EU tobacco directive and e-cigarettes: maladministration complaint to European Ombudsman

written by Clive Bates | 12 January 2014

Why complain?

There are two ways to criticise the proposals for regulating nicotine containing products, such as e-cigarettes: *substance* and *process*.

First, on the **substance of the proposals themselves**… I made a start on that in my reaction to the trilogue announcement: *Making sense of the proposed new e-cigarette regulations*. Dr Farsalinos has also hacked away at the scientific foundations used by the Commission: *The European Commission has misinterpreted my scientific research on nicotine in e-cigarettes*. (Update 13 Jan: now Dr Lynne Dawkins has also rejected the Commission's use of her work – see her letter – not much room for doubt there). And I have in mind a more unforgiving critique of the actual measures over the next few days. Within a month, I believe this proposal will be well and truly exposed for what it is… a mess, and a mostly unlawful and counterproductive mess. This type of complaint

is usually settled in court as the measures are tested against the requirements of the treaties. The treaties allow for the European Court of Justice to examine the lawfulness of the measures [see TFEU Article 263] and my post on Making bad law legal vulnerabilities in the tobacco products directive .

Second, on the **process followed to get to the proposals**. Regular readers will know that I think the EU institutions have gone rogue on this directive and *seem oblivious to their responsibilities under the EU treaties* that provide stabilising constraints on what they can do. The current proposals for regulating e-cigarettes have been hatched between October and December entirely behind closed doors driven by a rush to get it done, not to get it right. What should have happened is when the European Parliament rejected the Commission proposal to regulate these products as medicines, they should have paused and formulated a new proposal, and subject it to proper evidence based justification, impact assessment, consultation and scrutiny by national parliaments. This kind of complaint can be settled through an Ombudsman or in court.

So with the support of a group of European associations, I have made a complaint to the European Ombudsman, alleging maladministration on the part of the European Commission, in its role as guardian of the treaties and upholder of EU law. It is hard (at least for me) to tell whether an Ombudsman can require a change in process, but their involvement could either be decisive, or persuade European or domestic politicians that they need to do a proper job, and start a new legislative proposal.

The complaint

The full complaint is here: *Maladministration in the development of the revision of the Tobacco Products Directive with specific reference to Article 18 on electronic cigarettes* (PDF). The Ombudsman is there to: *investigate complaints about maladministration in the institutions and bodies of the European Union*. So let's hope they look into this.

Caution and cautious optimism: I suspect this is not typical of the complaints resolved by the Ombudsman, and I don't know what they will make of it or what power they have to intervene directly, but there is a new Ombudsman, Emily O'Reilly, and she has an encouraging attitude. She said in October:

> *The EU administration has to serve as a role model when it comes to openness, accountability, and good administration in the Union. This is a key precondition for winning the trust of Europe's citizens. A lot has been done in the past, but there is no room for complacency.*

Does anyone seriously think they have acted as a 'role model' in this case? I would say a complete lack of consultation on a brand new regulatory framework affecting millions of users and thousands of businesses, which includes elementary scientific errors and plays fast and loose with key principles of the EU treaties does not meet these ambitions. Not by far. And given the alternative was to take the provisions related to e-cigarettes out of the TPD and recast them as a new legislative proposal with appropriate consultation and a proper scientific basis, this makes this is a serious case of maladministration. Take consultation for example. The Treaty on European Union Article 11.3 and the second Protocol require consultation for legislative actions.

> *11.3 The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent*

> *Protocol Art 2. Before proposing legislative acts, the Commission shall consult widely. Such consultations shall, where appropriate, take into account the regional and local dimension of the action envisaged. In cases of exceptional urgency, the Commission shall not conduct such consultations. It shall give reasons for its decision in its proposal*

That seems pretty unambiguous to me. But there has been no consultation on the proposals that have emerged following the European Parliament rejection of medicine regulation in October. Update: I know there was a consultation in 2010, but that was only about whether nicotine containing products should be included in the directive, but not about the measures now proposed. This is discussed in the complaint and reproduced at Annex 2.

This is the summary of the complaint as lodged on the Ombudsman's web site:

> *The complaint relates to the negotiation of new regulations for electronic cigarettes as part of the revision of the Tobacco Products Directive, which is*

now heading towards conclusion. The complaint relates primarily to Article 18 of this draft directive, which covers non-tobacco nicotine products such as electronic cigarettes. The complaint arises because the institutions have changed the original Commission proposal beyond recognition (it is now five times the length and applies a conceptually unrecognisable), following a rejection of the Commission proposal by the European Parliament on 8 October 2013. Between October 2013 and December 2103 an entirely new and detailed regulatory framework has been created via amendment and negotiation in the closed trilogue process. It is for all practical purposes a completely new legislative proposal, but it has been created without regard to any of the following, which I understand requirements of the EU Treaties:

- ***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.*
- ***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 governments to react. The proposal has changed beyond recognition, and national parliaments will only get to see it at the very last minute before a deal is done, if at all, and not through the proper process. The process has effectively cut national parliaments out of the process, but they are integral to the Ordinary legislative procedure.*

The complaint is directed at the European Commission in its role as guardian of the treaties. At the point where the Parliament radically altered the Commission proposal for regulating these products (Article 18), it should have been withdrawn from the process of revising the Tobacco Products Directive,

and a new legislative proposal developed for these products. This would have allowed for consultation, justification, impact assessment and scrutiny. Most of the revised directive relates to tobacco products and this could have proceeded to completion. There is no reason to delay the rest of the directive.

Timing is critical – the ordinary legislative procedure is heading towards conclusion at first reading, which is likely in March 2014 in the European Parliament and shortly after in the Council.

I would like the Ombudsman to review the process followed as urgently as possible. If the Ombudsman accepts the complaint is valid, I believe she should request or require the institutions to meet these requirements before the directive becomes law and the process will have irreversibly failed. This is likely in March 2014, but certainly before the May 2014 elections. The elections are the primary reason for the rush to complete the directive.

The full complaint is set out with references and annexes to the various texts in the attachment. The complaint has the support of several consumer and producer organisations from different members states. These are listed in the attachment. I have no competing interests – my primary concern is public health.

Who's involved?

Associations supporting the complaint, and their short statements:

1. ECCA (UK) on behalf of consumers. The proposals would force a number of perfectly satisfactory and safe products from the market, limiting consumer choice and appeal, and potentially causing regress to smoking. We have not been consulted on the concepts of details of the proposals and what they would mean for users.
2. ECITA (UK) on behalf of businesses which will face unnecessary burdens and restrictions, with no justification will have their competitive position relative to cigarettes weakened, through for a example a ban on advertising. Many of the measures proposed are counterproductive or excessive given the risks. We should have been consulted properly.
3. AIDUCE (France) on behalf of users. Electronic cigarettes are deemed by

France’s health professionals to be infinitely less dangerous than smoked tobacco. The growth in the number of smokers who are adopting them is exponential. According to their testimony on our user forums, well over half eventually quit tobacco altogether. The proposed measures would severely restrict the attractiveness of e-cigarettes for smokers; and indeed for many vapers who would return to tobacco. They are absurd in terms of public health policy.

4. Villanypára Egyesület (Hungary) on behalf of users. The proposal as it stands would be a big mistake in the fight against tobacco and prevent adoption of a healthier alternative. We are vapers not smokers and we are much healthier thanks to e-cigarettes!
5. DADAFO – Dansk e-Damper Forening – Danish Vaping Society wholeheartedly supports the complaint issued by Clive Bates to the EU-ombudsman. The ignorance from the legislators, the denial from the Council and the Commission to understand what the European people wants, is horrendous. Vaping has nothing to do with tobacco, and even less to do with being a form of medicine. And trying to deny other smokers in the EU (and for that matter, in the whole world) the chance to choose a much safer alternative to smoking, will cause millions of premature deaths.
6. Acvoda (Netherlands) on behalf of consumers. The proposals would force a number of perfectly satisfactory and safe products from the market, limiting consumer choice and appeal, and potentially causing regress to smoking.
7. ABVD (Belgium) on behalf of users. ABVD.be (Belgium) on behalf of users. We are strongly convinced that ecigs must be taken out of the tobacco directive. According to us, ecigs devices and e-liquids should be considered in another specific regulation, elaborated in accordance with public health fair principles and in close collaboration with genuinely independent experts and scientists. Also users’ opinions and experiences should ideally be taken into account. We, ABVD.be, do not accept, or can’t agree with, this unfair proposed directive, written in a hurry, lacking any scientific background or evidences and obviously influenced by lobbies.
8. IG-ED (Germany / Austria) on behalf of users. German speaking vapers will not tolerate to be forced back into smoking tobacco, therefore we support this complaint.
9. LIAF (Italy) Italian League Anti Smoking on behalf of those who would

benefit from improved health with the widespread use of non-combustible nicotine containing products.

10. FIESEL (Italy) LIFE (Italy) e-cigarette retailers associations on behalf of Italian retailers, which strongly believe that these negotiations behind closed doors will bring unnecessary burdens and restrictions to their business.
11. SUEP (Polish Vapers Association) – on behalf of the users. We do not want to be forced to use tobacco cigarettes again – e-cigarettes are much less harmful alternative. It is our right to choose!
12. World Vaping Organisation (global) on behalf of EU users wishes to add support to this complaint to safeguard the right of the EU vapers regarding current and future regulation for electronic cigarettes.
13. Norsk Dampselskap (NDS) on behalf of Norwegian users. We also wish to add our support to this complaint, as the proposed Directive is a text with EEA relevance. The proposed regulation will greatly restrict ecigs/personal vaporizers and make them far less attractive as an alternative product for smokers of tobacco product.
14. This complaint is also supported by members of the expert community in the field of nicotine science and policy: Clive Bates (UK); Professor Gerry Stimson (UK); Dr Konstantinos Farsalinos (Greece); Professor Riccardo Polosa (Italy); Dr Jacques LeHouezec (France); Dr Lynne Dawkins (UK); Professor Jean François Etter (University of Geneva) on behalf of those who would benefit from wider public health objectives. The proposals include numerous statements that are without foundation and measures that will prove harmful to human health at individual and population level.

A bigger picture?

I have a further motive: I feel strongly that if it is to win more trust from the European citizens, the EU just cannot act like this – and that applies to how British officials and ministers conduct themselves when they cross the Channel. The institutions need to be much more rigorous about the EU Treaties and the constraints they impose on the legislature. My Manchester University policy blog goes into this a little more: *Do we need a 'new settlement' with Europe – or just a better sausage factory?*