air quality, putting bystanders at risk of second-hand exposure[6]. This is due to high concentrations of **particulate matter** resulting from the use of e-cigarettes, while studies suggest potential respiratory and cardiovascular effects from e-cigarette aerosols.

We believe the recent evidence from **EU-funded research project 'Tackling second-hand tobacco smoke' (TackSHS) should be included in this opinion** (page 58, lines 13-49), as it examined passive exposure to e-cigarette emissions and demonstrated an increased risk for respiratory health, including in certain inflammatory biomarkers[7].

[3] A. Lappas et al., ''Short-term respiratory effects of e-cigarettes in healthy individuals and smokers with asthma'', *Respirology,* 2018 https://pubmed.ncbi.nlm.nih.gov/28944531/

[4] H. Traboulsi et al., ''Inhalation Toxicology of Vaping Products and Implications for Pulmonary Health'', *International Journal of Molecular Sciences*, 2020 https://www.mdpi.com/1422-0067/21/10/3495/htm

[5] S. J. Chung 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*, 2020 https://pubmed.ncbi.nlm.nih.gov/32003899/

[6] L. Li, Y. Lin, Y. Zhu, ''Effects of Electronic Cigarettes on Indoor Air Quality and Health'', *Annual Review of Public Health,* 2020 https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-040119-094043#:~:text=The%20evidence%20in%20the%20literature,those%20attributed%20to%20t%2Dcigs.

[7] A. Tzortzi et al. ''Passive exposure to e-cigarette emissions: Immediate respiratory effects'', *TackSHS*, 2018 http://tackshs.eu/wp-content/uploads/2018/08/Passive-exposure-to.pdf

6.6 Role in the initiation of smoking (particularly focusing on young people)

One of the goals of the Tobacco Products Directive 2014/40/EU has been to reduce the consumption of smoking products in the general population, addressing specifically the commercialisation of tobacco among the younger generations.

Relevant surveys show a significant uptake of e-cigarette use amongst youth in some parts of the world[8]. In Europe, the use among young populations has followed the trajectory of increased marketisation: a Eurobarometer survey showed that 1 in 4 young people have tried e-cigarettes at least once[9]. Initiation to smoking through e-cigarettes increased in Europe between 2012 and 2014[10], prompting a broad discussion about the role of e-cigarettes as a gateway to smoking. However, e-cigarette use has been shown to increase the risk of smoking initiation of conventional cigarettes[11].

In light of the above alarming findings, **EFA believes that the commercialisation of e-cigarettes and other related smoking products should be regulated** in the same, or stricter, way as the tobacco products covered in the current Directive. This would include **prohibiting industry practices such as flavourings, and prohibiting marketing techniques such as device colouring** to counter-rest the evidence concluding that young people find e-cigarettes cool (Page 63, lines 33-43).

Finally, we consider that young people should be also asked about their knowledge of the health effects of e-cigarettes and not just about their opinion on these devices. We therefore invite the EU institutions **to launch or finance research linking health literacy and smoking and tobacco products**. In this like, we consider e-cigarettes should **include package warnings on health effects**, including an explicit mention to the risk of developing COPD.

[8] European Respiratory Society, ''ERS Position Paper on Tobacco Harm Reduction'', ERS Tobacco Control Committee, 2019 https://ers.app.box.com/v/ERSTCC-Harm-Reduction-Position

[9] Attitudes of Europeans towards tobacco and electronic cigarettes, *Eurobarometer 458*, 2017 https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146

[10] F. T. Filippidis, A. A. Laverty, V. Gerovasili, C. I. Vardavas, ''Two-year trends and predictors of e-cigarette use in 27 European Union member states'', *Tobacco Control*, 2017 https://tobaccocontrol.bmj.com/content/26/1/98

[11] L. Manzoli et al., ''Electronic Cigarettes Efficacy and Safety at 12 Months: Cohort Study'', *PLoS One*, 2015 https://pubmed.ncbi.nlm.nih.gov/26061661/