They just don't get it – Commission proposal for the regulation of e-cigarettes

written by Clive Bates | 25 November 2013

The special room in European Commission headquarters where new legislation is thought up

Late last week the European Commission circulated a **confidential new proposal for regulating e-cigarettes.** The document was sent only to those negotiating the future of e-cigarettes behind closed doors in Brussels – representatives of the European Parliament and European Council. This isn't a final proposal, but it provides the negotiators with something to discuss. The Nicotine Science and Policy website has obtained the document, and it is here (Update – all texts now here). *It is quite frankly appalling – lacking any legitimacy in public health or internal market policy-making…* Make no mistake, if implemented this proposal bans every product on the market today and would severely limit options for future products – and may make it commercially unviable to develop in future.

The main troubling features include:

- Allows only single-use cartridges. No refillable units or tanks will be permitted and so the most effective devices will be removed from the market.

- Allows only flavours already approved for use in NRT. Hands control to pharma companies and against the view of the Parliament that recognised the importance of flavours.
- Limits nicotine density to 20mg/ml maximum with no justification, cutting out the stronger liquids that appeal more to heavily addicted smokers and those just switching
- Limits nicotine content of any container to just 10mg/unit – this is extremely low and arbitrary (see new paper on lethal doses for nicotine) and makes no sense
- Allows only devices that "deliver nicotine doses consistently and uniformly" – a completely unnecessary, severe and limiting technical challenge derived from medicines regulation – *unlike with medicines, e-cigarette users control the dose*.
- Bans advertising in press or printed publications (except trade), on radio, TV and other audiovisual services and the internet (through "information society services") – this just protects incumbents (tobacco industry) and those who can rely on established distribution channels (tobacco industry)
- Bans e-cigarette sponsorships that have cross border impact (e.g. anything that might be shown on TV) – reduces competitiveness of disruptive technology
- Applies onerous and unnecessary warning, labelling and leaflet requirements that may be impractical and are disproportionate to risk deterring smokers who may wish to switch
- Bans *cross border* distance sales (internet etc) in clear contravention of the aims of the internal market
- Requires manufacturers to track so-called 'adverse effects' even though nicotine is widely used and understood
- Requires the submission of large quantities of seemingly irrelevant technical and commercial data despite recent high level commitments to reduce red tape
- Asserts (against the evidence) that e-cigarettes "simulate smoking behaviour and are increasingly used and marketed to young people and non-smokers" continuing the European tradition of smearing valuable harm-reduction option, notably snus, to the detriment of health in Europe.
- Update 2 Dec. A new version of this text (29 Nov) allows only electronic cigarettes "that cannot be operated or opened by children" – something

that does not actually apply to cigarettes and matches!
- Update 2 Dec. Its also requires toxicological data on ingredients *and emissions* – yet the emissions are highly dependent on the way the product is used.

Dr Farsalinos, an expert in the field, politely sums it up: *The European Union ignores science and common sense by making proposals that will damage the health of smokers and vapers*

Basically, the Commission has tried to smuggle in as much medicine-style regulation as possible, and then added the most restrictive commercial aspects of tobacco regulation on top – thus imposing the worst of both worlds for this most promising product. There are one or two acceptable things in the new draft, of course, but the very bad things listed above hugely outweigh them all. The total effect of this would be:

- to leave millions of smokers without an effective and reduced risk alternative to cigarettes;
- to close many businesses throughout the EU and beyond; and
- to greatly limit the potential for genuine harm reduction through alternatives to cigarettes in the future.

It's a proposal based on ignorance of how e-cigarettes work and why they are increasingly successful. If anything, it looks like a spiteful tantrum from Commission officials who didn't like having their really poor idea of mandatory regulation these products as medicines entirely rejected by the European Parliament in October – see 8 reasons why e-cigarettes should not be regulated as medicines Buzzfeed by Rebecca Taylor MEP (@RTaylor_MEP). When will they get it… regulation of harm reduction products involves a perilous 'double negative': *tough on harm-reduction is… easy on harm… and therefore …tough on health*.

How to respond…

There are two ways to try and challenge this (1) to explain how misguided the measures are; (2) to challenge the process by which this is being done. Both are important and related – the measures are so bad because the process is so close and unaccountable. Let's look at each in turn:

1. Explain how misguided these measures are

They can be criticised from four perspectives:

a) *From the consumer perspective*, these measures are completely unjustified blocks to products that millions of satisfied smokers like and find helpful as alternatives to smoking. They are likely to lead to rapid development of a black market that serves no-one's interests, and many former smokers will return to smoking tobacco products.

b) *From a business perspective*, these measures threaten legitimate businesses supplying a low risk alternative to smoking. They impose excessive burdens and restrictions, and restraint of commercial freedoms. They protect the tobacco industry from competition for its cigarettes, and help it to continue dominating the e-cigarette market with its own commoditised cig-alike products. They also protect the pharmaceutical industry from genuine competition for their own nicotine products.

c) *From a public health perspective*, these weaken a product that recognised by public health experts as being ~99% safer than smoking but needs to be able to compete through innovation, creativity and communication to attract smokers to switch. There is no evidence whatsoever that e-cigs are harming anyone, or attracting children and there is plenty of evidence that e-cigs are doing good. Remember, even use by young people can be regarded as positive when it diverts those who are already smoking tobacco [here].

d) *From a legal perspective*, these measures are disproportionate and cannot be justified as internal market measures designed to promote the free movement of goods. To achieve this, the restrictions would need to be based on securing a high level of health protection. However, these products do not cause ill-health: they relieve it. To introduce new legislation like this requires proper consultation, justification and impact assessment (see below) and none of this has been done.

2. Follow the rules for good policy-making

This new Commission proposal for Article 18 is in effect a new legislative proposal, or very substantial amendment to the existing Article 18. It has been

created in the last couple of months and is now embedded in the revision of the Tobacco Products Directive. This is not just an incremental change to an established proposal, but a completely new approach expanding the Commission's 271 word Article 18 proposal by five times, to 1,353 words. It has arisen because of the Parliament's rejection of medicines regulation, but it has not yet been subject to any of the disciplines of good policy-making required in the EU Treaties or by member states. It is a complete rewrite of the Commission's original proposal and goes far beyond it in many respects.

A new legislative proposal or significant amendment such as this should be put through the following four legislative steps:

A. Scrutiny by national parliaments.

The EU Protocol on the Application of the Principles of Subsidiarity and Proportionality makes clear that a new draft like this should be forwarded to national parliaments for comment, with 8 weeks for them to respond.

> ***Article 3****: For the purposes of this Protocol, 'draft legislative acts' shall mean proposals from the Commission, initiatives from a group of Member States, initiatives from the European Parliament […]*
>
> ***Article 4****: The Commission shall forward its draft legislative acts and its amended drafts to national Parliaments at the same time as to the Union legislator. The European Parliament shall forward its draft legislative acts and its amended drafts to national Parliaments. (underline added)*
>
> ***Article 6:*** *Any national Parliament or any chamber of a national Parliament may, within eight weeks from the date of transmission of a draft legislative act, in the official languages of the Union, send to the Presidents of the European Parliament, the Council and the Commission a reasoned opinion stating why it considers that the draft in question does not comply with the principle of subsidiarity. It will be for each national Parliament or each chamber of a national Parliament to consult, where appropriate, regional parliaments with legislative powers.*

B. Scrutiny by UK parliament.

It is clear from the guidance on scrutiny provided to the House of Lords requires

this proposal to go back to the UK parliament before the Council's first reading (see Companion to the Standing Orders and Guide to the Proceedings of the House of Lords Appendix L para 1 and 3(d))

> *(1) Subject to paragraph (5) below, no Minister of the Crown shall give agreement in the Council or the European Council in relation to any document subject to the scrutiny of the European Union Committee in accordance with its terms of reference, while the document remains subject to scrutiny. […]*
>
> *(3) Agreement in relation to a document means agreement whether or not a formal vote is taken, and includes in particular—[…]*
>
> *(d) in the case of a proposal on which the Council acts in accordance with [the ordinary legislative procedure], agreement to the Council's position at first reading, to its position at second reading, or to a joint text; (underline added – we are working towards Council first reading on 10 December)*

Cabinet office guidance confirms that amendments to draft legislative proposals should be subject to scrutiny in both Houses.

C. Consultation.

This is a significant measure affecting several million users and thousands of businesses across the EU. It is legislation that has life threatening potential if done wrongly, or great life saving potential if done right. Consultation with those affected, and with scientists, academics and public health experts is essential. It is not optional. Article 11.1-3 of the Treaty on European Union states:

> *1. The institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action.*
>
> *2. The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society.*
>
> *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.*

There has been no consultation on these proposals. This really should be done. There was not even any consultation on the Commission's proposal to regulate these products as medicines.

D. Justification and impact assessment.

The EU Protocol on the Application of the Principles of Subsidiarity and Proportionality is clear:

> *Article 5: Draft legislative acts shall be justified with regard to the principles of subsidiarity and proportionality.*
>
> *Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators. 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.*

The Commission has provided no detailed statement to justify these measures or to assess their impact.

What should be done?

The right way to approach this is obvious and simple. A new legislative proposal designed especially for e-cigarettes and other nicotine-containing products should be prepared. The proper processes of evidence gathering, options analysis, justification, impact assessment and, above all, consultation, should be allowed to proceed. This can start now, but will not complete until after the May 2014 European Parliament elections. Given there are absolutely no health problems associated with these products that require an urgent response (or any response) then it is essential to take time properly to set the regulatory framework for the next decade or more, especially given the damage these proposals will do if

allowed to pass into EU law as they stand.

It is highly unlikely that the trilogue process will produce proportionate, evidence-based legislation if its starting point is this flawed proposal that the Commission has now placed on the table. If that is the case, and these harmful proposals are agreed by the Council at its First Reading on 10 December, it will be necessary to press for a 'Delete Article 18' amendment when the draft directive returns to the European Parliament plenary in the New Year. Such an amendment would allow the rest of the TPD to pass into law, but allow e-cigarettes to go unregulated and force the issue to be taken seriously with a proper legislative proposal that follows due process.

What you can do...

You should urgently communicate your view on this to as many decisions makers as you can, in measured tones and as quickly as possible. These are the issues to raise (but you should use your own words and ideas and tell them how it will affect you directly)

1. Say what you don't like about the Commission's extensive and confidential proposals and especially how it will affect you personally or professionally. Define your own 'red lines' (things that shouldn't or should be done). Mine would be on refillables, flavours, advertising, nicotine strength and content.

2. Say what you think might be a better approach. I will be suggesting there are some quality standards for liquids and devices, some modest restrictions on advertising (like alcohol, for example), some tests and other information about the product to be disclosed, and application and enforcement of all the 17 directives that already exist and apply. Regulators should take a sensible proportionate approach and not wrap e-cigs in miles of red tape and restrictions.

3. Suggest that some regulation is probably necessary and may be beneficial if it increases consumer confidence, but that the Commission's ideas are overkill. New proposed EU regulation should be prepared with proper openness and transparency, a proper evidence base (no made-up or unfounded accusations), a credible justification, an impact assessment that shows risk benefits and unintended consequences of regulation and, above all, full consultation. It's about time that vapers were given a formal say, and not just ignored and

marginalised.

Who to contact… please be polite, concise and constructive!

1. Your MP [via www.writetothem.com]. Ask them to (1) contact Jane Ellison MP, Minister for Public Health to put your views across or (2) contact colleagues on the European Scrutiny Committee to demand that this is scrutinised properly.

2. Your MEPs [via www.writetothem.com]. Ask them to relay your concerns to those MEPs who are negotiating with the Council. These are:

- Matthias Groote (German S&D includes Labour) in the chair,
- Linda McAvan (British Labour / S&D)
- Karl Heinz Florenz (German EPP – the large centre-right grouping)
- Carl Schlyter (Swedish Green)
- Frédérique Ries (Belgian ALDE – group includes Lib Dems)
- Martin Callanan (ECR includes British Conservatives)
- Martina Anderson (Irish Nationalist)
- Giancarlo Scottà (Italian EFD right winger – his political group in EP includes UKIP)

3. Others to write to:

- UK Minister for Public Health, Jane Ellison MP [via here and @janeellisonmp]
- Secretary of State for Health, Rt Hon Jeremy Hunt MP [via here and @jeremy_hunt]
- Rt Hon Michael Fallon MP, Minister for Business and Enterprise here (only if you have a business interest)
- Presidency of the EU: Dr. Vytenis Andriukaitis, Minister of Health, Republic of Lithuania, Vilnius str. 33, LT-01506 Vilnius, Lithuania ministerija@sam.lt (please take care with this – no ranting!)