

Response to the extremely poor European Commission SCHEER preliminary opinion on e-cigarettes



....and *another* thing.

Further to my 30 Sept blog: [European Commission SCHEER scientific opinion on e-cigarettes - a guide for policymakers](#).

I have made a short submission to the consultation on the European Commission SCHEER Committee preliminary opinion on e-cigarettes. You can respond to the consultation on this very poor scientific assessment [here](#), where you can find all relevant documentation. The closing date is just before midnight CET, Monday 26 October 2020. All contributions are helpful, but keep it polite, objective and on the subject - the science of e-cigarettes - and most importantly, in your own words.

In my view, the problems with the report are too serious and fundamental to justify a line-by-line and paper-by-paper incremental review. I set out the

fundamental problems on my 30 September blog: [European Commission SCHEER scientific opinion on e-cigarettes – a guide for policymakers](#). So rather than pretend that this dreadful report can be easily fixed with a few more references and some different takes on the evidence, I have reiterated the main themes of that blog in the “Summary” box of the consultation submission form and provided the blog as a link and upload. I’ve no idea whether they will give this the slightest attention, but they should, because I’ll back when they’ve done the final report.

Update 26 Oct 2020. It’s the closing date and I’ve made an [additional submission](#).

Here’s my response:

Summary

The primary failure of the SCHEER preliminary scientific opinion is that it does not provide a scientific analysis that is useful to policymakers considering the effect of the Tobacco Products Directive and whether a future revision is necessary. In its current preliminary form, it is not fit for purpose.

The following eleven concerns are evident:

- 1. Inadequate comparison with cigarettes: the principal public health value of e-cigarettes is as a low-risk alternative to cigarettes.*
- 2. Inadequate comparisons with other benchmarks: there are exposures to toxins associated with e-cigarette use, but SCHEER does not compare these to realistic benchmarks of absolute tolerability of risk, such as occupational health exposure standards.*
- 3. Inadequate quantification of risk: it is of no value to report a hypothetical risk, such as the presence of a hazardous agent, without asking whether this is ‘material’.*
- 4. Poor differentiation between observable effects and markers for risk: nicotine use and vaping cause several observable effects on the body but it leaps to unjustified conclusions that such effects are markers for harms, but they are not.*
- 5. Overstating evidence on secondhand vapour: there is no evidence supporting a plausible risk from exposure to secondhand vapour and good reasons to believe any risk will be negligible. These reasons*

- include the low toxicity of vapour, the much smaller volumes produced compared to smoking and rapid dispersal in the atmosphere.*
- 6. Misunderstanding the public health mechanism of vaping: the report simplistically expresses concern that vaping might be appealing, yet that is how it works to attract smokers away from smoking.*
 - 7. Overplaying uncertainty over the long term: there is much less uncertainty than SCHEER suggests, given what we already know of vapour toxicity and human biomarkers of exposure.*
 - 8. Misunderstanding basic epidemiological concepts regarding the gateway effect: the report makes trivial errors with a failure to recognise the challenges of confounding and “common liability” as an explanation for associations between smoking and vaping.*
 - 9. Ignoring and selectively interpreting evidence: SCHEER has selectively reported and interpreted evidence concerning smoking cessation, ignoring compelling evidence that vaping displaces smoking.*
 - 10. Shifting and raising evidential hurdles: SCHEER demands evidence standards for e-cigarettes that are not routinely applied to standard smoking cessation methods.*
 - 11. The complete absence of policy impact research: the most serious failing is the omission of scientific research related to the effect of policies on smoking and vaping behaviour. Policy impact research is the most critical science for policymakers, and it is wholly absent from the preliminary opinion.*

To assist the Committee’s efforts to improve the final report, I have detailed these concerns on my blog [1]. I intend to produce a detailed critique of the final opinion to assist decision-makers and influential stakeholders in the European Parliament, European Council working group, the European Commission and relevant stakeholders. I hope that by then, SCHEER will have addressed most or all of these concerns and produced an opinion that provides a useful and objective assessment that assists policymakers.

[1] Bates, CD. European Commission SCHEER scientific opinion on e-cigarettes - a guide for policymakers, The Counterfactual, 30 September 2020. <https://www.clivebates.com/european-commission-scheer-scientific-opinion-on-e-cigarettes-a-guide-for-policymakers> [and uploaded attached]

Additional submission

I just wanted to make sure the point about the gateway effect was not lost on SCHEER.

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

The preliminary report does not cite the most up to date and credible review of studies relevant to the role of e-cigarettes in the initiation of smoking. This is:

Chan GCK, Stjepanovic D, Lim C, Sun T, Shanmuga Anandan A, Connor JP, et al. Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation. Addiction. 2020 Sep 4; <https://doi.org/10.1111/add.15246>

This review correctly recognises the methodological challenge of clearly distinguishing between a causal “gateway effect” and confounding by “common liabilities”. The SCHEER preliminary opinion does not adequately recognise these challenges, Chan et al draw a very different conclusion to that drawn by SCHEER.

The preliminary opinion abstract summarises the SCHEER conclusion:

“Regarding the role of electronic cigarettes as a gateway to smoking/the initiation of smoking, particularly for young people, the SCHEER concludes that there is STRONG evidence that electronic cigarettes are a gateway to smoking for young people.”

This conclusion and the confidence expressed in it are unsupported by any evidence and convincingly refuted by the analysis in Chan et al.

I include the abstract of Chan et al. below and attach the full study as an upload:

Background and Aims

Studies have consistently found a longitudinal association between e-cigarette use (vaping) and cigarette smoking. Many have interpreted such association as causal. This systematic review and meta-analysis evaluated the plausibility of a

causal interpretation by (1) estimating the effect of adolescent vaping on smoking initiation, adjusted for study quality characteristics, (2) evaluating the sufficiency of adjustment for confounding based on the social development model (SDM) and the social ecological model (SEM) and E-value analyses and (3) investigating sample attrition and publication bias.

Methods

Systematic review and meta-analysis of longitudinal studies that examined the association between e-cigarette use at baseline and smoking at follow-up. Participants were non-smokers aged < 18 at baseline.

Results

Meta-analysis of 11 studies showed a significant longitudinal association between vaping and smoking [adjusted odds ratio (aOR) = 2.93, 95% confidence interval (CI) = 2.22, 3.87]. Studies with sample sizes < 1000 had a significantly higher odds ratio (OR = 6.68, 95% CI = 3.63, 12.31) than studies with sample sizes > 1000 (OR = 2.49, 95% CI = 1.97, 3.15). Overall, the attrition rate was very high (median = 30%). All but one study reported results from complete sample analysis, despite those dropping out having higher risk profiles. Only two studies comprehensively adjusted for confounding. The median E-value was 2.90, indicating that the estimates were not robust against unmeasured confounding.

Conclusions

There is a longitudinal association between adolescent vaping and smoking initiation; however, the evidence is limited by publication bias, high sample attrition and inadequate adjustment for potential confounders.

Uploaded file: [here](#)

Next steps

My view is that the report is political and mainly sets out to serve the European Commission DG SANTE (health directorate) increasingly fanatical and captured anti-vaping posture. I doubt it will change much through consultation, but we must hope that it does. I think the most useful approach to the report will be a detailed science and policy-based critique of the final opinion. This document will

play a political role in formulating any future review of the Tobacco Products Directive. I am determined, therefore, that a thorough critique of the SCHEER report - as fair as possible and as harsh as necessary - will be available to policymakers, politicians and stakeholders once it is published in final form.