Briefing: the case for e-cigarettes

written by Clive Bates | 31 July 2014

In response to my longer briefing, sometimes people say: well could you please state the case more concisely? So here is a shorter briefing, starting with a one paragraph summary…

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. The UK 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 counterproductive 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 should be careful not to take measure 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 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.*