Incoherent tobacco directive – letter to European Scrutiny Committee

written by Clive Bates | 11 August 2013



I have written to the House of Commons European Scrutiny Committee to follow up on the appearance of the Minister for Public Health (see: *Write to Anna Soubry about e-cigarettes* for my take on this). The aim of this is not to press the procedural points (they're onto that!), but to argue that in this case scrutiny must be more than a formality. The directive is so poor (see 'gargantuan dog's breakfast' and 'negligent tobacco policy') that it is essential that the government's uncritical support for it is properly challenged in Westminster, with a view to significantly improving it or starting again in 2014.

William Cash MP
Chairman
European Scrutiny Committee
House of Commons
London SW1A 0AA

Dear Mr Cash

Incoherence in the proposed revision of the Tobacco Products Directive

I am writing to you concerning the revision of the EU Tobacco Products Directive (TPD). I watched the Committee's session with the Minister for Public Health on 17 July, and it is clear there has been a serious breach of scrutiny protocol. However, this is more than a formality: in its current form the proposed directive is one of the most incoherent legislative proposals the EU has ever produced, and the government is supporting much of it uncritically. It is exactly the type of proposal that needs close parliamentary scrutiny.

I am writing as a former Director of Action on Smoking and Health and a former civil servant, now running a small consultancy and advocacy practice. I

have long standing interest in public health, particularly the approach of 'harm reduction'. I should make it clear that these views are my own, not necessarily those of past employers, and that I have no competing interests.

There is no dispute about the seriousness of the problems arising from smoking and no shortage of political will to address them by any of the main political parties. There is, however, room for significant dispute about whether measures will work or could be counterproductive; measures that are unethical, breach principles of proportionality and non-discrimination or have inadequate legal base; and whether there has been proper consultation. For those reasons I am concerned about the incoherence of the proposals and the impact they are likely to have. I would like to summarise concerns as follows:

1. Political focus. *The government and European Commission have placed too much focus on labelling, packaging, warnings and not enough on the most critical aspects of the directive – low risk alternatives to smoking, such as e-cigarettes. The European Commission believes the measures defined in its proposal for the directive, will reduce cigarette consumption by only two per cent (see European Commission Impact Assessment Annex 5). That would be equivalent of a fall in EU smoking prevalence from 28% to 27.4%, which is in the statistical noise. On the other hand, e-cigarettes and other low risk forms on nicotine products have potential public health benefits that dwarf these other measures. Investment analysts see e-cigarettes as a major disruptive technology, with the possibility that e-cigarette use could surpass cigarettes within a decade (Wells Fargo Securities). That is huge potential in public health terms, given these products create a tiny faction of the risk of smoking (about 99% less would be a fair estimate) and no risks from second-hand smoke. The key issue is how these products will be regulated, and it is in this area that the directive is profoundly incoherent.*

2. Electronic cigarettes. *These are the least dangerous, most promising, fastest growing nicotine products with the greatest public health potential – likely to be two orders of magnitude (~99%) less dangerous than cigarettes. Goldman Sachs recently rated them among the top disruptive technologies. There are already 1.3 million users in the UK with growth of over 50% annually. Many users are very satisfied and fiercely loyal to their chosen products, which many regard as life-changing. A market of vibrant SMEs and diverse innovative products has emerged. Yet under the proposals, existing products are to be*

barred from the market unless authorised as medicines (Article 18 of the directive), even though they clearly are not medicines, both as a matter of common sense or law. As medicines they will be subject to an onerous regulatory regime increasing cost, limiting choice and appeal, holding back innovation and generally making the products less competitive relative to high-risk cigarettes. Many existing firms will never be able to turn themselves into quasi-pharmaceutical producers as required by medicines regulation. This imposes a wholly excessive standard given most recreational nicotine is currently delivered in an aerosol of toxic particles and hot gases – cigarette smoke. The views of the users, the supposed beneficiaries of e-cigarette regulation, have been ignored. The firms involved have had minimal consultation and the government's impact assessment is shockingly complacent about the impacts this regulation will have. The government and European Commission have made no credible attempts to explore alternative approaches – there are perfectly sound options – or to reconcile a burdensome regime with the true public health imperative of encouraging smokers to switch to these products.

***3. Novel tobacco products**. The proposed directive (Article 17) provides for the introduction of novel tobacco products. These are in the development pipelines of some companies and generally involve heating rather than burning tobacco. It is likely that using these products will be substantially less risky than smoking – perhaps 90% less. For these products, all that is required under the proposed directive is notification of the competent authority and disclosure of information on ingredients and emissions. There is nothing wrong with that approach: any nicotine product substantially less dangerous than cigarettes should have ready access to a market where cigarettes are pervasively available. What is deeply incoherent is the contrast with the approach to e-cigarettes (Article 18). A low risk nicotine product has much easier access to market if it contains tobacco. If it does not, it has to be authorised as a medicine.*

***4. Smokeless tobacco (snus).** The proposed directive (Article 15) imposes a ban on a subset of smokeless tobacco, popularly known as 'snus' and defined as 'oral tobacco' in the directive. The ban applies everywhere in the EU other than Sweden and is an uncritical continuation of a policy first introduced in 1992 in response to a panic about 'gateways' to smoking. It has been long*

established that snus is a clear gateway out of smoking. Sweden has the lowest smoking prevalence in Europe by far (13% compared to the EU average of 28%) and one of the fastest rates of recent decline. That translates to a major public health gain: for example, Sweden has approximately half the lung cancer rate of its near neighbour Denmark. Snus users are not at zero risk, but the reduction is thought to be 95-99% compared to smoking. The definition of oral tobacco is contrived to the point of absurdity: products that are put in the mouth and chewed rather than sucked do not count and are not banned, though they may actually be more risky. It is both bizarre and deeply unethical to use the force of law to prevent smokers switching to a product of much lower risk, on their own initiative and at their own expense. Even if there were only a few hundred people in Britain who wanted to use snus, why would the EU use the law to stop them? I cannot find any credible explanation for maintaining this ban and government cannot provide one.

5. Cigarettes. *Tobacco cigarettes can be put on the market pretty well at will, as long as they meet some routine and irrelevant tests for machine-measured 'yields' (Article 3 and 4), the results of which are no longer to be printed on packs because they are now recognised to be meaningless and misleading. A cigarette business does not have to seek authorisation, use pharmaceutical grade manufacturing facilities, introduce a rigorous quality regime, hire biomedically trained graduates, provide trial data, run a risk-management system, conduct surveillance, show they have optimised risks and benefits, or provide a comprehensive account of risks on its packaging or labelling. I raise these points not to advocate more regulation of cigarettes, but because these are all burdens that will be imposed asymmetrically on e-cigarette companies if their products are regulated as medicines. It cannot be sound policy to tilt the regulatory playing field in favour of cigarettes.*

6. Labelling and warning*. Much energy will go into deciding whether warnings cover 50% or 75% of the pack (Article 9), though there is little to suggest the difference would change smoking patterns. The key issue has been ducked: that is meaningful risk communication to inform smokers about the choices they have. Though e-cigarettes, novel tobacco products and smokeless tobacco are 90-99% less risky than smoking, the proposal reinforces an undifferentiated message that all these products are harmful and addictive (Article 8-11). In fact, the directive goes further and makes it illegal to*

suggest that a particular tobacco product is less harmful than others (Article 12) – even though there is an approximate 100-fold range in risk. Consumers are basically misled, perhaps lethally, by these evasions and the omission of useful information on relative risk.

7. Additives and flavourings. *The proposal seeks to ban most additives and flavourings (Article 6), but no one really knows what impact this will have on smoking behaviour and risk. It would probably be counterproductive if such measures were applied to lower risk products, making them less attractive relative to smoking. Less addictive nicotine may sound desirable, but it is plausible that smokers are looking for a satisfying nicotine dose: so 'less addictive' might mean more is needed, causing more exposure to smoke and more ill health. I do not know what the effects of bans on additives would be, but the apparent confidence of those proposing this is misplaced.*

8. Arbitrary measures*. I have no wish to protect any part of the cigarette industry, but as a matter of principle, I do think the European Union should avoid arbitrary evidence-free gestures in policy and legislation. With that in mind I can see no compelling rationale for measures related to menthol cigarettes, pack size and shape, or the diameter of cigarettes.*

I hope you agree there is much to be concerned about, both in terms of scrutiny process and the substance of the proposals. I hope this note assists the committee in its efforts to scrutinise this poorly conceived legislation. If a more detailed submission would be useful, I would be happy to provide one. I am copying this to committee members and to the Committee Clerk.

Yours sincerely

Clive Bates