From: Clive Bates <clivedbates@gmail.com>
Sent: mardi 26 novembre 2013 09:19
To: DELETED

Subject: Commission proposal on TPD Art 18 on e-cigarettes

Dear Health Council working group

As you consider options for the regulation of e-cigarettes in advance of the next trilogue, perhaps you could consider the following.

The Commission's suggested text for a revised Article 18 on e-cigarettes has unsurprisingly reached the outside world and is attracting a lot of attention, all of it hostile. It shows the problems of negotiating significant new regulation in a closed process.

You can see my views on it here:
http://www.clivebates.com/?p=1655

There are two main issues to consider:

1. Substance. What is proposed would amount to a de facto ban with numerous perverse consequences for health. There are several disproportionate measures not justified in health or internal market terms. The proposal overlooks the 'double negative' problem in harm reduction: tough regulation of harm reduction is easy on harm and tough on health. By the same reasoning it is also easy on the competitors to e-cigarettes... cigarettes. A quick summary with some critical observations:

- Allows only single-use cartridges. No refillable units or tanks will be permitted and so the most effective devices that many former smokers ultimately migrate to will be removed from the market.
- Allows only flavours already approved for use in NRT. Hands control to pharmaceutical companies and goes against the view of users and 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.* This requirement is of course not placed on cigarette vendors.

- 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 and important disruptive technology with no single market justification
- Applies excessive 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.

2. Due process. This is now a new legislative proposal or at least substantial amendment - it is now five times the length of the original Commission proposal and Council General Approach and unrecognisable from both of these. The Protocol on Application of the Principles of Subsidiarity and Proportionality requires scrutiny by national parliaments, justification, impact assessment and consultation. Article 4 of the Protocol requires *amended drafts* to be submitted to national parliaments. National parliaments will expect to scrutinise what is clearly a novel and controversial proposal directly affecting millions of EU citizens.

The case for consultation is overwhelming. The regulation of e-cigarettes will affect the health of millions and the prospects of thousands of small businesses, it should be settled in an open process that includes users, public health experts and the SMEs involved. The requirement for consultation is also embedded in the Treaties and is in any case essential practice for good policymaking.

Whilst I hope that the trilogue process does produce workable, proportionate pro-health legislative proposals, this now looks unlikely. There is a clear danger that poor proposals and bad process will delay the whole process and possibly lose the TPD itself. It would be better to give this issue the attention it deserves. This would mean:
(1) to proceed rapidly to secure the revised TPD for tobacco products;
(2) emphasise the application and enforcement of the substantial body of existing law to e-cigarettes;
(3) and to develop a new purpose built and evidence-based proposal into a full legislative proposal with proper justification, impact analysis and consultation.

There is time to get it right, but the consequences of getting it wrong could lead to thousands of unnecessary deaths and damaged businesses.

I want to emphasise that there is *no material problem* arising from e-cigarettes at present, and much benefit - any risks are currently hypothetical and in the future, and likely to be minor if they emerge at all. There is no evidence of a gateway effect, significant use by non-smokers, or deliberate marketing to children - and it is wrong to base policy on the assertion that there is.

Disclosure: no competing interests.

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On 18 November 2013 18:03, Clive Bates <clivedbates@gmail.com> wrote:
Dear members of Health Council working group

I was forwarded a copy of the Lithuanian presidency's 'non-paper' on options for TPD Article 18 (on e-cigarettes / NCPs), which I am sure you will have seen. It is an excellent paper and a very worthwhile initiative by the presidency as it raises a number of important questions under its 13 headings. In order to contribute constructively to what is an otherwise quite opaque process, I have annotated the Presidency's non-paper with comments on the main questions raised.

In summary, I think the Parliament's amendment is a substantial improvement on medicine regulation (you can read about why medicines regulation would have been inappropriate here: http://www.clivebates.com/?p=1546).

With respect to the presidency's non-paper, these are the main points I wanted to draw out:

1. The case for applying tobacco advertising restrictions to e-cigarettes is counterproductive and will only aid incumbent tobacco manufacturers. Advertising restrictions should be left to member states for now, with the option to amend 2003/33/EC and 2010/13/EU at a later date if a real cross-border problem emerges.

2. The 30mg/ml nicotine limit should only be *increased.* These stronger liquids are important for the more heavily addicted smokers and for people making the initial transition from smoking to e-cigarettes.

3. The Parliament was right to emphasise the importance of flavours in its vote. These are integral to the product and to the proposition to smokers. Unless and until a problem emerges with flavours, and none has to date, there is no case for imposing restrictions in an internal market directive.

4. Warnings are larger and bolder than justified by the risks. When combined with other labelling requirements (e.g. for the CLP regulation) they occupy more space than would be proportionate.

There are many other points of detail and explanation included in the commentary. I hope you find this useful as you consider the best way to draw the TPD negotiations to a successful conclusion later this year. I would of course be happy to discuss this if you have questions or disagreements.

I apologise if I have any incorrect email addresses or an incomplete list for the working group. If you have colleagues who might be interested I would be grateful if you could pass this on.

Disclosure: no competing interests. I am an independent advocate for improved public health through harm reduction.

Yours sincerely

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