

Plausible unintended consequences of excessive regulation of low-risk nicotine products

In its 2016 report on tobacco harm reduction, the Royal College of Physicians summarised the possible risks of unintended consequence arising from excessive regulation¹:

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.

However, if this 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 table below provides a checklist of the possible unintended consequences arising from excessive regulation of reduced-risk nicotine products - vaping, heated and smokeless tobacco.

Policy	Plausible unintended consequence
High compliance costs or barriers to market entry	A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy - users may find the experience less satisfactory, so continue to smoke or relapse. Alternatively, a black or grey market of possibly unregulated products develops – responsible domestic producers are destroyed and cross-border trade meets demand. Cumbersome or expensive authorisation regimes make innovation more difficult and expensive, so there will be less innovation and experimentation with consumer preferences.
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping. Heavier or more dependent smokers may find e-cigarettes unsatisfying – so those most at risk are denied the products more likely to work. May drive users to black market and/or home mixing with high strength liquids. Barrier to successful innovation like the Juul products, which use high strength e-liquids (~5%).
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased – creating points for possible relapse. Poisoning risk is not normally managed by limiting container size (e.g. for medicines, alcohol).
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and ‘denormalises’ vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking. May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.

¹ Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [\[link\]](#)

Policy	Plausible unintended consequence
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control products may become dull and sterile, diminishing appeal. Almost all e-cigarette advertising is a form of anti-smoking advertising provided without any call on public funds – it would be perverse to stop this and spend public money instead.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users without needing thousands of shops holding very large stocks of slow-moving inventory. If users are forced to purchase from ‘bricks and mortar’ outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive.
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through ‘regulatory barriers’ to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market and reduce the pace of innovation.
Bans on flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black-market flavours – which may be more dangerous. Even with young people, there is the possibility that any attraction to flavours is an attraction away from cigarette smoking and may be beneficial, meaning a ban would be harmful.
Bans on refillable systems	This idea was proposed by some tobacco companies for commercial and anti-competitive reasons. It means removing the ‘open system’ 2 nd and 3 rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black-market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.

Policy	Plausible unintended consequence
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco (e.g. “This is not a safe alternative to smoking”) Warnings do not adequately communicate relative risk and, therefore, understate smoking risks or downplay the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications. Warnings about nicotine may exacerbate misperceptions about the (minimal) role of nicotine in causing disease. Warnings about addiction play on fears of loss of control or harm to the user that exaggerate the consequences of nicotine use through vaping.
Ban sales to under-18s	There is near universal support for this policy. But US studies found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that ‘harm reduction’ should start at 18.
Controls on “addictiveness”	Limiting the psychoactive impact of nicotine by, for example, controlling pharmacokinetics (PK), acidity, additives etc. risks limiting the capability of e-cigarettes to replace cigarettes for some smokers – and therefore implies a trade off in favour of reducing dependence rather than reducing serious disease. The problem of ‘abuse liability’ is why NRTs have not been that successful.
Prohibit health or relative risks claims	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers. Those determining whether a health claim should be allowed are often “loss averse” – concerned about what might go wrong if they allow a claim to be made. However, they rarely pay equivalent attention to the “false negative” error: the lost benefit arising from rejecting a claim that is in fact valid.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT (which in the UK actually receives an unjustified VAT discount). Establishing a tax regime is costly for both authorities and manufacturers – those costs are passed on to consumers depressing demand and reducing the price sensitivity of users to increases in cigarette prices. If the tax is made risk-proportionate, it would likely be too low to be worth the expense of collecting – so any tax on vaping is likely to be disproportionate by default.