European Commission SCHEER scientific opinion on e-cigarettes – a guide for policymakers

"C'mon… we'll never get away with *that*"

Introduction

The SCHEER opinion on e-cigarettes

On 23 September 2020, the European Commissions' Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) provided its *Preliminary Opinion on Electronic Cigarettes* (context & abstract, preliminary report PDF). This opinion is important because it is one input to the report on the implementation of the EU Tobacco Products Directive 2014/40/EC, under Article 28 of the Directive. This review should complete by 20 May 2021, and it may form the basis for a further revision of the Tobacco Products Directive. The Committee's mandate (Request for Scientific Opinion) sets out its terms of reference.

Consultation

The preliminary scientific opinion is open for consultation responses until 26 October 2020. The consultation system is here: Public consultation on electronic cigarettes and looks designed to deter responses to the extent possible. ETHRA,

European Tobacco Harm Reduction Advocates, provides guidance on responding here. However, that is not the only way to respond to it, though responding directly is important. Another way is to approach the people who are intended to make sense of and use the opinion – policymakers in EU member states and European Commission, politicians in the EU legislature, and stakeholders in the political policymaking process. This post is for them.

This post

In this post, I discuss why the SCHEER preliminary opinion offers no useful analysis or relevant insights to policymakers. It is not that the committee has not reviewed a lot of literature: it has. It stems from a more fundamental problem: a failure to frame the scientific knowledge in a way that will assist policymakers in considering what, if anything, to do next. Though policymakers should be the primary audience, the report also provides little of value to other communities of interest – smokers, vapers, parents, public health or medical practitioners, or businesses.

It starts with reproducing the report abstract and then groups my advice to appropriately sceptical policymakers under ten headings.

Contents

The SCHEER preliminary opinion – abstract

The following text is the abstract of the SCHEER opinion. Though short, it is a guide to the messages that the committee wishes to convey to policymakers.

SCHEER WG on Electronic cigarettes
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On request from: *European Commission*
Adopted on: *23 September 2020*

Following a request from the Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed the most recent scientific and technical information on electronic cigarettes.

The SCHEER concludes that on health effects

a) for users of electronic cigarettes

1. the overall weight of evidence for risks of local irritative damage to the respiratory tract is i) moderate for heavy users of electronic cigarette due to the cumulative exposure to polyols, aldehydes and nicotine, and ii) not to be excluded for average and light users. However, the overall reported incidence is low.

2. the overall weight of evidence for risks of long-term systemic effects on the cardiovascular system is strong.

3. the overall weight of evidence for risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde is weak to moderate. The weight of evidence for risks of adverse effects, specifically carcinogenicity, due to metals in aerosols is weak.

4. the overall weight of evidence for risks of poisoning and injuries due to burns and explosion, is strong. However, the incidence is low.

5. the overall weight of evidence for risks of other long-term adverse health effects, such as pulmonary disease, CNS and reprotoxic effects, plausible based on the hazard identification and limited human evidence, cannot be established due to lack of consistent data.

6. to date, there is no specific data that specific flavourings used in the EU pose health risks for electronic cigarette users following repeated exposure (but may enhance attractiveness).

b) for second-hand exposed persons

1. the overall weight of evidence is moderate for risks of local irritative damage to the respiratory tract.

2. the overall weight of evidence for risks of systemic cardiovascular effects in second-hand exposed persons due to exposure to nicotine is weak to moderate.

3. The overall weight of evidence for carcinogenic risk due to cumulative exposure to nitrosamines is weak to moderate.

Electronic cigarettes are relatively new in terms of exposure to humans. More research is needed, in particular on long-term health effects.

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. There is also strong evidence that nicotine in e-liquids is implicated in the development of addiction and that flavours have a relevant

contribution for attractiveness of use of electronic cigarette and initiation.

Regarding the role of electronic cigarettes in cessation of traditional tobacco smoking, the SCHEER concludes that there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as weak to moderate.

Preliminary advice for policymakers on the SCHEER opinion on e-cigarettes

This is a preliminary critique, and I expect to update this over the next few weeks.

The overall problem with the SCHEER opinion is that it does not provide useful scientific information for policymakers. However, it is intended as input to the policymaking process in the European Union, as the effect of the Tobacco Products Directive is reviewed and a new revision to the directive is under consideration. To the extent that it does provide judgements on the literature, these are selective and often misleading. I set out the main problems under ten headings below:

1. Inadequate comparison with cigarettes

Electronic cigarettes are primarily used as alternatives to smoking and their health impact when used a substitute for cigarettes is highly *beneficial,* involving large decreases in exposures to toxicants. 26% of EU citizens smoke and this subpopulation is at the most serious risk of disease and premature death – with 700,000 dying each year. If Europe really wants to "beat cancer" (see Europe's Beating Cancer Plan), then this is the population most at avoidable risk of cancer. *So it is inexplicable that e-cigarette risks are not positioned relative to cigarettes*. This essential information about *relative risk* is absent throughout the whole assessment, yet it is the central public health proposition offered by e-cigarettes.

For example, one study found that e-cigarette users were typically exposed to

0.4% of the lifetime cancer risk of smokers (Stephens et al, 2018).

> *Most e-cigarette analyses indicate cancer potencies <1% that of tobacco smoke*

There is also evidence (George et al, 2019) of significant improvements in cardiovascular outcomes in smoking switching to e-cigarettes:

> *TC smokers, particularly females, demonstrate significant improvement in vascular health within 1 month of switching from TC to EC. Switching from TC to EC may be considered a harm reduction measure.*

In the case of explosions and fires, the relevant comparator is fires and related injuries caused by smoking materials – there is around three *orders of magnitud*e difference. For example, according to the US National Fire Protection Association, around 18,000 fires were caused annually in the US by smoking materials from 2012-16. Yet the same association reported just 15 fires and explosions with e-cigarettes in 2015.

These relative risk findings are clear 'must-know' scientific insights for policymakers, yet they are wholly absent from the SCHEER assessment.

2. Inadequate comparisons with other benchmarks

Modern societies do not generally have a zero-tolerance for individual risk, especially if this arises from choices made by users and the risks fall primarily on them. If we did, we would have little work, leisure, travel, food or sport. There is no sign that the SCHEER has placed the risks they discuss into a useful context by using other frameworks for assessing tolerability of risk, for example, occupational health exposures limits. Burstyn, 2013 made an early assessment of e-cigarette toxic exposures relative to 'total limit values' (TLV) for occupational health exposures. Burstyn concluded:

> *The vast majority of predicted exposures are <1% of TLV. Predicted exposures to acrolein and formaldehyde are typically <5% TLV. Considering exposure to the aerosol as a mixture of contaminants did not indicate that exceeding half of TLV for mixtures was plausible.*

These study findings are highly relevant to policymakers yet they would struggle to extract this important insight from the SCHEER report – the committee simply did not think of risk in this way. Burstyn suggests that a deliberately chosen and voluntary exposure falls far below standards set for involuntary exposure from sources outside the control of the user, for example in the workplace.

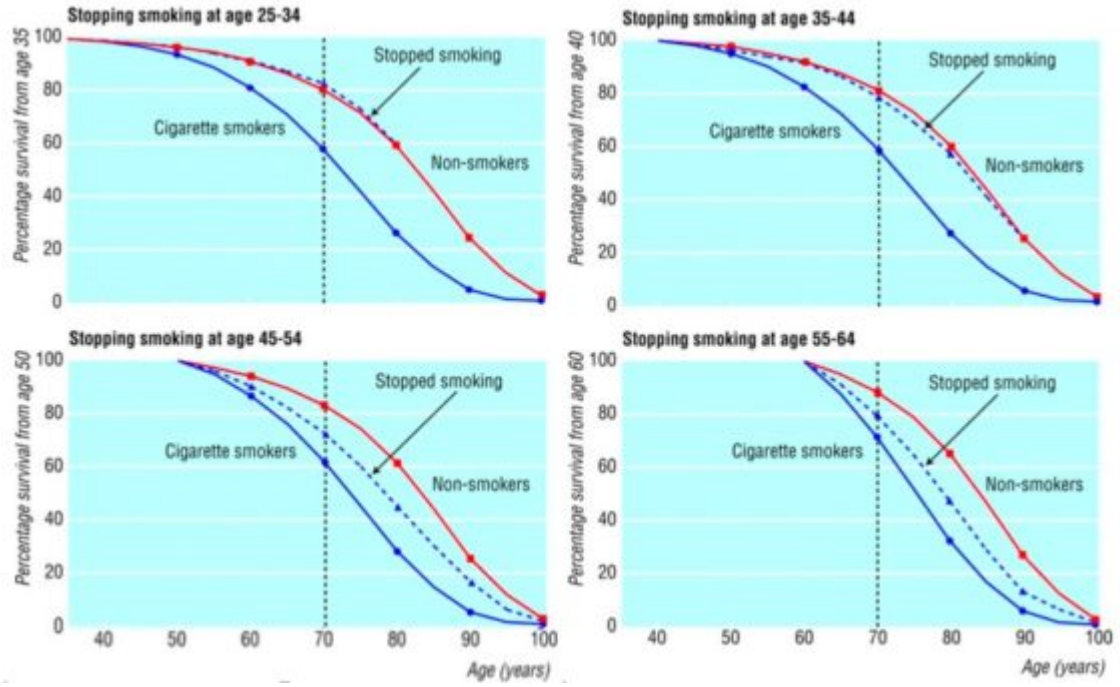
[aside: strangely, Burstyn's study is in the list of citations at the end of the opinion, but I could not find it referenced in the opinion itself – I guess someone realised it was off-message and removed the citing text without removing the citation].

3. Inadequate quantification of risk

The assessment gives a view on the *strength of evidence* about various risks. But the strength of evidence is not the same as incidence (likelihood a user will experience it) or the severity of the risk (how much harm it does). It would, in theory, be possible to have *strong evidence* of a *rare occurrence* of a *minor* irritation to the respiratory system, for example. Because the assessment provides no meaningful quantification of risk, it is of little value to policymakers. A policymaker presented with assertions about risk should be trying to understand materiality – *is that a lot or a little?* A statement like *"may cause cancer"* provides virtually no policy-relevant information. The opinion provides no frame of reference for assessing the seriousness of the risks it discusses.

4. Poor differentiation between observable effects and markers for risk

It is possible for something to create a change in the body (or in a test tube or in a rat) and for this not to translate to a risk to health. This is because the body is resilient and has evolved defences and repair mechanisms to cope with external hazards. It should be recalled that even in the case of smoking, with extremely high toxic exposures, users avoid nearly all the lifetime mortality risk of smoking if they quit by age 40, perhaps after 20 years smoking. See the groundbreaking 'doctors study' Doll et al, 2004 *Mortality in relation to smoking: 50 years' observations on male British doctors* – especially see Figure 4)



> *Thus [those who stopped at age 25-34 or 35-44] had, on average, had substantial exposure to cigarette smoking for about 20 years before giving up the habit, yet they still avoided most of the excess mortality that they would have suffered if they had continued to smoke.*

The question is what would these mortality curves look like for the vastly lower exposures arising from decades of vaping? SCHEER typically looks at *markers* of exposure or risk and leaps to a conclusion about potential harm.

The use of nicotine, a mild recreational drug, intentionally creates a variety of effects on the body, including on the cardiovascular system. However, long term epidemiological studies of nicotine use without smoke inhalation, for example through the use of nicotine gum or snus, do not show serious health effects. For example, on page 47 of the report attention is drawn to the effects of vaping on 'arterial stiffness" and cites Vlachopoulos C et al. 2016. *Electronic Cigarette Smoking Increases Aortic Stiffness and Blood Pressure in Young Smokers*.

But it does not draw attention to a similar study by the same author about caffeine: Vlachopoulos C et al. 2003 *Effect of caffeine on aortic elastic properties and wave reflection*. The latter study concluded:

> *Caffeine affects unfavorably aortic stiffness and enhances wave reflections. This finding has implications for the impact of caffeine consumption on*

cardiovascular risk.

But there is no established cardiovascular risk associated with routine coffee consumption – see Wilson & Bloom, 2016. The point here is to give a specific example of a general problem with the opinion and science in this field more generally.

5. Overstating evidence on secondhand vapour exposure

It is claimed, for example, that second-hand vapour may be a cause of cancer and cardiovascular disease in bystanders, with the evidence described as 'weak to moderate'. There is in fact, *no evidence* at all that supports the contention. The associations between secondhand smoke exposure and cancer and cardiovascular disease are weak and contested, and largely rely on data from long-term spousal exposure (i.e. in people who live together). The only way SCHEER could have drawn these conclusions is to make speculative assumptions about cancer and cardiovascular risk from direct active vaping exposure and then assumed some sort of relationship between active and secondhand vapour exposure. The problem here is a set of nested assumptions about vaping risks each of which is speculative and all of which may add in reality to e negligible or non-existent effect. The question here is in what circumstance would they ever say "no evidence" – i.e. is there a *de minimus* at which the risks are so small or unlikely, that it is no longer appropriate to raise them?

Anyone trying to present insights on an issue would first provide a conceptual explanation, perhaps drawing on a comparison with risks arising from secondhand cigarette smoke, and then fill in with data to quantify. If SCHEER had done that, it would look something like this:

There are three key differences in the way bystanders are exposed to secondhand vapour aerosol compared to secondhand smoke.

1. *The quantity emitted*. Most of the inhaled vapour is absorbed by the user and only a small fraction is exhaled (15% or less, depending on the constituent). In contrast, about four times as much environmental tobacco smoke comes directly from the burning tip of the cigarette than is

exhaled by the smoker. There is no equivalent of this "sidestream smoke" for vaping.

2. *The toxicity of the emissions*. Tobacco smoke contains hundreds of toxic products of combustion that are either not present or present at very low levels in vapour aerosol. Vapour emissions do not have toxicants present at levels that pose a material risk to health. Exposure to nicotine, itself relatively benign, is unlikely to reach a level of pharmacological or clinical relevance.
3. *The time that the emissions remain in the atmosphere*. Environmental tobacco smoke persists for far longer in the environment (about 20-40 minutes per exhalation). The vapour aerosol droplets evaporate in less than a minute and the gas phase disperses in less than 2 minutes.

To the extent that there is evidence of cancer risk, it suggests the risk is negligible. See, for example, Avino et al. 2018 *Second-hand Aerosol From Tobacco and Electronic Cigarettes: Evaluation of the Smoker Emission Rates and Doses and Lung Cancer Risk of Passive Smokers and Vapers* – found cancer risk from e-cigarette aerosol to be vastly lower than for cigarette smoke.

> *…excess life cancer risk (ELCR) for second-hand smokers was five orders of magnitude larger than for second-hand vapers.*

"Five orders of magnitude" loosely translates to 10,000 times. So does the SCHEER report convey the sense that passing vaping risk is 1/10,000th that of passive smoking? No, it does not. Yet this is more useful information than saying the evidence for "*carcinogenic risk due to cumulative exposure to nitrosamines is weak to moderate*".

6. Misunderstanding the public health mechanism of vaping

SCHEER points out that e-liquid flavours do not cause known health problems (correct), but may "enhance attractiveness". This is true – flavours are integral to the product appeal of e-cigarettes. However, this expression "enhance attractiveness" is used throughout the opinion as though attractiveness is a bad thing and therefore that *unattractive* products would be better. This betrays a poor understanding of e-cigarettes cause a reduction in population disease

burden

In a situation where 26% of European Union adults are smoking and approximately 700,000 dying as a result annually, the availability of an attractive low-risk alternative provides options for smokers to switch and greatly reduce their personal risk – on their own initiative and at their own expense *because they find the idea attractive*. The correct way to conceptualise the public health mechanism of vaping is as presenting smokers with a rival "value proposition". This rival value proposition includes the flavour, the pharmacological effect (reward from nicotine), the user's perception of risk, price, accessibility, the branding, the aesthetics etc. The Royal College of Physicians spell this out very clearly – degrading the value proposition of e-cigarettes risks prolonging the epidemic of smoking:

> *However, if [a risk-averse, precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer-friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)*

A similar problem applies to the discussion of nicotine addiction. SCHEER opinion makes liberal use of the term 'nicotine addiction' without really being clear what they mean by it or what role it plays, though the Committee clearly believes this is a bad characteristic of e-cigarettes. But is it? Assume for a moment that e-cigarettes are capable of matching the physiological reward provided by smoking, but concerns about "nicotine addiction" caused regulators to reduce the potential of e-cigarettes to deliver in some way. This would be handing a decisive advantage to the cigarette trade.

The conceptual framing matters a great deal to regulators as interventions can have strongly perverse impacts if they are based on a misunderstanding of the mechanisms that create health benefits or detriments. If European policymakers read this opinion as advice to reduce the attractiveness of e-cigarettes, then they will be introducing regulatory protections to the cigarette trade and, in relative terms, improving the attractiveness of the remaining as a smoker – with certain harm to health.

7. Overplaying uncertainty over the long term

It is a statement of the obvious that we do not have long term data on vaping health effects (i.e. a multi-decadal cohort study of exclusive vaping). This is always the case for relatively new products, and given that most vapers have previously been smokers, it is unlikely we will have a 'clean' cohort without confounding by prior smoking for many decades, if ever.

However, it is a logical fallacy to shift from "we don't know everything about the long term impacts" to "we don't know anything about the long term impacts". While it is true that it took many decades to understand the impacts of smoking, there has been dramatic scientific advance since the work of the pioneers in smoking research. We now have extensive data on toxicology and chemical risks and numerous guidelines for controlling long term risks, for example, occupational exposure limits. If cigarettes were invented today, we would know within a day that they were extremely hazardous. The basis for believing the risks will be very much less than smoking over the long terms rests on several contemporary insights:

- *Physics and chemistry of the respective aerosols*. E-liquid aerosols are fine liquid droplets with relatively simple chemistry that evaporate easily compared to the viscous particles that make up complex chemical 'tar' in cigarette smoke.
- *Toxicology*. In vaping aerosol, there far are fewer detectable hazardous agents and at much lower concentrations than found in cigarette smoke.
- Exposures. Biomarkers of exposure studies show the concentrations of toxins in the blood, saliva and urine of vapers is far lower than in smokers and approaches the levels seen when people quit smoking
- *Experience*. In over ten years of use so far, only minor symptoms and risk markers have been found.
- *Control*. So far, there has been little to concern users. However, should a concern arise, the products are more readily modifiable by manufacturers or regulators. This is important because it means problems can be addressed if they emerge, for example by addressing particular ingredients or contaminants. The complex combustion chemistry of cigarettes does not allow much scope for that.
- *Uncertainty*. Any uncertainty cuts both ways. It is entirely possible that

long term evidence will show no material risk at all – this has been the experience with snus.

8. Misunderstanding basic epidemiological concepts regarding the gateway effect

SCHEER is remarkably confident in its conclusion that e-cigarettes are a gateway to smoking or the initiation of smoking, declaring that the evidence of a gateway effect is "strong". No other authorities share this confidence.

The widespread scepticism about gateway claims is for the simple reason that it is impossible to eliminate confounding or "common liability" from any observed associations between vaping and smoking. Smoking and vaping are very similar behaviours (albeit with radically different risks) and therefore the factors that cause people to smoke are likely also to cause them to vape. These factors include family, home environment, mental health status (itself a hugely complicated variable), personal efficacy, community factors (homeless, veteran, prisoner), school environment and performance, delinquency, genetics, consumption preferences (i.e. liking nicotine) and many other factors. These are difficult (by which I mean *impossible*) to measure and characterise in a way that allows them to be eliminated from the observed associations between vaping and smoking.

This view is shared by the authors of a recent systematic review of gateway effect claims: Chan GCK et al. 2020, *Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation*. After reviewing much of the literature also considered by SCHEER, the authors concluded:

> *Only two studies comprehensively adjusted for confounding. The median E-value was 2.90, indicating that the estimates were not robust against unmeasured confounding. 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.*

It is difficult to see, therefore, how the SCHEER could arrive at such a confident and opposite conclusion.

However, the problem runs deeper than that in the SCHEER opinion. The gateway concept itself is barely defined by SCHEER – i.e. what is the relevant exposure and the outcome of concern, and how would you test that the exposure caused the outcome? Whether vaping or smoking came first in a period of teenage experimentation is of little interest and it would never be possible to show that one caused the other. In its 2015 report, E-cigarettes: an evidence update Public Health England's expert reviewers showed that there was little of substance to gateway claims made at the time and advised:

> *We strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field.*

SCHEER does not heed this wise advice but also does not articulate how its gateway theory can be tested, it just cites papers showing associations and mistakenly treats these as amounting to evidence of a causal relationship.

A more useful definition of a gateway effect would be if a substantial number of young people were reaching, say, age 20 as regular smokers because of a period of vaping in their teenage years. This would be a genuinely concerning outcome. There is no evidence to support this effect. Not only that, it is impossible to tell what these young people would have done in the absence of e-cigarettes. To the extent that there is evidence, (see Jarvis et al, 2020 analysis of US data) it suggests the more frequent adolescent users of e-cigarettes are those who were previously smokers or would-be smokers – for these teenage users, e-cigarette use may be beneficial, if not now, in the future as a diversion from smoking. SCHEER comes nowhere close to wrestling with these issues.

9. Ignoring and selectively interpreting evidence

SCHEER declares that is there is "*weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit*". There are two initial questions here:

- What evidence would the committee be satisfied by?
- What does SCHEER mean by "helping smokers to quit"?

What evidence did the SCHEER consider? There are now four strands of evidence that suggest e-cigarettes are effective in helping people to quit smoking. I give

examples of each, but each of these can be developed with further citations.

1. Evidence from randomised controlled trials, notably, Hajek et al 2019, which showed vaping to be about twice as effective as NRT; "*E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support.*" The RCT evidence was recently synthesised by the Cochrane Collaboration, which concluded: "*There is moderate-certainty evidence that ECs with nicotine increase quit rates compared to ECs without nicotine and compared to NRT. Evidence comparing nicotine EC with usual care/no treatment also suggests benefit, but is less certain.*".
2. Observational studies (watching what happens when people use e-cigarettes) for example, Jackson et al 2019; "*Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England.*"
3. Population data (unusually rapid reductions in smoking prevalence or cigarette sales visible in market data), for example, Zhu S-H et al, 2018. "*The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.*"
4. User experience. The thousands of testimonials of users who have struggled to quit smoking using other methods. See, for example, CASAA (12,500 testimonials) and, before dismissing 'anecdotes' please see Carl V Phillips on why Anecdotes ARE scientific data

It is unclear why SCHEER found this evidence unpersuasive or insufficient (or failed to find it). The danger is expecting consumer products and behaviours change to conform to protocols that work for testing drugs. To understand the impact of e-cigarettes, the policymaker needs a sysnthesis of several strands and types of evidences – in this case they converge clearly on e-cigarettes displacing smoking.

What does SCHEER mean by "helping smokers to quit? Here again, the problem is poor framing – there are several pathways by which vaping can displace smoking, not simply as a quit aid. The following mechanisms are possible:

1. As an aid for someone who already wants to quit smoking – a kind of souped-up NRT.
2. By encouraging people who would not otherwise try to quit to give it a try, because it continues pleasurable aspects of a habit they like. In this way, it increases the number of quit attempts.
3. It may form part of a (reluctant) response to a tobacco control measure – for example, the economic pressure created by cigarette taxation
4. It may never be a conscious effort to quit smoking, but become a change of behaviour by default.
5. It may prevent relapse to smoking among people who have already quit smoking, but miss it or are vulnerable to relapse to smoking (e.g. due to stressful life events).
6. It may displace smoking uptake in young people or be a diversion from smoking experimentation that would otherwise consolidate into a more entrenched smoking habit

SCHEER should have avoided simplistic analogies with smoking cessation treatments and recognise that the emergence of e-cigarettes emergence and other reduced-risk products are a pervasive technology diffusion and disruption in a market dominated until now by a very dangerous product. E-cigarettes are a rival product and rival 'value proposition' to smoking, not a stop-smoking aid. They work by appealing to smokers as an innovative and continually evolving consumer product.

10. Shifting and raising evidential hurdles

It feels as though one problem for the concept of tobacco harm reduction is constantly shifting evidential hurdles. For several years the opponents of e-cigarettes called for 'randomised controlled trials' as the supposed 'gold standard' of evidence. But as soon as a large credible trial was done showing highly positive results, the e-cigarette opponents tried argued it was inadequate, that people were still using nicotine and more real-world data was required. However, how much real-world data is available to support favoured tobacco control measures? The answer is very little. Let me give one example: the use of NRT.

Brown J, et al. 2014. *Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study*. Also, press release 20 May

2014

> *People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum*

In fact, this study showed NRT to be no better than trying to quit without aids. That perspective was confirmed by a later study. Jackson SE et al. 2019 *Moderators of real-world effectiveness of smoking cessation aids: a population study.*

> *Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England. Use of prescription of nicotine replacement therapy is also associated with higher abstinence rates, but only in older smokers, and use of websites only in smokers from lower socio-economic status.*

Policymakers need consistency and completeness in the way evidence is assessed – not one standard for established tobacco control measures and a higher standard for alternatives that tobacco control academics do not like. The SCHEER opinion appears to ignore much of the evidence that does exist, frames the mechanisms of smoking displacement too narrowly and erects evidential hurdles that are not applied evenly in other areas of tobacco policy.

11. The complete absence of policy impact research

If I was going to reserve the most serious criticism until last, it would relate to research not even considered by SCHEER. SCHEER has completely overlooked the most relevant body of research for policymakers: research that investigates the effects of measures. This would include investigation of whether TPD measures worked and had intended effects or whether they had perverse consequences – for example, restrictions on e-cigarettes that have the effect of increasing smoking and so cause ill-health while providing regulatory advantages in the internal market to cigarettes at the expense of e-cigarettes. Recall the statement of the Royal College of Physicians (*Nicotine without smoke: tobacco harm reduction*, 2016) mentioned above:

> *However, if [a risk-averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)*

The most relevant science for decision-makers reviewing the impact of the Directive and considering whether a further revision is justified is the science that tests whether the Directive is reducing harm or, in the ways suggested by this statement from the RCP, increasing harm by perpetuating smoking. Yet there is nothing in the SCHEER report that covers this – that is an inexcusable omission.

SCHEER may claim that, despite its obvious relevance, this type of science was beyond its terms of reference. It is quite possible that the European Commission would find a review of the intervention science troubling as it might show that the Directive is harmful and ill-conceived and deliberately chose not to see this evidence. However, the terms of reference do in fact allow for open-ended exploration of the impact of measure implemented in the TPD. These are the terms of reference:

2. Terms of reference

The main purpose of the scientific opinion is to assist the Commission in assessing the most recent scientific and technical information on e-cigarettes. Findings presented in the scientific opinion will feed into the Commission's reporting obligations under Article 28 of the TPD and also help the Commission in assessing the potential need for legislative amendments under the Directive or other regulatory/enforcement measures.

The assessment should include and address the role of e-cigarettes, looking into potential impacts on the EU context, in relation to:

- their use and adverse health effects (i.e.; short- and long-term effects)
- risks associated with their technical design and chemical composition (e.g.; number and levels of toxicants) and with the existing EU regulatory framework (e.g. nicotine concentration and limits)
- their role as a gateway to smoking / the initiation of smoking (particularly focusing on young people)
- their role in cessation of traditional tobacco smoking

While drawing-up the scientific opinion, the committee should take into consideration the most recent and up-to-date scientific evidence and technical developments and, as appropriate, the existing provisions concerning e-cigarettes under the TPD (in particular Article 20(3)) and the evolution of new products on the market. The scientific opinion should address considerations relevant both at individual level and at a population level, from a public health perspective.

How can you assess e-cigarettes' "*role in cessation of traditional tobacco smoking*" if you don't evaluate the impact of the 20mg/ml nicotine limit on making e-cigarettes less competitive with cigarettes?

How can you know if there are "*risks associated with their technical design*" if you don't evaluate those aspects of the technical design imposed by the Directive, including warnings, limitations on the tank and refill container size, strange pack inserts and nicotine concentration limits?

How can you evaluate their "*use and adverse health effects*" without understanding whether the advertising ban in Article 20(5) makes it less likely that smokers will try them as an alternative to smoking?

How can you assess "*the potential need for legislative amendment under the Directive or other regulatory/enforcement measures*" if you do not know what effect the existing measures have had, including whether they have made the situation worse?

Comments

Having been a civil servant from 2003 to 2012, I've seen quite a lot of scientific assessment designed to inform policymaking. But I have rarely seen anything quite as misjudged, poorly executed and unhelpful as this – it simply does not shine any useful light on the actual scientific issues policymakers have to address. If I had received this, to be honest, I'd have sent it back and asked someone else. To do science that is relevant for policymakers, you have to frame the advice around the realities of the issue. It is no good saying that you can get all the information by reading the full report – in this case, you can't. In this case, a policymaker would be unable to extract any useful meaning from the thicket of citations that are basically listed (as if to show they are paying attention) but are not assessed within in any coherent intellectual framework. But few policymakers or elected representatives will stray deeply into the document. The abstract and summary therefore *really* matter – but they are woefully inadequate both as scientific synthesis and science communication.

Please leave your comments and suggestions for improvement and I will update this through October 2020.

- My response to the consultation on the SCHEER preliminary opinion: Response to the extremely poor European Commission SCHEER preliminary opinion on e-cigarettes (21 October 2020)

Other criticisms

- Snowdon, CJ. A response to the SCHEER preliminary opinion on electronic cigarettes, EPICENTER (European Policy Information Center), 21 October 2020. [link]

> *The authors of the SCHEER report appear to be biased against e-cigarettes and harm reduction. The report reheats several arguments, such as the 'gateway effect' and the 'renormalisation' hypothesis, which are now a decade old and have been contradicted by real world evidence. While it downplays strong evidence showing that e-cigarettes have been a gateway from smoking for millions of people, it amplifies speculation about hypothetical risks. When the authors are unable to find adequate evidence for anti-vaping claims, they quote from organisations which share the same prejudice. Much of the evidence is*

treated selectively and some of the conclusions made about the strength of evidence are baffling.