Mr Dominik Schnichels
DG Sanco
European Commission
1049 Brussels
By e-mail: Dominik.Schnichels@ec.europa.eu
Your reference: Ares(2014)198193

From: Clive Bates
London, UK
By e-mail

E-cigarettes and Tobacco Products Directive

Dear Mr Schnichels

Thank you for your reply of 29 January 2014 to my email of 23 October 2013. I am grateful for your considered response. However, the most substantive points I made in my 23 October message remain unaddressed.

In a closed process between October and December 2013, over 4,500 words of new legislation have been formulated to apply to e-cigarettes, which are a significant emerging technology with great public health potential. Article 18 of the TPD is now for all practical purposes a new legislative proposal and could be written as a separate directive. As I am sure you are aware, there are treaty obligations to consult on legislative proposals, to provide a reasoned justification, and to develop an impact assessment. It is the Commission's responsibility to see that these requirements are met, but none of this has been done. The Parliament does not have the power of legislative initiative, but had rejected the essence of Commission's proposal to regulate these products as medicines. At that point, the Commission should have withdrawn the proposals that related to e-cigarettes so that a proper legislative process could be followed, meeting the treaty requirements for consultation, supporting analysis and timely scrutiny by national parliaments. The Commission is the 'guardian of the treaties' but appears to have sides-stepped these important treaty obligations when it had the power to do otherwise. This was the primary point of my letter of 23 October.

I was not trying to be obstructive – the treaties require consultation, reasoned argument and impact assessment *for good reasons*. Though I support the Parliament's rejection of medicines regulation for e-cigarettes in October, I do not think the text that emerged from the trilogue process in December is worthy of the EU legislature. Like many others, I believe it is disfigured by scientific misunderstandings, arbitrary and inconsistent measures and legal weaknesses. In my view, these would have been flushed out had there been proper supporting analysis and a more open Commission-led process in which the views of consumers, businesses and experts could have been considered properly.

I am sorry to say that after 23 October, I had given up communicating with the Commission.

However, I accept your point that my letter may have appeared to be sent to you for information rather than for a response. I have subsequently elaborated at greater length on the technical and legal deficiencies of the directive, most recently in the attached letter to ENVI committee MEPs of 19 January 2014. I realise now that I should have also sent this to you and asked you for a response.

I would be grateful therefore, for your response on the following:

1. Why the TPD provisions related to electronic cigarettes were not withdrawn and recast as a new legislative proposal in order that the requirements of the treaties with respect to consultation, justification, impact assessment and scrutiny could be met.

2. A response to the criticisms I have made of the measures described in the attached letter in the appendix under the heading ‘unlawful measures’. I think an explanation and justification for the controversial provisions of this directive would be very helpful at this point, before the formal first reading.

It is a matter of regret that I am compelled to ask these questions and make these points almost in retrospect and as the legislative process is drawing to a close. It would be better in future if the proper process was followed and such widely held concerns were understood and anticipated in advance through consultation.

I look forward to receiving your reply.

Yours sincerely

Clive Bates

Appendix – letter to ENVI MEPs 19 January 2014

Dear members

On Wednesday 22nd January the ENVI committee will consider the text for the revised Tobacco Products Directive that has emerged from the trilogue process. I would like to draw your attention to the significant weaknesses in the text as it applies to e-cigarettes (primarily Article 18, with cross references to other articles).

I hope you will consider speaking, voting or persuading colleagues in favour of ***recasting the parts of the directive relating to e-cigarettes as a new legislative proposal*** built on credible science, due process and adequate legal base.

Flawed science

The underpinning science is flawed and misrepresented. Two individual scientists and a group of scientists have rejected the underlying science in letters to the Commission and key MEPs:

10 January 2014. Dr Konstantinos Farsalinos wrote to the Commision: *The European Commission has misinterpreted my scientific research on nicotine in e-cigarettes*

12 January 2014. Dr Lynne Dawkins wrote to the Commission: *Please do not distort my words to justify your policy*

17 January 2014. A group of eminent international experts in nicotine and tobacco science have made a broader challenge: *Scientific Errors in the Tobacco Products Directive*. This group includes: Professor Jean-François Etter, Dr. Konstantinos Farsalinos, Professor Peter Hajek, Dr. Jacques Le Houezec, Dr. Hayden McRobbie, Professor Chris Bullen, Professor Lynn T. Kozlowski, Dr. Mitchell Nides, Professor Riccardo Polosa, Dr. Karl Fagerström, Professor Martin Jarvis, Dr. Lynne E. Dawkins, Dr. Pasquale Caponnetto, Professor Jonathan Foulds.

The scientific errors listed are not trivial and in fact underpin the most controversial aspects of the directive. They related to:

- Incorrect assertion of 'equivalence' between smoking and e-cigarette use
- Greatly exaggerated toxicity of nicotine
- Poor understanding of nicotine using behaviour to justify inappropriate tests
- Inappropriate assertion of user requirement for consistent dosing based on misunderstanding of consumer behaviour
- Inappropriate approach to risk management (by limiting container size)
- Incorrect assertions regarding 'gateway effects' to exaggerate risks and to justify advertising bans

Irregular procedures

The European Parliament rightly rejected the inappropriate and unlawful classification of e-cigarettes as medicines on 8 October 2013. However, that abrupt change of direction has not allowed for the proper procedures that should be integral to the EU legislative process, in particular the following:

- **The requirement to consult** – there has been no consultation on the new proposals, though the new regulation will affect millions of users and thousands of business and are subject of great controversy among experts.
- **The requirement to provide reasons** – virtually no argument has been offered to justify the measures, and to the extent there is any, it is based on scientific misunderstanding (see above).
- **The requirement to provide an impact assessment** – no new assessment has been produced to support the new proposals, yet they could have serious negative effects on users, distort competition in favour of smoking, impose high and unnecessary burdens on businesses and consumers, and have an overall negative impact on health in Europe.

- **The requirement to allow scrutiny** – legislative proposals and amendments should be sent to national parliaments for scrutiny with time for parliaments and governments to react. The proposal has changed beyond recognition since it was circulated in December 2012. If they see it at all, national parliaments will only see it at the very last minute before a deal is done and not through the proper process.

These are not just 'nice-to-have' but are requirements of the EU Treaties. The sidestepping of these requirements is now the subject of a complaint to the European Ombudsman which is set out in detail here: *Maladministration in the development of the revision of the Tobacco Products Directive with specific reference to Article 18 on electronic cigarettes* - with explicit backing of consumer organisations from Germany, France, Italy, United Kingdom, Poland, Netherlands, Belgium, Denmark and Hungary, with others indicating their support.

Unlawful measures

As well as the unlawful procedural irregularities above, the flawed science and arbitrary unjustified measures cast severe doubt over the lawfulness of key provisions when tested against the principles of proportionality, non-discrimination and adequate legal base. The internal market legal base (TFEU 114) is intended to promote free movement of goods and competition, with a high level of health protection. In this case the market is in itself highly beneficial to health - e-cigarettes compete with cigarettes, but are 99-100% less risky. This legal base requires a health justification for departing from the principle of the free movement of goods:

- **Advertising bans**. The directive bans many forms of advertising, promotion and sponsorship in many media. Why? Advertising is a service in its own right and integral to free movement of goods. The 2003/33/EC tobacco advertising directive recital (3) refers to 500,000 deaths among Europeans as part of the justification for banning tobacco advertising. There is no equivalent rationale for e-cigarettes - indeed e-cigarette advertising may drive switching from smoking and be beneficial to health. A more proportionate approach would apply the type of restrictions applied to alcohol advertising in member states, not tobacco. *Verdict: disproportionate, no health rationale, no legal base.*
- **Limiting the strength of liquids.** Based on a flawed assertion of the equivalence between cigarettes and e-cigarettes a limit of 20mg/ml has been set for e-liquids, yet 20-30% consumers currently use stronger liquids. What is the health rationale for imposing this limit and denying consumers and producers of stronger liquids access to the internal market? Stronger liquids matter to more heavily addicted smokers and those just beginning to switch, so this arbitrary limit is more likely to increase relapse and protect the cigarette category. *Verdict: discriminatory, no health rationale, no legal base.*
- **Imposing small container sizes**. The proposal aims to control acute toxicity risks by limiting the container size. The reasoning greatly overstates toxicity risks and ignores the widespread practice of controlling hazardous substances through labelling and packaging, not least under the EU Classification, Labelling and Packaging Regulation 1272/2008. *Verdict: discriminatory, no health rationale, no legal base, risk covered by other legislation*.
- **Ban on mentioning flavours on flavoured products.** The interaction between 18.4(b)ii and 12.1(c) has the effect of banning any reference to flavours on e-cigarette or refill containers, even on products that are flavoured - so depriving everyone involved of legitimate information about the product. *Verdict: in legal terms, disproportionate, no legal base. To everyone else, a fiasco.*
- **Insisting on consistent 'dosing'**. This is a matter for consumer preference and has no health rationale given the way consumers use nicotine (see flawed science above), yet it is technically difficult to do. This has been imported from medicines regulation, where drug dosing to passive patients is an important requirement, but it is not appropriate here. *Verdict: disproportionate, no health rationale, consumer protection covered by other legislation*.
- **Excessive warnings and information leaflets.** The warnings are factually incorrect (nicotine is not 'highly addictive', it depends how it is administered), excessively large, bold and off-putting given the risks are so low, and potential health benefits so high. The requirement to include an 'information leaflet' is not a requirement on cigarette makers. *Verdict: discriminatory, disproportionate, no legal base*.

- **Requirement for surveillance and pharmacokinetic testing**. There are several costly burdens placed on e-cigarette producers that are not applied to cigarettes. Much information is requested, but it is unclear what will be done with the information supplied. *Verdict: discriminatory, disproportionate (fails to meet the requirement to minimise burdens to achieve objectives)*.
- **Member state discretion.** Member states are left with discretion to ban flavours, regulate these products as medicines (another form of ban for most products) or to remove refillable devices from the market. What is the purpose of an EU internal market directive that does little to uphold the principle of free movement of goods? *Verdict: will create more arbitrary protection of the cigarette market and defeats for member states in national courts.*

Missing elements. At the same time, regulation that would *actually be useful* has been omitted - for example, purity standards for e-liquids or relevant technical standards (eg. operating temperature ranges) for devices.

This focus on e-cigarettes and liquids in this letter reflects the high degree of controversy over the subject during the trilogue. It is not intended to endorse the rest of the directive, notably the ban on snus (Article 15), for which there is no basis whatsoever. Twelve experts recently wrote to the UK Secretary of State to call for the snus ban to be lifted on scientific, ethical and legal ground.

What to do?

The right approach
The sections of the TPD that deal with e-cigarettes now total 4,400 words and fill 12 pages - more than enough to form a new stand-alone EU directive. Most of this text has been created from scratch in the period October to December 2013 with no consultation, inadequate analysis, and poor reasoning based mainly on scientific misunderstandings. It would be better to proceed with a simple amendment of the following form:

Article 18: After completing broad consultations and no later than [31 December 2014] the Commission shall report on the market for non-tobacco recreational nicotine containing products, taking account of health implications and impacts on tobacco consumption. The report shall include policy options and appraisal, and, as appropriate, proposals for legislation to develop the internal market in these products, with the aim of securing a high level of health protection.

The decisions made by the EU on this important and usefully disruptive technology will set the agenda for the next decade or more, and probably set norms internationally. It would be better to get this right, rather than rush through half-baked and very controversial legislation before the May 2014 elections.

The wrong approach
It would be wrong for MEPs to wave through an important component of a directive, knowing that it based on flawed science, following irregular procedures and comprising measures of unlikely legal validity. How could that be justified? The European Union needs to win trust and respect, not to haemorrhage credibility by passing bad laws and sidestepping the proper constraints of the treaties.

Please contact me if I can provide further information or if you wish to discuss any of the points raised.

Please note: no competing interests. Transparency register ID = 810709012348-60

Yours sincerely

Clive Bates