CONSULTATION QUESTIONS

Age restriction for e-cigarettes

1. Should the minimum age of sale for e-cigarette devices, refills (e-liquids) be set at 18?

Yes ☒ No ☒ Proxy purchase should not be enforced. Harm reduction should be allowable.

2. Should age of sale regulations apply to:

a. only e-cigarette devices and refills (e-liquids) that contain nicotine or are capable of containing nicotine, or

b. all devices / refills (e-liquids) regardless of whether they contain or are capable of containing nicotine?

a ☐ b ☐ This is a misleading question. It would be impossible to police either way.

3. Whom should the offence apply to:

a. the retailer selling the e-cigarette a ☐
b. the young person attempting to purchase the e-cigarette b ☐
c. both c ☐

4. Should sales of e-cigarettes devices and refills (e-liquids) from self-service vending machines be banned?

Yes ☐ No ☒

5. Should a restriction be in place for other e-cigarette accessories?

Yes ☐ No ☒

6. If you answered "yes" to question 5, which products should have restrictions applied to them?

I did not answer yes. I think the wrong question is being asked. At what age should tobacco harm reduction begin? – remembering that there is now good evidence that vaping is less 'addictive' than smoking.

Proxy purchase for e-cigarettes

7. Should the Scottish Government introduce legislation to make it an offence to proxy purchase e-cigarettes?

Yes ☐ No ☒

Domestic advertising and promotion of e-cigarettes

8. Should young people and adult non-smokers be protected from any form of advertising and promotion of e-cigarettes?

Yes ☐ No ☒ Protected? The advertising of these products NORMALISES NOT SMOKING. This is a good thing. Everyone should be exposed to as much positive and well thought out publicity as possible. Vaping has the potential to save millions of Scottish lives.

9. In addition to the regulations that will be introduced by the Tobacco Products Directive do you believe that the Scottish Government should take further steps to regulate domestic advertising and promotion of e-cigarettes?

Yes ☐ No ☒ The TPD will not be implemented as it stands. It was based on very poor science and is currently being challenged.

10. If you believe that regulations are required, what types of domestic advertising and promotion should be regulated? I think common sense would go a long way. This is scaremongering before the non-issue is even looked at.

a. Bill boards a ☐
b. Leafleting b ☐
c. Brand-stretching (the process of using an existing brand name for new products or services that may not seem related) c ☐
d. Free distribution (marketing a product by giving it away free) d ☐
e. Nominal pricing (marketing a product by selling at a low price) e ☐
f. Point of sale advertising (advertising for products and services at the places where they were bought) f ☐
g. Events sponsorship with a domestic setting g ☐

11. If you believe that domestic advertising and promotion should be regulated, what, if any, exemptions should apply?

The ASA has already looked at this and produced good guidelines. Simply adopt these and don't overthink an issue that does not exist.

12. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic adverting in relation to impacts on children and adults (including smokers and non-smokers)?

There has already been a comprehensive consultation on the advertising by the ASA. It reported here and ads for vaping products are allowed.

13. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic advertising in relation to impacts on business, including retailers, distributers and manufacturers?

Comments

Inclusion of electronic cigarettes on the Scottish Tobacco Retailer Register

14. Do you agree that retailers selling e-cigarettes and refills should be required to register on the Scottish Tobacco Retailers Register?

Yes ☐ No ☒ There is no TOBACCO in vaping products, therefore it is simply wrong to classify them as tobacco. Are NRT products regulated as tobacco? No. Ridiculous even to suggest it.

15. Do you agree that the offences and penalties should reflect those already in place for the Scottish Tobacco Retailers Register?

Yes ☐ No ☒

16. If you answered 'no', to question 15, what offences and penalties should be applied?

E-cigarettes – use in enclosed public spaces

17. Do you believe that the Scottish Government should take action on the use of e-cigarettes in enclosed public spaces?

Yes ☐ No ☒

18. If you answered 'yes' to Question 17, what action do you think the Scottish Government should take and what are your reasons for this?

19. If you answered, 'no' to Question 17, please give reasons for your answer.

It harms no one. Despite efforts by many in public health to mine the literature for signs of the faintest risks to others, there really isn't any material risk to others – if you read the most authoritative assessments of risk rather than cherry picking studies that detect tiny traces of toxins this would be clear. As you know, the dose makes the poison and exposure makes the risk. That doesn't mean it should just be allowed everywhere, but it does mean that use of the coercive force the law to ban it is inappropriate. Obtuse theories for how introduction of a much safer product can somehow lead to greater harm are baseless and contrived: there is no evidence for gateway effects (other than *exits*), for re normalisation of smoking or that vaping is somehow 'undermining tobacco control' rather than supporting it. The opposite effects are more likely to be true and more consistent with the evidence there is.

20. Are you aware of any evidence, relevant to the used of e-cigarettes in enclosed spaces, that you think the Scottish Government should consider?

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/
http://onlinelibrary.wiley.com/doi/10.1111/add.12659/abstract
http://www.biomedcentral.com/1471-2458/14/18

Three good assessments of the actual risk profiles of vaping. Please also see the problems with the science produced by Professor Stanton Glantz outlined here: http://antithrlies.com/2014/11/18/what-is-wrong-with-ecig-particulate-claims-the-simple-version/

In simple terms if laws are based on this flawed science, then they will be wide open to legal challenge. Anything put in place based on this kind of misinformation will cause horrendous issues in the future.

Smoking in cars carrying children aged under 18

21. Do you agree that it should be an offence for an adult to smoke in a vehicle carrying someone under the age of 18?

Yes ☐ No ☒

22. Do you agree that the offence should only apply to adults aged 18 and over?

Yes ☐ No ☒

23. If you answered 'no' to Question 22, to whom should the offence apply?

To no one. Ever.

24. Do you agree that Police Scotland should enforce this measure?

Yes ☐ No ☒

25. If y ou answ ered 'no' to Question 24, w ho should be r esponsible for enforcing this measure?

A??vehicle??is??private??space??The??thin??end??of??the??nannystate??wedge??has??already??been??proven??not??to??be??a??myth??as??a??result??of??the??statement??from??Deborah??Arnott??in??relation??to??this??legislation??in??England??

It would also be the first time that the police were tasked with enforcing a Public Health law - the smoking ban is self policed and a civil offence. This is the very basis of the beginnings of a police state. I can't condone this in any form.

26. Do y ou agree that there s hould be an exemption for vehicles w hich are also people's homes?

Yes ☒ No ☐

27. If y ou think there are other categor ies of vehicle w hich should be exempted, please specify these?

The??smoking??ban??already??covers??this??There??is??no??reason??to??expand??it??There??is??no??reason??to??ban??vaping??in??any??vehicle

28. If you believe that a defence should be permitted, what would a reasonable defence be?

The??policing??of??this??is??impossible??

<u>Smoke-free (tobacco) NHS grounds</u>

29. Should national legislation be introduced to make it an offence to smoke or allow smoking on NHS grounds?

Yes ☐ No ☒

30. If you support national legislation to make it an offence to smoke on NHS grounds, where should this apply?

a. All NHS grounds (including NHS offices, dentists, GP practices) a ☐

b. Only hospital grounds b ☐

c. Only within a designated perimeter around NHS buildings c ☐

d Other suggestions, including reasons, in the box below

No??one??considers??the??needs??of??short??stay??disabled??people??who??have??to??rely??on??the??good??will??of??medical??staff??to??allow??them??to??smoke??OR??vape??while??in??hospital??It??is??impossible??for??me??to??get??outside??to??vape??during??a??hospital??stay??as??I??am??a??wheelchair??user??who??canFriday, April 24, 2015t??move??myself??in??a??manual??chair??I??rely??on??being??pushed??If??I??get??an??interfering??busybody??who??thinks??they??are??preventing??me??from??vaping??“for??my??own??good”??I??have??no??recourse??Discrimination??against??the??disabled??in??this??way??can??and??will??be??challenged

31. If you support national legislation, what exemptions, if any, should apply (for example, grounds of mental health facilities and / or facilities where there are long-stay patients)?

Vaping??should??be??allowed??–??there??is??no??evidence??of??harm

32. If you support national legislation, who should enforce it?

I??do??not??support??national??legislation

33. If you support national legislation, what should the penalty be for non-compliance?

Comments

34. If you do not support national legislation, what non-legislative measures could be taken to support enforcement of, and compliance with, the existing smoke-free grounds policies?

A??lot??less??demonisation??and??a??lot??more??understanding??of??individual??needs??

<u>Smoke-free (tobacco) children and family areas</u>

35. Do you think more action needs to be taken to make children’s outdoor areas tobacco free?

Yes ☐ No ☒ There is no proof of harm. Until there is there should be no legislation.

36. If you answered 'yes' to Question 35, what action do you think is required:

a. Further voluntary measures at a local level to increase the number of smoke-free areas a ☐

b. Introducing national legislation that defines smoke-free areas across Scotland b ☐

c. That the Scottish Government ensures sufficient local powers to allow decisions at a local level as to what grounds should be smoke-free c ☐

d. Other actions. Please specify in the box below

Comments

37. If you think action is required to make children's outdoor areas tobacco-free, what outdoor areas should that apply to?

<u>Age verification policy 'Challenge 25' for the sale of tobacco and electronic cigarettes</u>

38. Do you agree that retailers selling e-cigarettes, refills and tobacco should be required by law to challenge the age of anyone they believe to be under the age of 25?

Yes ☐ No ☒

39. Do you agree that the penalties should be the same as those which are already in place for selling tobacco to someone under the age of 18?

Yes ☐ No ☒

<u>Unauthorised sales by under 18 year olds for tobacco and electronic cigarettes</u>

40. Do you agree that young people under the age of 18 should be prohibited from selling tobacco and non-medicinal e-cigarettes and refills unless authorised by an adult?

Yes ☐ No ☒

41. Who should be able to authorise an under 18 year old to make the sale, for example, the person who has registered the premises, manager or another adult working in the store?

Comments

42. Do you agree with the anticipated offence, in regard to:

a. the penalty a ☐

b. the enforcement arrangements b ☐

Equality Considerations

43. What issues or opportunities do the proposed changes raise for people with protected characteristics (age; disability; gender reassignment; race; religion or belief; sex; pregnancy and maternity; and sexual orientation)?

Everyone??has??the??right??to??choose??to??use??a??legally??available??substance??By??restricting??it??further??the??disabled??have??less??access??to??these??substances??imposed??on??them??as??they??are??often??unable??to??access??them??without??help??In??the??case??of??vaping??this??is??a??safer??way??to??access??a??substance??that??may??help??their??conditions??–??as??my??cognitive??impairments??are??helped??by??vaping

44. If the proposed measures are likely to have a substantial negative implication for equality, how might this be minimised or avoided?

Make it clear to medical staff that a request by a disabled person to be allowed to access somewhere where they can vape or smoke should be as acceptable a request as allowing their use of NRT.

45. Do you have any other comments on or suggestions relevant to the proposals in regard to equality considerations?

The finger wagging demonisation of nicotine use needs to stop; medical treatment is stressful enough as it is. Support people, don't impose your views on others by restricting their access where they can't argue against it.

Business and Regulatory Impacts Considerations

46. What is your assessment of the likely financial implications, or other impacts (if any), of the introduction of each of these proposals on you or your organisation?

Comments

47. What (if any) other significant financial implications are likely to arise?

Comments

48. What lead-in time should be allowed prior to implementation of these measures and how should the public be informed?

Comments

49. Do you have any other comments on or suggestions relevant to the proposals in regard to business and regulatory impacts?

Comments

As a party to the World Health O rganization's Framework Convention on Tobacco Control (FCT C), Scotland has an obligation to protect the developm ent of public health po licy from the vested interests of the tobacco industry. To meet this obligation, we ask all re spondents t o disclose whether they have any direct or i ndirect links to, or receive fundin g from, the tobacco industry. We will still c arefully consider all consultation responses from the tobacco industry and from those wit h links to the tobacco industry and include them in the published summary of consultation responses.

I have no financial links with any tobacco, pharmaceutical or e-cigarette (mod, battery, atomiser or juice) vendor or manufacturer.

I think this is the statement you should require - pharmaceutical links are just as much a conflict of interest here.

Additional comments. The framework of this consultation does not allow me to make these necessary points in relation to any one question. This is a general response to questions 19 and 20. Please allow me the leeway I need as a disabled person with cognitive issues to make these points without having them dismissed as irrelevant because they have not been framed correctly by consultation standards. I'm finding this whole process very difficult and have spent weeks on this statement from my bed. As I have been almost constantly bed-bound for the duration of this consultation period and have now hit the deadline for submission I have had to use the words of Clive Bates (http://www.clivebates.com) edited to make some of the points I wanted to make. This should not invalidate my comments. This form is also not compatible with the only word processing program I can afford which is Open Office. Any errors in formatting as a result of this should also not invalidate my response.

I vape because I like it. Vaping is a recr eational activity – the use of the lega l m ildly psycho active drug nicotine, cu rrently used by about 10 m illion ad ults in the UK, mainly through its m ost dangerous deliv ery system – cigarettes. The drug itself is not very harmful to health and does not cause intoxication (violence or accidents). It is often co mpared to caffeine in term s of its risk profile. It isn't ev en as addictive as you m ight think, and less addictive when vaped rather than smoked. Vapers are m aking a choice to use it without combustion of tobacco (hence the enorm ous health di vidend), but with lots of technology, flavours, and personalisation instead – it's m ore than just nicotine self-administration. For m any it is fun and geeky, and it is has a thriving sub-culture. Rem ember no one ever says "I like Cham pix" or "NRT is fun" and there are no "Patch-meets" to distract vapers fr om Vape-m eets. Vapour products are not medicines. Vapers are not to be considered patients, in treatm ent, undergoing smoking cessation or in any way to be incorporated into any medicalised model of public health.

Vapers think you don't understand this m odel – and you don 't care what the evidence says. You have shown no sign of understanding how th is works – and keep seeing it as a tobacco industry plot (they were late to the

party) or some sort of rogue medical product. Neither is true. But vapers rightly suspect you are careless with the truth: most public health organisations united to support a ban on snus in the European Union in 1992, again in 2001, and once again in the 2014 Tobacco Products Directive. This is despite indisputable evidence that snus, a very low risk way of taking recreational nicotine, has been highly positive for public health where it is permitted and used in Scandinavia – displacing smoking, diverting smoking onset, and supporting user-driven quitting. There is no scientific, ethical or legal case for banning it – but you supported it anyway. This is the same public health model as vaping, so it is no wonder they don't trust you. Until you face up to the lethal error you have made on snus, you have not earned the right to a hearing on vaping. To the extent that smokers believe what you say, you are likely to be protecting cigarette sales by creating unfounded fear about a much safer alternative and causing damage to health that would otherwise be avoidable.

Activism explained. You seem surprised to find there are people who get up and do something, and do it for nothing – you seem to assume someone must be paying if vapers do anything. I can see why you might think this: it rarely happens in your world or it is a distant memory from your more idealistic youth. There are no grass roots or unpaid individuals campaigning for the things you want in this field. You should think of these people more like the activist campaigners you know in drugs or HIV/AIDS. Many vapers are passionate about their experience: they have escaped the death trap of smoking – or are heading that way – and having feelings of pride, empowerment, agency and control, as well as immediate welfare and economic benefits, and a much better long term health prognosis. They want others to benefit from the experience and they <u>really</u> don't want you to take it all away through clumsy or excessive regulation based on poor science, comprehensive misunderstanding or for ideological reasons. And they don't want to be collateral damage in your war on Big Tobacco, which is of little relevance to them. **The relationship between vapers and public health people**. Your relationship with vapers is <u>asymmetric</u> – and you really do need to understand this. They are the 'public' in *public health*. They should be a matter of professional interest to you. In your profession, you need to understand them and why they do what they do, in order to make professional public health judgements.

Statement On the Declaration of the 6 th Conference of the Parties of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC).

By **Professor Gerry Stimson*** , Emeritus Professor at Imperial College, London and co-director of Knowledge-Action-Change (KAC)

Saturday, 18 October 2014 (London, UK)

The Conference of the Parties meeting on the WHO Framework Convention on Tobacco Control (FCTC) which took place this week to in Moscow issued a declaration that is unambiguously bad for e-cigarettes, bad for public health and scandalously bad for evidence based policy-making

In a meeting tainted by the exclusion of the public and a ban on all media representatives from attending, the WHO FCTC seems unashamedly indifferent to the endemic disregard for evidence and the harmful unintended consequences of the kind of actions that have been agreed in Moscow – the most obvious one being the protecting of conventional cigarettes from competition from far less dangerous products like e-cigarettes.

The 'Moscow Declaration' calls for countries to take steps to minimise the proliferation of new nicotine products – which includes the much safer e-cigarettes.

The ultimate irony has successfully managed to take the *public* out of public health.

The meeting has just got it plain got it wrong because:

It places all its emphasis on minor, hypothetical or imaginary risks and gives no emphasis to the great opportunities that arise from having a popular replacement for smoking with likely 95-100 per cent lower risk than cigarettes.

It seeks to marginalise the industry and innovation behind these products, and encourages forms of regulation – including outright bans on the products and total bans on advertising – that would have the obvious effect of

protecting conventional cigarettes fr om competition from far less dang erous products. If im plemented these measures would reduce the likelihood that people will switch to lower risk products and so cause more smoking and disease than would otherwise be the case.

It views electronic nicotine delivery systems (ENDS) as part of the probl em, but in reality they are part of the solution – and the widespread uptake of these products is essential if ther e is to be any hope of m eeting the commitment to reducing tobacco co nsumption by 30 per cent by 2025 (UN comm itments on reducing non - communicable disease).

The question needs to be asked – is the WHO capable of getting that particular job done?

**Professor Stimson is a signatory to the letter addressed to WHO Direct or General Margaret Chan by 53 leading scientists in May 2014 urging the WHO not to tr eat e-cigarette regulation in the same manner as traditional tobacco.*

Vaping cannot normalise smoking, because it is not sm oking. vaping normalises not smoking. It's like saying sugar use norm alises cocaine use. Li ke banning water because it looks like gin and vodka . It's a diversionary campaigning tactic without any evidence to back it up. Utterly meaningless, and with no foundation in truth or fact. Saying that there is not enough evidence to assum e that they are com pletely safe m isses the point entirely; no one is suggesting that vaping is 100% safe. Nothing is 100% safe. They are **SAFER** than smoking. We are arguing for harm reduction by switching to a **SAFER** alternative.

Opponents say that they "have to p roceed on the precautionary principle" But they are both misinterpreting and misapplying that principle.

From the EU guidance to applying the precautionary principal,

> The precautionary principle must also seek balance. It m ust balance out the ha rm of regulation s imposed with the possible harm of no regulations;
>
> Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:
>
> - proportional to the chosen level of protection,
> - non-discriminatory in their application,
> - consistent with similar measures already taken,
> - based on an exam ination of the pot ential benefi ts and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
> - subject to review, in the light of new scientific data, and
> - capable of assigning responsibility for producin g the scientific evidence necessary for a more comprehensive risk assessment.

To which Clive Bates says this:

> "the key guideline is the 4th in the list above: th e requirement to apply a symmetric assessment of risks and benefits arising from both regulatory intervention and non-interv ention. In other words, if a regulator wants to com e down heavily on a product like e-ciga rettes because of hypothetical dangers, it has to tak e into accou nt the lo st bene fits th at m ight aris e if it bans , restricts o r otherwise reduces the positive potential of the product. For e-cigs th is is particularly salient as th e benefits are to health, not just economic."

There is no "pile of evidence which suggests that [vapi ng] may cause harm in the future." There is a great deal of evidence which s uggests that there is a very sm all risk as sociated with v aping. A sim ple ch emical analysis of the system will tell you that. In rebuttal of this point I submit this:

> Authorities concerned about our health often request marketing of electronic cigarettes be banned until their safety is proven. To prove safety, one has to prove the absence of harm. So we encounter similar difficulties as described above for proofing the absence of Nessie.
>
> **What evidence is required for declaring electronic cigarettes as "safe"?**
> Electronic cigarettes may be regarded as safe if users don't experience toxic effects. Since millions of users haven't suffered any damage so far, this criterion appears to be met. However, there could be subtle chronic effects that become apparent only after a while. To account for this possibility, health advocates ask for long-term studies. But what is "long" (1, 5, 10 or even 20 years?) and for what kind of effects should we look for? [Safety of electronic cigarettes and the Loch Ness Monster Bernd-Mayer]

"In America research has been conducted that suggests that vapour could be harmful to the user" Yes, there have been a few studies which suggests that this could be the case, mostly by Stanton Glantz and his disciples. For a good insight into why policies should not be based on this research I turn to ECITA's blog. See this post and this post to begin with. Stanton Glantz has also been called out on the so called "gateway" effect. His research has been discredited as utterly inaccurate even by the ACS: Stanton Glantz is such a liar that even the ACS balks: his latest ecig gateway "study" . For a brilliant analysis of the flaws in that study please also see Clive Bates on the subject.

I support a ban on selling to under 18s with reservations . We give out nicotine patches to 12 year olds. At what age should harm reduction in smokers be allowed to start? Beware the unintended consequences of good intentions.

Where has the idea of harm reduction in tobacco use been considered at all in these proposals? If smokers switch to a safer alternative, there are health benefits:

> Stated estimates for how much less risky ST is compared to smoking vary somewhat, but the actual calculations put the reduction in the range of 99% (give or take 1%), putting the risk down in the range of everyday exposures (such as eating french fries or recreational driving), that provoke limited public health concern. Even this low risk is premised on the unproven assumption that nicotine causes small but measurable cardiovascular disease risk (as do most mild stimulants such as decongestant medicines, energy drinks, and coffee), since such risks account for almost all of the remaining 1%. Perhaps just as important, even a worst-case scenario puts the risk reduction at about 95%, meaning that any scientifically plausible estimate shows THR has huge potential health benefits. There is no epidemiology for the new electronic cigarettes and very little useful epidemiology for assessing long term use of pharmaceutical nicotine products. But since most of the apparent risk from ST comes from nicotine, and the other ingredients in the non-tobacco products are believed to be quite benign, we can conclude that the risks across these product categories are functionally identical from the perspective of THR.
>
> […]
>
> One common misleading claim is a risk-risk comparison that has not before been quantified: A smoker who would have eventually quit nicotine entirely, but learns the truth about low-risk alternatives, might switch to an alternative instead of quitting entirely, and thus might suffer a net increase in health risk. While this has mathematical face validity, a simple calculation of the tradeoff — switching to lifelong low-risk nicotine use versus continuing to smoke until quitting — shows that such net health costs are extremely unlikely and of trivial maximum magnitude. In particular, **for the average smoker, smoking for just one more month before quitting causes greater health risk than switching to a low-risk nicotine source and never quitting it.** Thus, discouraging a smoker, even one who would have quite entirely, from switching to a low-risk

alternative is almost certainly more likely to kill him than it is to save him. [Source] *Emphasis mine.*

- **The case for an enlightened policy on e-cigarettes**

The outline of the argument:.. e-cigarettes are proving to be a very valuable market based positive public health phenomenon, that consumers like and costs the state nothing. The danger is that clumsy regulation to address minor or implausible risks will destroy large parts of the market and leave the products less appealing to adult smokers. In that event, we will end up with more smoking, disease and death than would otherwise be the case. **Scotland should champion a liberal market based approach with only light touch regulation.**

In more detail…

1. Strong value proposition relative to smoking is a cause for optimism. E-cigarette and related products offer a successful new value proposition to smokers that has emerged since 2008. They meet demand for recreational nicotine but also replacing behavioural and ritual aspects of smoking, while greatly reducing the risk of diseases, improving immediate welfare, reducing social stigma and saving money. The health risks are likely to be at least 95% lower than smoking, and likely to be considerably less than that. We know this from the basic chemistry and physics and dozens toxicology studies. It does not require a 50 year cohort study to make an educated estimate of the health risk.

2. Widespread uptake by smokers and significant health gains already. About 2.1m people are now using e-cigarettes, and 700,000 of these are now ex-smokers (there were about 10m smokers in 2010, about 20% adults). Use among never-smokers is negligible (~0.2%). Given that the health value of quitting is estimated by DH economists at £74,000, the 700,000 switchers represents a huge health dividend (£53bn), achieved with no public money, no call on the NHS and no coercive laws or punitive taxes. It is a disruptive consumer and market based phenomenon, and is has wrong-footed many in the public health establishment. We have seen this before with 'snus' in Sweden – nicotine taken as smokeless tobacco is the reason why Sweden has the lowest smoking rates in Europe by far (13% rather compared to 28% EU average in 2012) and hence much lowest rates of smoking related disease. Absurdly, snus is banned in the EU outside Sweden but serves as a reminder of how arbitrary and counter-productive EU public health regulation can be.

3. Negligible unintended consequences in reality. A number health bodies have worried about e-cigarettes being a 'gateway' to smoking, or that because they make the life of a smoker less intolerable, the incentives to quit completely will be reduced and quit rates will fall. There are no signs of either of these hypothetical effects. Quite the contrary – youth uptake is very low and highly concentrated in existing smokers, where it may divert from smoking and hence be beneficial. Quit rates in the UK have picked up with the rise of e-cigarettes. There have been accusations that the industry targets children – these are unfounded and extremely unlikely given there is a huge smokers' market to go for and that is where their value proposition works. There are also claims that certain flavours 'target children'. Again highly unlikely – and based on a confusion about what adolescents are looking for – teenagers are more likely to seek out 'adult' flavours, than to emphasise their own childishness. However, many adults do like frivolous fruity or candy flavours.

4. The greatest threat to these highly positive public health developments is excessive or ill-fitting regulation. The products are already subject to general consumer protection legislation, and some light touch specific regulation would be valuable in building consumers confidence, protecting health and safety, and avoiding uptake by young people. However, excessive or arbitrary restrictions, heavy burdens and costs can have a number of malign effects – essentially degrading the value proposition of e-cigarettes and in doing so, protecting cigarettes from competition, causing lower uptake and leaving more people smoking. The proponents of 'tough'

regulation *never* acknowledge this health risk or weigh it against the supposed benefits of their proposals.

5. The emerging UK/EU regulatory regime is likely to cause significantly more harm than good. The EU/UK regulatory regime will start to bite in 2016 and will consist of the ad hoc provisions of the EU Tobacco Products Directive just agreed this year (the 'TPD') and the UK's proposal to regulate e-cigarettes as medicines. UK is to allow both pathways to market (TPD and medicines). Internationally, WHO has expressed intent to regulate e-cigarettes as tobacco products and subject them to the same controls used to reduce tobacco consumption.

5s. Problems with Tobacco Products Directive. In brief the main problems with TPD:

- a ban on most forms of advertising – wholly disproportionate and anti-competitive measure in a 'single market directive'
- a limit on the strength of liquids (to 2% nicotine concentration), ruling out stronger liquids used by more heavily addicted smokers and those first switching – liquids of this strength are used by 25-30% of smokers
- a limit on container sizes that is unnecessary and unjustified
- bold warnings covering 30% of the packaging – disproportionate to risk and creating unwarranted fear
- a large compliance burden and heavy notification regime that will raise costs and rule out a large number of perfectly good SMEs and products
- members states are free to regulate/ban flavours – but these are integral to the value proposition
- despite overwhelming evidence of the beneficial effect of snus in Sweden the directive reaffirmed the ban on snus outside Sweden

5b. Problems with regulating as a medicine. In brief, the main problem with medicines regulation for e-cigarettes is that it is a strict and burdensome authorisation regime, requires pharmaceutical grade manufacturing and process controls and imposes numerous requirements that make sense for medicines but not for recreational products. MHRA has yet to show how it can deal with the massively diverse range of products and suppliers without creating a violent restructuring of the industry, closing many SMEs and tending to commoditise the products into a few varieties made by big companies. It will destroy the consumer focussed rapid innovation model in the e-cigarette industry and slow down innovation – weakening the category relative to cigarettes. It will create a DIY and black market that will present greater risks to users than medicines regulation would avoid.

6. Poor policy-making process . This regulatory regime has been assembled with only the most meagre consultation and stakeholder engagement . In 2010, in the UK the MHRA consulted on whether the products should be classified as medicines and banned or continue unregulated (a false choice) and gave no alternative options or detail. In the EU, the Commission consulted on whether e-cigarettes should be included in the TPD, but without saying how they would be treated. *There has been no consultation at all* on the actual measures now adopted or anything close to them – even though this is an EU treaty requirement. Much of the TPD violates principles of the treaties and has suspect legal base: scientific advice was ignored, impact assessment not done (EU) or done poorly (UK), anti-red tape machinery failed, and proper Westminster scrutiny was sidestepped. 6,000 words of e-cig regulation were created from scratch behind closed doors in the European Parliament and through a '*trilogue*' process. The directive is vulnerable to legal challenge both for the compatibility of the substantive measures with the treaties and for the process to create them.

7. What should happen? What is needed is a light touch regulatory framework that is designed for the products in question – not something different like medicines or tobacco. This would comprise, for example:

a. Purity standards for liquids and flavours

b. Some operational standards for devices – electrical safety, what happens when liquid runs out etc

c. Sensible labelling conveying risks and benefits

d. Tamper proof containers for liquids – there is an ISO standard
e. Verification of consumer information – e.g. nicotine content
f. Marketing restrictions similar in concept to those used for alcohol – i.e. avoiding overt targeting of young people
e. Owners and operators of public spaces should decide whether to allow vaping – not the law
f. Flavours are integral to the value proposition and a high standard of evidence of harm or risk should be required before banning or restricting them
g. Better science and understanding is essential, but this is not a reason for paralysis

8. How could this happen?

a. European Union. Ideally policy change in the light of new evidence of the benefits of e-cigs should mean revising the TPD before it is implemented – this is politically highly unlikely to happen voluntarily, but may happen through legal challenge, at which point there is opportunity for a rethink. Failing that the government should seek the maximum flexibility and minimum restriction where there is remaining discretion – and start to insist that measures agreed are scientifically grounded, compatible with legal base and do actually comply with principles of proportionality, non-discrimination etc.

b. UK/England. MHRA should be encouraged to define a truly light touch regime or be clear to policy-makers that the the requirements of Medicines Act do not allow this. Much of the UK policy support proceeded on the basis that the MHRA can offer a light touch regime. An updated impact assessment would be a good idea. UK/England and SCOTLAND **should be careful not to take measures that appear to protect children but are based on little more than opinion or assertion – the danger is that they will harm adult smokers for no gain.** This is especially important where UK has discretion over flavours, marketing etc.

c. WHO – the WHO Framework Convention on Tobacco Control meets in Moscow on 13-18 October. Under no circumstances should the UK or Scotland compound errors already made in the design of the EU directive by agreeing that e-cigarettes should be classified as 'tobacco products' under this convention. They are not tobacco products and the measures used to control and suppress demand for tobacco are completely unsuitable for products that are an alternative to smoking and deliver a large health dividend when smokers switch. WHO needs a fundamental reappraisal of its approach to 'harm reduction' before it gets further involved in this area.

d. The e-cigarette industry and consumers. The industry is professionalising and better organised, and is capable of producing good proposals for self-regulation or idea to build into enforceable standards. The government should apply some open-policy-making principles and start to take the firms involved more seriously and find out more about what consumers actually want. In neither case do they want 'no regulation', but it is most definitely not what is on offer.

e. Science. The Stop Smoking Services offer terrific possibilities for policy randomised controlled trials – for example comparing success rates in services where: (1) e-cigarettes are not offered or recommended; (2) where only only licensed medical products can be offered (i.e. the NICE guidance); (3) where the service offers a range of e-cig starter packs; (4) where a voucher is provided to spend in a vape shop. This might be a good test of the government's policy guidance.

f. Surveillance. The UK has one of the world leading systems for understanding what is happening in smoking and quitting smoking. This system should be upgraded to take account of increasingly complex environment and behaviours created by the emergence of vaping – taking a more nuanced view of dual use, the way behaviour evolves as people learn to vape, reasons for relapse. A way to use e-cigarettes industry money without conflicts of interest should be found to do this. Source: http://www.clivebates.com/?p=2309