From: Clive Bates <clivedbates@gmail.com>
Sent: lundi 18 novembre 2013 19:03
To: DELETED

Subject: Presidency 'non-paper' on the TPD Art 18 on e-cigarettes - a commentary
Attachments: TPD - Article 18 LT Presidency - annotated FINAL.doc

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

Clive Bates
Counterfactual
+44 77 6879 1237
Twitter: Clive_Bates
Web: www.clivebates.com

Commentary on:

Presidency non-paper on nicotine containing products (Article 18)

This is a commentary on the Lithuanian Presidency's recently circulated 'non-paper' on regulation of nicotine containing products (NCPs) through Article 18 of the proposed revision of the Tobacco Products Directive. The paper was prepared to assist the Council in forming views in the trilogue process progressing through November and December 2013. It constructively raises questions about the appropriate approach to regulating e-cigarettes and related products. The paper is reproduced below, with comments provided in shaded boxes throughout the text:

My comments on the text are shown like this

The Presidency's paper is reproduced, with my comments, starting on the following page. I recognise that the document was for internal use within the Council, but the process of settling these important public health issues is unfortunately closed and opaque, and the usual function of a non-paper is to open up debate. This is intended as a constructive contribution to the trilogue deliberations.

Disclosure: I have no competing interests. My interest is in securing the best public health outcome in the design of the new Tobacco Products Directive.

16 November 2013
Clive Bates
Counterfactual Consulting and Advocacy
Former Director, Action on Smoking and Health (UK) 1997-2003
London, UK

Proposal for a Directive of the European Parliament and of the Council concerning the manufacture, presentation and sale of tobacco and related products

Presidency non-paper on nicotine containing products (Article 18)

THE EP AMENDMENT

The EP (amendment 170) proposes to treat nicotine-containing products (NCPs) as consumer goods subject to notification before their placing on the market according to Article 17 (the same notification as for 'novel tobacco products'). They shall comply with the requirements of the General Product Safety Directive 2001/95/EC. The maximum level of nicotine allowed in such products is 30 mg/ml.

Only NCPs presented as having properties for treatment or prevention of diseases shall be authorised according to the pharmaceutical legislation, i.e. Directive 2001/83 on the Community code relating to medicinal products for human use.

The EP does not want the additives set out in Article 6.4 of the Commission's proposal (i.e. vitamins, caffeine, taurine, additives having colouring properties) to be used, thus NCPs containing those additives shall be banned. On the other hand, the EP is expressly allowing the use of "flavourings" (including ingredients with characterising flavour) and they should be available on sale as tobacco products, meaning the EP is against limitation of their sale to pharmacies.

The EP suggests additional provisions for NCPs that are comparable to those available for tobacco products:

a) ban on cross-border distance sales of NCPs
b) health warnings;
c) reporting on ingredients and emissions by brand name and type;
d) limitations on advertising and sponsorship according to the Directive 2003/33 (ban on advertising in the press and printed publications, radio broadcasting and the sponsorship of events with cross-border character) and the prohibition of commercial communications

and product placement in television broadcast or on-demand audiovisual media service according to the Directive 2010/13/EU (Audiovisual Services Directive).

THE ISSUE AT STAKE

The **main objective of the Parliament** seems to be that the **NCPs are available on the market** in the same way as tobacco products. It is expected that the EP will show limited flexibility on this issue.

The European Parliament did recognise that it would be anomalous to place restrictions on availability of NCP relative to tobacco products (for example, restricting them de facto to pharmacy sales only), but it had other concerns too:

(1) The EP Legal Affairs committee found it to be unlawful on proportionality and non-discrimination grounds – a view supported by decisions in member state courts.

(2) It would be hugely burdensome, costly and restrictive and destroy many small businesses, gifting the market to the tobacco industry.

(3) It would slow innovation and limit the harm reduction potential of these products. It would tend to protect the cigarette market.

(4) Creates a de facto ban on most products currently on the market and used successfully and without complaint by millions of citizens in the EU. The diversity of products would be greatly reduced.

(5) Its restrictiveness would promote illicit markets and increase home mixing

(6) The Parliament recognised that flavours are integral to the viability and success of these products as alternatives to smoking

So the **question that arises** is whether Member States could agree to a solution that would not make the NCPs subject to pharma. legislation, provided adequate safeguards are added for these products.

In order to assess this question it is important to reflect about the underlying reasons for subjecting NCPs above a certain nicotine threshold to the pharmaceutical legislation.

Ultimately the issue is whether the underlying concerns could be adequately addressed in a legislative framework, which applies to NCPs regulated as consumer products.

In this respect it is important to recall that already the General Approach foresaw the possibility that nicotine-containing products below a certain nicotine threshold are subjected to consumer products legislation. Their placing on the market was allowed subject to two conditions (beyond the existing regulatory framework): a text warning and ingredients reporting.

POINTS TO BE CONSIDERED

There are several issues to be considered. The attached list – whilst already quite long - is not meant to be comprehensive and Member States are invited to comment and share their own considerations:

The list of issues and questions raised in the non-paper is very helpful. However, there are some technically complex areas– for example on setting technical standards and applying a GMP standard – that should be subject to careful design, impact assessment and consultation (a requirement under Treaty of the European Union Article 11.1-3). Article 18 in a revised TPD could provide a framework with detailed implementation coming later, or through a more thorough consultative exercise with a new legislative proposal from the Commission.

All of the questions in this paper are important and require answers, but raising them may create the impression that a medicines regime would have been easier. This is not the case. Under a medicines regulation regime the same decisions (and more) would need to be taken, but would have been left to individual member state regulators, operating under an ill-fitting regime, who may have taken differing and arbitrary decisions. The issues raised are not purely implementing matters, and it is important that they are subject to political and policy scrutiny by the Council and Parliament, not just devolved to regulators. For that reason, the Presidency's non-paper is a welcome contribution to determining the appropriate regulatory framework for NCPs.

1. ***Product scope***

Would there be a need to limit the product scope to "e-cigarettes" only or should all NCPs be covered by the new rules (knowing that some NCPs are currently authorised according to pharma. legislation in some Member States)? It would seem that the main concern of the EP is on "e-cigarettes".

The Parliament's amendment allows for products to be authorised as medicines if they make a claim compatible with the medicines directive 2001/83/EC (i.e. For treating or preventing disease). The TPD should cover the existing types of products and could provide a framework for *all other NCPs*. It will be hard to anticipate all future innovations, so do this it will need to be capable of adaptation to allow for unforeseen developments.

2. *Safety and quality*

Would there be a need for additional safety and quality requirements beyond those in the General Product Safety Directive 2001/95/EC?

Much can be achieved by properly applying and enforcing the directives that already apply, including the GPSD, but also several others in relation to labelling and packaging, electrical safety, weights and measures, and fair commercial practices. Before proceeding with further regulation it is necessary to determine what risks these directives do not address. There may be a case for giving precise, specific, and harmonised meaning to the general obligations to make products that are safe under the GPSD. However, some care should be taken – the experience of measuring and displaying 'yields' for cigarettes proved misleading for several generations and is only now being (partially) addressed. It is important to avoid hasty but arbitrary standard setting. The TPD should establish the mechanism by which such standards can be developed, rather than attempt to develop them by December. The starting point should be recognition that these products have vastly lower risks than the products that they displace. There is no need for hasty 'emergency' regulation to address an unfolding crisis, because there is no crisis.

Are different rules needed for the nicotine containing cartridges and the devices through which the nicotine is "vaped/inhaled"?

No – the focus should be on the liquid or other nicotine source. There are too many device and liquid combinations for this to be possible.

Is there a need for a CE standard or for subjecting NCPs to good manufacturing practices?

This is potentially very costly and disruptive if the GMP is set at a pharmaceutical standard, which is unnecessary for these products and would destroy much of the established supply chain. The proposal should be subject to impact assessment and consultation with the affected industries – with an attempt to assess how this will impact on existing supply chains and if it will create a counter-productive barrier to entry that would leave only tobacco companies and existing pharmaceutical companies able to comply. The pharmaceutical GMP standards are unnecessarily exacting, and exist to ensure consistent dosing of potent pharmaceuticals. That is unnecessary for these NCPs. Some clarity on options for different forms of GMP should be investigated (eg. a variation on ISO22716) and may be adaptable to NCPs.

Is there a need to clarify that the ultimate responsibility for product safety lies with the manufacturer?

The EU-based manufacturers, importers and distributors should all have responsibilities. The Cosmetics Regulation (1223/2009) provides a reasonable model for allocating responsibility to various actors in the supply chain.

Is there a need for safety alerts beyond the existing RAPEX system? Is there a need to ensure consistent dosing?

The RAPEX system is sufficient and is already functioning well for these products. A pharmaceutical surveillance notification regime is unnecessary. It is primarily designed to capture *adverse reactions to the active drug* – for example, the cardiovascular and neuropsychiatric events associated with Varenicline, the licensed smoking cessation drug. This sort of adverse reaction is not an issue for nicotine, which is now widely used and understood.

There is no need or case for a regulator to ensure consistent dosing, this will be a matter for competition, user preferences and willingness to pay. For medicines consistent dosing is essential, but not for NCPs. It still important that marketing any claims and labelling are valid – but there are existing directives that cover this. It is not the job of a regulator to define what makes a 'good product', that is a matter for the functioning of consumers and producers in the internal market. Nor is it up to the regulator to regulate 'efficacy' unless an 'effect' is claimed. The regulatory responsibility is to ensure safety and fair commercial practices.

With inhaled nicotine products, the user always controls 'dosing' (so-called nicotine self-titration) and adjusts their use of the device to gain the nicotine dose and 'hit' that they want. The idea that nicotine products provide a 'dose' underpinned the practice of measuring yields for cigarettes, and lead to harmful misunderstandings about 'light' cigarettes – some of which are addressed in the revised TPD (by not printing yields on packs).

3. *Maximum nicotine content*

What would be an appropriate limit of nicotine content for NCPs? The EP is proposing 30 mg/ml.

It is not clear why this quantity should be limited at all, at least within the ranges available on the market today. The 'nicotine density' (specified as 30 mg/ml by the Parliament) is an inappropriate quantity to use for regulating NCPs. It would be better to focus on product standards as discussed above. This threshold could have several counterproductive effects:

(1) it works against NCPs that are attractive to the most heavily addicted smokers who use the stronger liquids

(2) smokers who are just making the switch often start on the stronger liquids to recreate the effect of smoking and then reduce the strength over time as they learn to

use the products and/or they start to reduce dependence. It is likely that the strongest liquids are important 'bridging' products for smokers.

(3) it works against innovation that might assist in development of more compact products;

(4) it would encourage DIY, illicit and unregulated markets in stronger liquids to develop with greater risks than would be avoided by setting this limit;

Any hazards associated with high nicotine concentrations are addressed by application of CLP regulation (1272/2008) on classification, labelling and packaging. It is far more important to set standards for quality/purity – i.e. thresholds for contaminants.

If there is concern about lethal exposure to nicotine through ingestion or skin contact, then officials should be aware of the latest work in this area, suggesting the widely quoted adult lethal dose of 60mg nicotine is based on no substantial science and is too low by a factor of 10-20 times. (see Bernd Mayer, University Graz, Austria, *How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century* Archives of Toxicology 10.1007/s00204-013-1127-0, October 2013).

However, if Parliament and Council agree there must be a threshold for nicotine density, *it should be increased to 50mg/ml* to allow for perfectly good products now on the market that do not pose additional risk to health and are likely to produce significant health benefits through competition with cigarettes. These products should not be subject to arbitrary and discriminatory regulation and policy should not invite legal challenge.

Is there a need to act against refillable cartridges that allow the blending by consumers?

There is no need to act against refillable cartridges. In fact this is an important part of the 'vaping' experience for many users. Most refillable cartridges are used for adding purchased liquids rather than blending by consumers, so these are two distinct issues. Home blending is difficult to prevent and used because it can offer costs savings and options to tailor the experience more precisely to needs. The main way of containing the use of home blending, and any resultant risks, is to have a highly diverse and lightly regulated market that makes it unnecessary because a wide variety of affordable products is available to buy.

4. Use of ingredients with characterising flavours

The EP excludes certain ingredients, but proposes to allow any flavour, including those which could be attractive to children and non-smokers.

What should be the appropriate regulation regarding ingredients in general and flavourings in specific ?

The Parliament is absolutely right to protect flavours for e-cigarettes. Flavours are integral to e-cigarettes and all products use them. Even tobacco flavours are artificial and added. Banning flavours would make the products unusable and would be a de facto ban on the products themselves. In fact, there is a very positive health role played by flavours – it is the non-tobacco flavours that help smokers 'denormalise' their own smoking. Many graduate from smoking to tobacco-flavoured e-cigs and then, as their sense of taste returns, they go on to develop a taste for non-tobacco flavours like vanilla or apple. Flavours also add to the appeal by allowing for greater personalisation. Flavours are integral to the 'harm reduction' concept as they help smokers to switch. Flavours could be limited to those approved for use in food, plus tobacco flavours.

Flavours and children: It is wrong to assume that sweet flavours will somehow attract teenagers. Young people are mostly seeking to try an adult experience rather than reinforce their childish characteristics. It is impossible, and not necessary, to design a regime that differentiates between flavours that appeal to children and to adults.

It would be wrong to assume that any sign of use by teenagers is an adverse population effect. It depends on what they would have done otherwise (they may have smoked) and what they do next (they may use e-cigs to stop smoking).

5. *Reporting on ingredients and emissions*

The EP is proposing reporting on ingredients, which is similar to that introduced by the Council for "below threshold NCPs"). Is there a need to oblige companies to provide marketing studies and sales volumes?

There should be no requirement to report commercial data. Regulators should only ask for information that will be used in making regulatory decisions. One of the UK 'Hampton Principles' for better regulation is "*Businesses should not have to give unnecessary information, nor give the same piece of information twice*". Unless there is a plausible use for this data in making regulatory decisions then it should not be collected via regulators. There is, however, a good case for governments understanding what is happening in the market for tobacco products, NCPs and smoking cessation medications. This should be commissioned from independent researchers and based on market wide sampling (as with the UK smoking cessation toolkit survey) but enhanced with appropriately worded questions for NCPs recognising that the product is not seen as a smoking cessation treatment by most of its users.

6. *Labelling*

Is the health warning (and accompanying leaflet) proposed by the EP appropriate?

In the Presidency's assessment the EP proposal for the health warning is even stronger than the Council's text given the fact that the nicotine content would be higher.

The EP health warning text ("highly addictive") is excessive: e-cigs are less addictive than cigarettes and that differentiation is important. The warning should be a useful communication of *relative risk* for potential users. Regulators should be providing health messages that promote informed choice for smokers, and encourage switching by contrasting the risks with smoking. It should not be frightening them back to smoking. The size and boldness of the health warning proposed by the Parliament is disproportionate to risk and too reminiscent of the warnings on cigarette products, and therefore implicitly overstating the risks. There are also a number of practical problems associated with very small containers and additional text that needs to be added to cover CLP regulations etc.

The question remains whether the limitations on presentation of tobacco products in Article 12 should apply also to NCPs if they would be widely available on the market?

These limitations in Article 12 should not apply – this article is there to avoid misleading implied claims. There are sufficient protections in general consumer protection in 2005/95/EC (unfair commercial practices) and 99/44/EC (sales of consumer goods etc).

Is there a need to list on the package of the NCP the ingredients and nicotine level, considering that for tobacco products the TNCO levels will no longer be presented?

The labelling requirement should only include what the consumer needs to know to make an informed choice: nicotine strength, flavourings, excipient and any other ingredients. Nicotine strength is covered by the CLP regulations, so some care is needed to avoid duplicating labelling requirements. The comparison with TNCO yields is not relevant. There is no need to provide data on inhalation or nicotine delivery as this will be under the control of the user and would be as misleading as it is for TNCO yields.

7. *Packaging*

Shall any requirements/limitations on packaging of NCPs apply similar to those applicable to cigarette packs (prescribed shape or size)?

These products have to be appealing to smokers to encourage switching, and unless

there is a health rationale for limits to packaging there is no basis for limiting innovation in this area. The controls on packaging (Article 13 in TPD) are unnecessary and quite specific to tobacco packaging, and justified by the risks arising from tobacco products. The 'CLP Regulation' (1272/2008) on classification, labelling and packaging of substances and mixtures is the important regulatory control on packaging of NCPs. This adds specific protections beyond the GPSD for containers of potentially hazardous liquids. No other controls are necessary or justified in an internal market measure.

8. Notification vs. pre-marketing authorisation

Should the notification applicable to the 'novel tobacco products' in Article 17 apply also to NCPs or would there be a need for pre-marketing authorisation?

NCPs should be allowed on the market subject to a notification regime only. It makes no sense for it to be harder to place a non-tobacco NCP on the market than a novel tobacco product (or indeed a new cigarette). An authorisation regime would be a barrier to innovation and growth of this important alternative to smoking, and unless harmonised it would create a barrier to free movement of goods in the internal market. The contrast between Article 17 and 18 was a significant anomaly in the Council general approach and Commission proposal. So the Parliament's proposal to more closely align the procedures for novel tobacco products and non-tobacco NCPs is reasonable and should be supported. Authorisation procedures require clear criteria on what would qualify and it is difficult to see on what basis an NCP would be withheld from the market while cigarettes can be placed on the market subject to a few simple tests for yields and no authorisation regime.

9. Product on the market

Is there a need for a special or at least transitional regime for products currently on the market?

The proposed 36-month lead in should remove the need for a special transitional regime. However, some progress could be made faster than that. It would be possible, for example, to specify now that nicotine and any excipients used must be of pharmaceutical grade and any non-tobacco flavouring ingredients used must at least be permitted as food flavourings under permitted under regulation 872/2012 – this might be regarded as meeting the general safety obligation of the GPSD. The interim regime does not require new provisions but should focus on ensuring compliance with and enforcement of the various directives that already apply, covering general safety, electrical safety, packaging & labelling, weights and measures, commercial practices and data protection.

10. Need for a safeguard clause

Is there a need for a safeguard clause allowing Member States to restrict the placing on the market of NCPs if it turns out they develop into an entry gate for new nicotine addiction or even smoking or if the products fail to demonstrate their potential as cessation product ?

This makes little sense when cigarettes can remain freely available. Furthermore, regulating for population effects, such as so-called gateway effects, is problematic because it is impossible to know what would have happened without the presence of NCP. The EU has already made a significant blunder in misunderstanding the population effects of snus, which were defined as a problem in 1992, but have turned out to be highly beneficial. If a survey shows young people using e-cigarettes, is that bad, or is it good because perhaps they would have smoked otherwise? This beneficial effect has been seen in Sweden through snus use as an alternative to smoking. This would also open the way to arbitrary difference in practice between member states and work against internal market objectives.

If a safeguard clause is introduced it should also apply to possible unintended consequences of regulation and the right to lift counter-productive restrictions.

11. Advertising

Do Member States agree with the EP that NCPs which are not subjected to pharmaceutical legislation have to comply with the same restrictions on advertising and promotion as tobacco products?

The advertising restrictions are excessive and not justified on health or internal market grounds. The application of 2003/33/EC and 2010/13/EU to NCPs is disproportionate and vulnerable to legal challenge. It will tend to protect incumbents (tobacco industry) and those with established distribution channels (tobacco industry). These restrictions are justified for (combustible) tobacco only because these products are harmful, whereas as NCPs are two orders of magnitude less risky. Furthermore, they provide a *major net health benefit* when smokers switch. From an internal market perspective, NCPs will be relatively new brands that aim to gain market share from established incumbent tobacco brands. It makes no sense legally, for public health or for the internal market to apply any broad prohibitions to NCP advertising.

The ECJ annulment of the original tobacco advertising directive 98/43/EC showed regulation of advertising is primarily a member state competence. Some controls may be appropriate at member state level, but these should not attempt to limit advertising to health messages. These restrictions could be defined by member states in much the same way that controls on alcohol advertising are implemented (in the UK as Code of Practice).

The EU should retain the option to develop EU-wide regulation of cross-border

advertising that could be introduced later, but not implemented at this stage.

Can Member States agree to the EP proposal that addresses the risk of brand stretching (identical brand names for tobacco products and NCPs)?

Is there a need to prohibit celebrity endorsement?

The existing restrictions on tobacco brand-stretching provide all the necessary controls.

Celebrity endorsement is desirable in promoting switching and should not be banned. There should be a general responsibility on responsible persons not to direct marketing to young people.

12. Need for internal market coordination

What would be an appropriate mechanism to ensure that diverging decisions on specific NCPs are avoided/limited to the extent possible?

There may be a case for a technical working group that will informally co-ordinate member state activity, but the directive should provide a clear basis for harmonisation where there is EU competence. Conflicts are likely to be reduced if there is a light touch framework of proportionate standards, responsibilities and a generally permissive and encouraging approach to these products.

13. Practicalities

Is there a need to regulate the powers of regulators (e.g. inspections). Is there a need/possibility to introduce a fee based system?

The funding regime and policing of the directive is primarily a matter for member states in implementing legislation. The Commission has a general responsibility to supervise implementation of directives, to ensure consistency and to guard against arbitrary barriers to trade arising through different implementation in the member states.

In addition the Presidency will request the view of the Council's Legal Service whether the EP proposals on sales arrangements (minimum age and sales outside pharmacies) are compatible with the legal basis of the TPD (Art. 114 TFEU).
