Briefing on e-cigarettes for policy makers

I am occasionally asked for a briefing on e-cigarettes and related policy issues – so here's one I produced recently, that I hope some readers of this blog might find useful – for example in talking to Directors of Public Health, NHS officials etc. This is the longer one… I also did a shorter one with more recommendations.

E-cigarettes briefing – a disruptive public health technology threatened by excessive regulation

What are they? E-cigarettes generally consist of a battery, a heating coil and a liquid containing nicotine. A switch triggered by hand or by sucking pressure activates the battery to heat the coil, which vaporises the liquid. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids contain nicotine, water, a 'diluent' such as propylene glycol or glycerol, and a flavouring, such as tobacco, mint, vanilla or fruit. There are now

hundreds of flavours and these are an intrinsic part of the appeal. The devices and the liquids can be sold as integrated units or separately. Some look like cigarettes (1st generation 'cig-a-likes' in the jargon), some look like pens (2nd generation 'Ego' type), and the larger ones with tanks can look very distinctively different (3rd generation 'tanks' or 'mods'). The products have emerged only recently due to advances in batteries, which can now provide sufficient power and battery life in a small unit.

Public health case. There are 10 million smokers in the UK (~20% adults), about 110 million in the EU and around 1.3 billion worldwide – the current annual premature death toll attributed to smoking is 100,000, 700,000 and 6 million respectively. WHO estimates one billion premature deaths from smoking in the 21st Century on current trends. The public health proposition is that: e-cigarettes can substitute for cigarette use through market-based competition; provide a satisfactory alternative to smoking; and, in doing so, dramatically reduce risks to health, perhaps by 97-100% among those who switch. The alternative public health approach is to quit smoking and nicotine altogether – this is much slower and harder to achieve, and may leave ex-smokers with cravings and withdrawal and a sense of loss. Global tobacco sales are variously estimated at $700-800 billion (Bloomberg), mainly cigarettes, whereas sales of vapour products are likely to be $5 billion in 2014 (Euromonitor) – there is scope for a major structural change in the market for recreational nicotine.

The benefits to the smoker. From the smoker's perspective, e-cigarettes create a new value proposition: they offer many of the experiences of smoking (a nicotine hit, something to hold and gesture with, sensory experience etc) with few of the harms (long term risk much lower, less social disapproval, minimal odour nuisance) and at a lower cost. Prior to the emergence of e-cigarettes, the alternatives were broadly cast as 'quit or die' – this new value proposition fits between the two.

Harm arising from vaping. No-one claims vaping is entirely benign. Nor does it need to be to make very large inroads into the risks of disease if people switch. Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful, but at levels generally two orders of magnitude lower than in cigarette smoke and unlikely to pose a material threat. The most comprehensive literature review so far

concluded:

Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. … Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

(Burstyn I, 2013) Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks.

Legitimate regulatory agenda. Burstyn rightly recommends continued surveillance and measures to reduce exposures to residual harmful substances in vapour and e-liquids, and this would make a worthwhile regulatory agenda. There is no basis for believing that bystanders are at any material risk: in public places the issue is one of norm-setting and etiquette and should be a matter for owners and operators, not the law

Current use in the UK. A recent GB survey by ASH showed that 2.1 million people are using e-cigarettes and about one third are now ex-smokers – this represents a very substantial health gain. The Department of Health estimates a value of £74,000 per successful quit attempt (£60,000 health value per life-year and 1.24 life-years gained), so 700,000 switchers gives approximately £52 billion welfare benefit – with possibly a small deduction (1-3%) for detriments arising from extra vaping. More information of use of e-cigarettes is given at Appendix 1.

What is the potential? One Wall Street analyst projects that vapour use will surpass smoking (in the US) within a decade (by which she means 2023). Much will depend on whether regulation encourages or suppresses innovation – and her forecast is contingent on an effective pro-innovation regulatory framework. Other analysts are less bullish, but all see great potential. If half of smokers convert to vaping, it would be one of the most remarkable public health phenomena ever: in UK, 5 million smokers switching would create a health benefit of ~£370 billion, on the basis given above.

What are critics concerned about? Most opponents of e-cigarettes are slowly giving up the argument that 'we don't know what's in them' or concerns about

the safety of the products themselves. They are instead concentrating on 'population' arguments. This is the idea that though vaping is very much less hazardous than smoking, at population level it could be more dangerous because it causes changes in the way people smoke, for example:

- *It could be a 'gateway' to smoking for adolescents;*
- *It might divert people from quitting smoking because they don't feel under so much social pressure if they can avoid smoking restrictions by vaping;*
- *By visible displays of smoking-like behaviour it might 'renormalise' smoking.*

There is no basis to believe any of these effects are real rather than contrived tactical campaign arguments. The UK's foremost expert in smoking cessation, Professor Robert West, puts it thus:

Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking (Electronic cigarettes in England – latest trends 6 July 2014)

Fear of the tobacco industry. A further source of critics' concern is the possible negative role of the tobacco industry. In practice it is hard to see what this could be: they are threatened by e-cigarettes, and will need to produce high quality attractive alternatives or risk losing share in the recreational nicotine market to other tobacco companies or non-tobacco e-cigarette companies. It is more likely that they will become important drivers of a wholesale switch from smoking to vaping.

The case of snus – a cautionary tale. Many of the same 'population' arguments were made on a precautionary basis in the case to ban 'oral tobacco' in 1992 throughout the EU, even though it is 95-98% less hazardous than smoking. On accession, Sweden was granted an exemption from the ban. In fact, this product – 'snus' or oral snuff – has become popular in Sweden and is the reason why Sweden has by far the lowest rate of smoking in the EU: 13% Swedish adults vs 28% EU average (Eurobarometer, 2012). Snus has three main effects in Sweden and Norway: it is used to quit smoking; it is used to substitute for smoking; it diverts young people from onset of smoking. Despite overwhelming

evidence to justify lifting the EU ban on snus, the ban was re-affirmed in 2014.

To summarise: a market based public health phenomenon. The electronic cigarette has emerged through the interplay between consumers and innovative suppliers, with no public sector involvement or endorsement, no call on the taxpayer or NHS resources, and minimal regulation. Yet this product is already providing very substantial health benefits as a relatively benign alternative to smoking. It has empowered smokers to take control of their risks and has greatly enhanced the welfare of hundreds of thousands of UK citizens. It has challenged the tobacco industry, but also interests in the public sector and civil society who have played no role – or a hostile role – in its rise.

Regulatory issues

The primary risk to these otherwise highly positive developments is poor and excessive regulation. At the heart of the regulatory challenge there is a 'double negative': being tough on e-cigarettes is being tough on the competitive alternative to cigarettes. There is a danger that loss-averse regulators and officials will place excessive focus on the residual risks associated with vapour products, but in doing so render them less effective and appealing as alternatives to smoking and thereby potentially increase total health risks through the unintended consequence of continuing smoking. All the regulatory proposals advanced so far suffer from this weakness.

- *The UK's favoured approach has been to regulate these vapour products as medicines. This onerous regime applies costs, burdens and restrictions that would dramatically contract the range of products and number of suppliers, whilst acting as a barrier to innovation. It creates very high barriers to entry and is unsuitable for an evolving disruptive fast moving consumer goods industry. It is likely that only the largest companies could make and pass these requirements – so far only one, the subsidiary of British American Tobacco, has attempted it. The regime is wholly unnecessary: the products are not medicines in law or common sense, the vendors are not healthcare providers and users do not regard themselves as in treatment.*
- *The EU's favoured approach is to regulate using measures designed for*

tobacco products. After the European Parliament rejected the Council's proposal to regulate e-cigarettes as medicines (for many of the reasons given above), a closed trilogue process created 5,000 words of new regulation in three months – with no consultation or impact assessment and inadequate justification – with scientists pointing out numerous errors of fact and interpretation. The resulting directive (2012/40/EC – Article 20) has numerous flaws of arbitrary and unscientific policy and poor policy-making process, and is likely to be found in breach of key treaty principles if challenged in the European Court of Justice. The UK will now offer both the medical route and the approach negotiated under this directive as alternatives. The directive has entered into force and its provisions apply from 2016/17.

- *The US favoured approach is to treat e-cigarettes as tobacco products on the basis that the pure nicotine used is originally extracted from tobacco. In April, the FDA announced its intention to apply tobacco legislation to e-cigarettes – that was designed with the primary purpose of slowing innovation and creating burdens for the cigarette manufacturers.*
- *The WHO's favoured approach is to classify these products as tobacco and to apply the restrictive measure of the WHO's tobacco treaty (the Framework Convention on Tobacco Control). The WHO would also include these products in UN targets to reduce tobacco consumption by 30% by 2025. In practice the only hope of coming close to meeting this target is to use vapour products to meet the targets, not to reduce them. 53 of the world's top experts in the field recently wrote to WHO to implore them to take a more positive approach. Their letter is appended at Appendix 2.*

The best outcome would be an amendment or legal challenge to the EU directive to remove its most egregious features. The EU directive offers the best promise for a decent regulatory regime, but contains some absurd and unjustified measures, notably:

- *A ban on most advertising sponsorship and promotion. The anti-competitive ban protects the incumbents from a disruptive challenger and is unjustified in a directive with a single market legal base, and disproportionate relative to tobacco. Most tobacco advertising is*

banned in the EU, but tobacco kills 700,000 per year. In contrast, vaping is likely to reduce premature deaths.

- *Limiting the strength of nicotine liquids to 20mg/ml. Approximately 25-30% of consumers use liquids stronger than this. They may be more important for more heavily dependent smokers and those just switching. The threshold is arbitrary and pointless.*
- *Limiting liquid container sizes. We manage hazardous liquids (like bleach) by having packaging and labelling standards not by limiting the containers to tiny inconvenient sizes.*
- *Requiring large warnings. The directive requires cigarette-like warnings that contain misleading and off-putting information covering 30% of the pack. The warnings are not proportionate.*
- *Numerous technical measures that would fail a reasonable risk-benefit assessment.*
- *A continuing ban on snus – despite it being the reason, beyond doubt, for the best tobacco-related health outcomes in Europe in Sweden, it will remain banned throughout the rest of the EU. It is unscientific, unethical and probably unlawful to ban this product.*

Conclusion: too big and too bossy. The tobacco products directive, at least as it applies to reduced risk alternative to smoking, is poor policy made in a poor process. The directive, and the way it was created, fits the Prime Minister's characterisation of the EU being 'too big and too bossy'. It is also a useful case study in the challenges for 'open policy-making'. It is not strictly an EU problem: UK officials have been closely involved in forming this policy and there are many lessons to be learned from the experience.

Appendices

1. *Data briefing by Professor Robert West and colleagues (2 pages)*

2. *Letter by 53 scientists and experts to WHO (3-page letter + signatures)*