Tobacco products directive – poor legislation harmful to health

written by Clive Bates | 7 May 2013

I felt moved to write to MEPs…

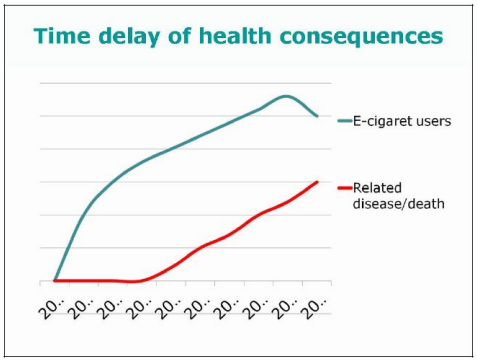
To: the ENVI committee rapporteur for the Tobacco Products Directive, Linda McAvan MEP

CC: ENVI MEPs

7 May 2013

Dear Ms McAvan

I wanted to make a few points about the draft tobacco products directive, your draft report and some of the points raised by you and other members on 24 April (from 16:43) I hope this will be useful additional input in advance of your hearing on e-cigarettes on 7 May and deadline for amendments the following day. I apologise for the length of this communication, but there is rather more to say than I would have hoped.



Hearing on 7 May. The list of invited experts and lobbyists is heavily weighted to those who favour more regulation or prohibitions. What no-one should assume is that more regulation of low-risk alternatives, even in the name of health and safety, will mean better health overall, when high risk cigarettes are freely available and largely unregulated as products. I have just seen the presentations to be given by two health lobby groups (the European Respiratory Society and European Society of Cardiology). I cannot see

what MEPs will gain from such poor analysis. The presentations are unscientific advocacy directed against e-cigarettes, full of vacuous conjecture, fabrications, no serious attempt to approximate the scale of risk, no comparisons with cigarettes (the key issue), and grossly overstated uncertainties. In one particularly mendacious slide (see chart), a disease risk is projected into the future that has been *entirely made up*. It is simply not the case that because we do not know *everything* that might happen over 50 years, we do not know *anything* – we know that e-cigarettes do not contain burning organic matter, and therefore do not create the hazards associated with thousands of products of combustion. To claim, incredibly, that most e-cigarette users say their health has worsened, on the basis of an obviously flawed internet survey, would be laughable if it was not such a serious deception. I think most Members will recognise this from the accounts they have received from constituents and from common sense. I hope Members will see through these shallow presentations and recognise that what matters is the dramatic reduction in risk and immediate health gains experienced by switching from smoking to e-cigarettes.

> *Update: an equally ludicrous presentation from WHO became available later. Further update: a terrific takedown of these absurd presentations has been done by ECITA's excellent chief scientific officer Tom Pruen: see his analysis of the World Health Organisation, European Respiratory Society and European Society for Cardiology presentations. Note to tobacco control community: this is your collective professional shame – you own this. Note to European Parliament – your time was wasted by these people as part of the flagging effort to justify excessive regulation, when you could have heard more from knowledgeable users.*

E-cigarettes as tobacco products. You appeared minded to label e-cigarettes as *tobacco products*. That is unnecessary and would be counter-productive. It would do nothing to protect and inform the consumer or to improve public health. The FDA had to define e-cigarettes as tobacco products when its attempt to define them as medicines was struck down in court (see FDA letter). It is a peculiarity of American legislation, which doesn't allow a third way, and we should not pursue this in Europe. In Europe, we have the opportunity to craft regulation that reflects the reality of e-cigarettes – they are nicotine-containing consumer products that compete with cigarettes but with many superior characteristics, mainly by virtue of not using combustible tobacco. We would not classify an

energy drink as a coffee product if it contained pure caffeine extracted from coffee. E-cigarettes are best considered as 'nicotine products' for the purpose of regulation.

E-cigarettes as medicines. It is not just the FDA that failed in the attempt to classify e-cigarettes as medicines. Four courts have now rejected this definition in Europe, and there is ECJ case law that suggests it would fail at a European Union measure too. That legal perspective is also supported by common sense and the fact that users do not see themselves as ill or in treatment and vendors do not claim they are offering a therapy. NRT products are mostly sold to relieve cravings from nicotine withdrawal. E-cigarettes on the other hand, meet the demand for nicotine as a recreational drug that is not especially harmful itself. NRT and e-cigarettes are totally different in character and purpose, as the European Parliament Library briefing on electronic cigarettes makes abundantly clear in its table. You can follow these arguments in depth in my briefing: *Are e-cigarettes medicines?*. You were precise in referring to e-cigarettes as medicines 'by function', but it is this definition (as opposed to 'by presentation') that has repeatedly failed. It is obvious why. Several widely used products modify physiology and metabolism – nicotine in tobacco, alcohol, and caffeine for example – but they do not do this to treat any sort of medical condition, and are so not regarded as medicines. E-cigarettes are no different.

Excessive regulation. Classifying e-cigarettes as medicines and would not have the effects its proponents believe. It would be damaging to health and support the cigarette market by protecting it from competition from superior nicotine products. The key health benefit of these products is determined by how many smokers switch to using them or use them as a staging post to quitting completely. Whether e-cigarettes are 99% or 99.5% less dangerous than cigarettes matters much less than whether they are attractive to smokers. To be attractive to smokers we need diverse, customisable products and lots of innovation – I recommend this video Open message to European MEPs from e-cigarette user David Dorn to help with understanding how this works. Medicines regulation works against diversity and innovation – it adds costs, imposes burdens, applies restrictions and holds back innovation. Unlike cigarettes, which have easy access to the market, medicines regulation creates a default prohibition and requirement for approval. Why make it easier for cigarettes and harder for e-cigarettes? I have explained the risks of excessive regulation in this

post: *Medicines regulation for e-cigarettes: when caution can kill*.

Light touch regulation. A representative from the UK medicines regulator (MHRA) is invited to the hearing. Though they promise a 'light touch', they haven't so far managed that with the products they are currently evaluating. Medicines regulation would also hand very significant powers to regulators in other EU states, who could take a much less progressive approach than the MHRA – not least making these products 'pharmacy only' or banning flavours (a move anticipated by the Commission). Even 'light touch' medicines regulation starts from the position that the products are banned unless approved, whereas cigarettes can be placed on the market if they comply with rudimentary standards for tar, nicotine and carbon monoxide 'yields'. There is a role for medicines regulation where a vendor wishes to make a health claim and/or where they see advantages in having the approval of a medicines regulator, for example in accessing healthcare providers. But this should be *optional* – a 'premium' option alongside a robust mandatory 'floor standard' set by consumer protection legislation.

E-cigarettes as consumer products. It is much more realistic and proportionate to consider e-cigarettes as consumer products. That does not mean they are unregulated. Far from it: they are covered by at least 17 directives (I have set these out here). This is not to say that the regulation is currently perfect – though there is little sign of any problems that are not addressed by the current consumer protection system. For example, security and packaging of e-liquids is covered by the Dangerous Preparations Directive (99/45/EC) and CLP Regulation (1272/2008) from 2015. What problem do you see that needs additional regulation? There may be scope to set specific standards, for example for e-liquids, and member states could develop proper enforcement regimes. But developing regulation within the broad framework of consumer protection legislation should be the focus of efforts in Europe. It is important to recall that the Treaty on European Union (Art 5 Protocol 2) requires:

> *Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.*

This means that unless the European institutions can show that consumer protection legislation is *inadequate*, there is no basis for applying the much more burdensome medicines regulation. The Commission has not shown this to be the case, and nor have any rapporteurs.

The Commission proposal on e-cigarettes and nicotine containing products. The Parliament and Council have been let down by the Commission's proposal in Article 18. It is poorly thought through, contains an arbitrary and pointless threshold, it takes an easy short cut by applying medicines regulation rather than designing appropriate and proportionate regulation, and it has failed to consult on its proposal or listen to the industry and users. The best that Parliament could do is to insist that the Commission starts again and does a thorough job, looks properly at all the regulatory options and comes back with sound, legally robust, proportionate and non-discriminatory proposals once it has done the necessary work. In the mean time, member states should enforce the existing legislation properly and report on what they are doing.

Snus and smokeless tobacco. I noticed you barely mentioned snus or oral tobacco in your report or speech, simply reaffirming that it should be banned, but not providing any justification for this. No MEP seemed willing to attempt a justification for the ban. The reason is obvious: there is no justification, and the case for the ban made by the Commission has been comprehensively discredited. Can any MEP suggest any reason at all why smokers outside Sweden should be prevented by the EU from saving their own lives by switching to snus as a way of quitting or as a substitute for smoking? The evidence on snus in Sweden is very compelling, as I hope you know by now. In Sweden smoking prevalence and disease is by some distance the lowest in Europe and there is no evidence of gateway effects. As Professor John Britton and Ilze Bogdanovica argued last week in their Lancet article: *Tobacco control efforts in Europe*.

> *The rationale of tobacco harm reduction is to make nicotine products that are more satisfying as a smoking substitute available to smokers at least as easily as cigarettes, and at competitive prices, hence providing all smokers with an easily obtainable lower-risk alternative to smoking. Proof of concept is provided by Swedish snus, an oral smokeless tobacco product that delivers high doses of nicotine, is culturally accepted in Sweden and freely available alongside cigarettes in tobacco retailers, and has been used increasingly during recent decades as an alternative to cigarettes by existing smokers and new tobacco*

> *users. Sweden has the lowest prevalence of smoking in the EU, and, in 2008, a European Commission expert committee concluded that the availability of snus has contributed to that. Legitimate concerns exist that snus might be a gateway into smoking for some people, and that it sustains nicotine addiction and could perpetuate smoking in dual users. However, the low health risk of the product compared with smoked tobacco, and predominant use as a gateway from smoking, indicate that at population level wider availability of this product would reduce harm to society from tobacco use.*

It is true: snus in Sweden is 'proof of concept' for harm reduction and many thousand Swedish lives will be saved as a result. It is a travesty to deny this to others for supposed political reasons. It looks to me like everyone involved believes everyone else involved is immovable. But the scientific, ethical and legal arguments are so strong, and the solutions so easy and sensible, that it may just need some political leadership to unlock the huge potential health gain. You are well placed to provide this.

Novel tobacco products. Your draft report proposes a mandatory authorisation process for novel tobacco products. While at first glance this might seem like a good idea, it will in practice become a highly politicised unscientific process, and will be likely to create more arbitrary anomalies like the snus ban. Some loud but misguided campaign groups do not believe there should be *any* novel tobacco products – even ones that are 10-100x lower risk than cigarettes. For example Cancer Research UK argues "*There is no legitimate reason to introduce a new tobacco product on to the market*". These views should be dismissed as unscientific and unethical. To assist in the development of the internal market an authorisation process would need harmonised objective criteria, but none are suggested in your draft report. Given that any novel tobacco products are likely to be novel due to their significantly reduced risk, it is hard to see what justification there would be to keep these products from the market, when it is possible to introduce a new cigarette brand simply by complying with a crude and easy ISO standard (Art 3-4 of the TPD). The right approach here is to have a notification system as envisaged in the proposal and to establish *a safeguard* – if a members state has reason to believe a novel tobacco product is more dangerous than conventional cigarettes, they should have the power to prevent it entering the market pending further investigation. The bureaucratic blockage of developments in this area is not a theoretical concern. There are 'heat not burn'

tobacco products under development that would be significantly lower risk than smoking, and may have the appeal to get many smokers to switch.

Flavours. 5% of cigarettes use some sort of characterising flavour, but 70% of smokeless tobacco products use flavours. An across the board ban on flavours in all tobacco products looks even handed, but in fact it is much more restrictive on the much lower risk category. It defies belief that the European institutions would wish to ban important ingredients in the products that have contributed to the great success that Sweden has had in reducing smoking related disease, and against the will of the Swedish government. The answer is to confine this ban to smoking tobacco products.

Descriptions. The idea that it would not be permitted to describe one tobacco product as less harmful than another would be to codify a life threatening deceit into European law. We know that some tobacco products are 90-99% less risky than cigarettes. That difference is too great to legitimately conceal from users. The JURI rapporteur correctly expressed this in his draft opinion:

> *By prohibiting any labelling that suggests that a particular tobacco product is less harmful than others, the proposal causes an additional problem. The development and promotion of less harmful means of tobacco use is essential in order to support tobacco users to stop smoking cigarettes and the like. Manufacturers must be able to communicate that a certain product is less harmful than others if this is scientifically proven and if it is not misleading.*

Conclusion. The draft TPD fails to provide a sound basis for regulating the emerging range of nicotine products in a way that reflects their dramatically different risks. In just about every way that directly affects the product, the directive is discriminatory and disproportionate towards the lower risk products. Until this is addressed, the directive will do more harm than good overall. Please see my guide to amending the TPD for in depth suggestions on how it should be improved.

Yours sincerely

Clive Bates

Disclosure: no competing interests. I am former director of Action on Smoking

and Health 1997-2003 and a civil servant from 2003-2012. My only concern is to secure maximum possible health benefits from enlightened regulation of tobacco and nicotine products. Any views expressed are mine not necessarily shared by former employers.