

The SCHEER Preliminary Opinion fails to address the potential health benefits for millions of EU adult smokers using e-cigarettes as alternatives to smoking, ignoring the public health principle of tobacco harm reduction. SCHEER fails to address the opinion’s terms of reference, to address individual and population public health considerations, and overlooks the required scientific analysis to help the Commission assess the potential need for legislative amendments under the Tobacco Products Directive. SCHEER state that e-cigarettes have negative impacts on health but does not position these harms in comparison to cigarettes. SCHEER disregards a growing body of international, independent scientific evidence that indicates exclusive e-cigarette use reduces users’ exposure to toxicants and an effective component of tobacco harm reduction helping smokers to quit¹.

SCHEER’s selective evidence fails to meet the required standards set out in its Rules of Procedure, including requirements of transparency and consideration of the best available scientific evidence.

LN13-14 “the overall weight of evidence for risks of long-term systemic effects on the cardiovascular system is **strong**” is inconsistent with available evidence. There is strong supportive evidence of cardiovascular improvements when adult smokers switch to e-cigarettes (relative risks), and no increased cardiovascular risk of nicotine exposure in consumers who have no underlying cardiovascular pathology. SCHEER derive conclusions by reviewing limited and older studies, mistakenly inferring short-term, transient effects with longer-term outcomes supported by misleadingly and unscientifically assuming e-cigarette effects are comparable with those of cigarettes. A significant amount of scientific literature on the cardiovascular effects of e-cigarettes was omitted.² This statement should be reconsidered to reflect the current scientific evidence.

LN42-44 “there is **strong** evidence that electronic cigarettes are a gateway to smoking for young people” is inconsistent with evidence presented in available studies. A number of experts have concluded that these studies fail to provide evidence to support a direct association between e-cigarette use and resulting cigarette smoking or to define how to test the gateway theory. Many comprehensive reviews and studies have also criticised e-cigarette ‘gateway’ arguments and conclude that there is no reliable evidence of a gateway effect, with ASH UK recently finding youth smoking rates at an all-time low. This statement should be reconsidered to reflect a more comprehensive review of the literature.³

LN50-52 “there is **weak evidence** for the support of electronic cigarettes' effectiveness in helping smokers to quit” is inconsistent with scientific evidence. While e-cigarettes are not medicinal smoking cessation devices, evidence from a number of studies not considered by SCHEER, shows that millions of EU and other smokers have successfully switched to e-cigarettes. The 2020 Cochrane Review evaluated the effect and safety of using e-cigarettes to help smokers achieve long-term smoking abstinence. Based on the scientific literature⁴ this statement should be reconsidered, and evidence should not be ‘weak’.

We respectfully urge SCHEER to review their conclusions and to transparently explain the analysis. The selective analysis, omission of the latest scientific evidence, and lack of transparency assessing the evidence does not meet the Committee’s own standards and the Opinion’s terms of reference. We support regulation grounded in science, considering objectively all evidence at hand and recognizing tobacco harm reduction to provide adult smokers who would otherwise continue to smoke the option of potentially less harmful nicotine products.

¹ See attachment in annex

² See attachment in annex

³ See attachment in annex

⁴ See attachment in annex