Everyone is involved but no-one is responsible – amending the tobacco directive

written by Clive Bates | 2 October 2013



Updated 3 Oct. The amendment number 170 on e-cigarettes [here] is now published and ready for consideration by the European Parliament on 8 October. As this was circulating on Monday 30th Sept, I wrote with comments and advice to the MEPs negotiating the amendment. Given they ignored most of it (!) that, these comments and the advice can now be read as concerns and criticisms. The proposed amendment is good and bad. Good mainly because it rejects medicines regulation. Never-the-less, I consider it significant progress and a breakthrough overall for which vapers should be proud.

It is good because it looks likely to succeed and therefore the destruction that would be caused by mandatory medicines regulation *may* be averted. If the Parliament did agree mandatory medicines regulation on 8 Oct then that would have aligned it with the Council and Commission – and this bit of the directive would be a done deal *and over*. So now we have an alternative, and on the face of it acceptance in the Parliament that medicines regulation is not appropriate. **But it is bad** because it has introduced some really counterproductive stuff to appease the regulatory obsessives in the European Parliament, in order to secure a majority for it. The amendment is **overall good** because it allows *two* paths to market – everything is still possible under medicines regulation that would have before, but if this is agreed there would be an additional option. Most importantly it would signal that the Parliament is *not convinced*, and understands that medicines regulation is not 'light touch', not a good fit for these products, is laden with unintended implicit support for the tobacco industry and probably not lawful. So it is good for its 'hang-on-a-minute' intrusion into the sloppy negligent consensus of the Council and Commission.

Sadly, the idea of standing aside and letting beneficial commerce take its course

unhindered by bureaucratic burdens isn't really what the European Parliament does, so we are stuck with this and their unbearable itch to regulate. Also remember this isn't the final text – it has to be agreed by the Council next (see what next? below). This then opens the prospect of finding a better way forward through the negotiation with the Council ('trilogue'), Council first reading in December, EP second reading etc. [see note on process] All the while, we would expect awareness of the costs, risks and unintended consequences to grow.

Here is my note to the MEPs from earlier in the week:

> *Dear Members*
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> *I am writing to you because it is likely you are or will be involved in negotiating amendments on the tobacco products directive related to e-cigarettes and 'harm reduction' more broadly.*
>
> *I have seen some of the proposals for amendments circulating and I would like to offer some brief comments and advice with a view to securing the best public health outcome and avoiding unintended support for the cigarette market.*
>
> ***1. Clarify that medicines regulation only applies where the products in question meet the legal definition of a medicine** – that is where there are presented as treating or preventing disease. The courts have repeatedly and rightly rejected other definitions, and would likely do so again. The aim should be to achieve proportionate, non-discriminatory legislation, recognising that e-cigarettes are promising alternatives to smoking.*
>
> ***2. Avoid thresholds in nicotine density such as 30mg/ml**. These limits provide no meaningful protections, but they do mean more heavily addicted smokers have to work harder to get a satisfactory experience from an e-cigarette, thus making switching less attractive to one of the most at-risk groups. The result would be a black market in stronger liquids, more home mixing and more smoking.*
>
> ***3. Applying the directives on tobacco advertising 2003/33/EC and 2010/13/EU to e-cigarettes would be disproportionate and counterproductive**. These directives are highly restrictive but justified as internal market measures on the basis of harm to health caused by smoking. No such harm is remotely plausible for e-cigarettes. In fact, the opposite is true –*

wider uptake of e-cigarettes will be highly beneficial to health by reducing smoking. Removing valuable options for advertising e-cigarettes simply protects the incumbent cigarette brands. Controls on advertising e-cigarettes are justified to prevent marketing to children or making misleading actual or implied claims (2006/114/EC)

***4. Protect Internet sales**. There is a case for limiting internet sales of tobacco products primarily based on excise duty fraud. No equivalent case exists for e-cigarettes. The e-cigarette retail market has a strong on line presence and this allows small businesses to compete for large markets beyond their physical locality, and ensures diverse supply and good consumer choice available throughout Europe. Internet based suppliers should of course meet the same standards as any other supplier, and be governed by established rules of e-commerce (2000/31/EC) and distance selling (97/7/EC).*

***5. Be wary of technical terms like 'Good Laboratory Practice'.** These have very specific meaning and should be used appropriately, and only where they offer benefits proportionate to costs. The application of GxP standards would be better introduced through a review and proper impact assessment with adequate consultation. [note they didn't use this]*

***6. Don't ignore smokeless tobacco**. Snus is banned, it should not be – the public health harm reduction case is overwhelming, and there is no scientific, ethical or legal case for preventing smokers having access to it. There are three options: (1) treat it like any other smokeless tobacco – the most obvious and proper course; (2) allow it to be authorised as a novel product under Article 17 (it is 'novel' in most markets as it has been banned for more than 20 years; (3) allow it to be sold in those member states where it has been used traditionally.*

I hope you find these points useful as you finalise amendments over the next couple of days. I am sure the e-cigarette industry will have additional points to make regarding practicalities, but these are the issues that I think are most important from a public health perspective.

Please contact me if you would like to discuss or would welcome further clarification.Yours sincerely
Clive Bates

Frédérique Ries, the MEP negotiating this from the Liberal 'ALDE' group wrote to

MEPs today explaining their hopes the amendment.

Dear Colleague

The common amendment on e-cigs that I circulated last Friday on behalf of the ALDE group has now officially been co-signed by EPP and ECR. It is also gaining support by a lot of individual colleagues within the S&D delegations.

Our aim is to reduce smoking-related disease, and e-cigs can play a major role in helping smokers cut their use of tobacco. We want e-cigs to be safe, and we want to ensure they are not promoted to young people as a gateway to tobacco. But we do not agree that they should be classified as medicines because this will increase costs and, in many countries, severely restrict their availability.

It should not be made more difficult for smokers to buy e-cigs than tobacco cigarettes.

Most of the suggestions for changes received call for the requirements I propose on e-cigs manufacturers to be REDUCED. It is argued, for example, that we should not restrict advertising if it encourages smokers to move away from tobacco.

However, if we are to secure a large majority in Parliament for an alternative to medicinal regulation we must address the issues which concern many MEPs, so I maintained the restrictions.

We vote in Strasbourg on the issue on October 8. We should not miss the opportunity to curb the world's single-most-harmful addiction.

With regards

Frederique Ries,

Shadow of the ALDE group on the Tobacco Products Directive

My personal view… is that this is huge progress on where we were in February – not just in terms of text, but particularly in terms of real awareness and support for e-cigarettes amongst legislators, and recognition that . Many allies in the Parliament – I'm thinking of Chris Davies, Rebecca Taylor and Martin Callanan have done a great job in pressing this case having listened to their constituents.

However, I do not think this amendment is a great credit to the European Parliament overall. It is mainly good by virtue of not being terrible. It is the sort of policy-making that emerges when *everyone is involved but no-one is responsible* – and Ries's note reflects that. And that, I'm afraid, rather well describes the European Parliament and the EU more broadly. It takes enormous efforts to penetrate the insular world of the Brussels hive with its lobbyists and interest groups, and even more to reach its monstrous outpost in Strasbourg.

What next? If this passes on 8 October, it's not over… there has to be reconciliation with the Council. This is done through a process called 'trilogue' (the third party being the Commission), which aims to find consensus between Parliament and Council in time for new amendments to be presented at the Council first reading (likely 10 December).. Some member states who don't support medicines regulation and have been hectored into it by others may feel emboldened and break cover and new interesting politics might yet emerge. On October 9th, campaigning focus switches to the member state governments. This could set in train a process of actually doing what governments should do – working out how to regulate these things properly. On the other hand, there may be a effort to add in further restrictions and to make the Parliament's alternative to medicines regulation unworkable. In that case, options will include moving to outright opposition to the directive with a view to stopping it and starting again with a new Commission, Parliament and Rapporteur, and of course legal action to protect the rights of people and economic actors harmed by capricious unlawful legislation.

Diary note: – on 8th October the debate starts and 09.00 and voting at 12.00, with a press conference at 14.00 – all Strasbourg time.