To: Mr William Cash MP, Committee Chairman
CC: House of Commons European Scrutiny Committee
Via: Committee Clerk
From: Clive Bates
Date: 27 November 2013

Dear Mr Cash, Committee members

Re: Tobacco Products Directive – Article 18 (electronic cigarettes)

I would like to draw your attention to a significant development in the negotiation of the revised Tobacco Products Directive. I know the Committee has taken a keen interest in this to date. I would like to suggest that further scrutiny is now justified, given the very substantial changes made to the proposal since the Committee last examined it.

On 8 October, the European Parliament rejected the Commission's proposal to regulate e-cigarettes as medicines. With minor modification, the Commission proposal also formed the basis of the Council's General Approach, on which your committee examined the former minister Anna Soubry MP on 17 July.

The Commission has now produced a completely new informal proposal based on a very substantial amendment made by the European Parliament at its first reading on 8 October but with many additional provisions and restrictions. The new 'suggested text' is now five times the length of the Commission's original, and takes a completely different approach. Instead of classifying and regulating e-cigarettes as medicines, it establishes detailed regulation within the Tobacco Products Directive itself, much of which would be counterproductive for health and disproportionate in my view.

This new proposal for Article 18 of the directive could easily stand as a new legislative proposal for a complete stand-alone directive, yet it is being negotiated behind closed doors through the trilogue process, in a rush to reach agreement. This proposal has not been subject to scrutiny in national parliaments and has not been open to consultation with those businesses, consumers and public health professional affected by it. There is no supporting evidence-based documentation to justify the proposal and no impact assessment to examine its consequences or whether it is compatible with principles of proportionality, non-discrimination, subsidiarity and its internal market legal base.

I believe there are two scrutiny issues to consider:

1. Given this important aspect of the proposal is radically different to the Council's General Approach, should the Commons and Lords European scrutiny committees examine this again before the government takes a position at the Council's first reading, which is most likely in December? The Cabinet Office guidance and Lords procedural guidance suggests that they should.

2. Given the significant amendment, should the European legislature have circulated amended text to national parliaments for scrutiny and with the option to provide further reasoned opinions on the new proposal. The EU's Protocol on the Application of the Principles of Subsidiarity and Proportionality suggests that they should.

I have added an appendix on these that I hope the Committee finds useful.

Leaving aside procedural requirements, I do believe that negotiating major changes through a closed trilogue process is about the worst way to make policy and legislation. A proposal that will affect, positively or negatively, the health of millions of users and the prospects of thousands of businesses large and small is being negotiated behind closed doors and without meeting any of the requirements of EU legislation: evidence-based justification, impact assessment and, above all, consultation with those affected: consumers, businesses, and experts in public health.

I believe the most pragmatic approach now is the following:
(1) Bring the tobacco parts of the TPD to a rapid and satisfactory agreement – there should be no problem with this.
(2) On an interim basis, regulate e-cigarettes by applying and enforcing the substantial body of safety and consumer protection legislation that already exists and press the industry to reach higher standards.
(3) Take the European Parliament's proposed amendment and develop this into a new legislative proposal, with evidence-based justification, impact assessment and consultation to develop a workable and proportionate regulatory framework that is compatible with the internal market legal base.

I would like to stress that there is no material problem that demands an urgent regulatory response on e-cigarettes at this time. There is no sign of any gateway effects, no sign of deliberate marketing to children, no sign of anyone being harmed. In fact the experience so far is very positive. There is therefore time to design the regulation of these important and disruptive products in a way that maximizes public health. That will happen only if the process is open and transparent.

Yours sincerely

Clive Bates
Appendix 1: Basis for suggested further scrutiny
Appendix 2: Commission proposal (19 December 2012)
Appendix 3: Council General Approach (21 June 2013)
Appendix 4: European Parliament Amendment 170 (8 October 2013)
Appendix 5: Commission 'suggested text' in trilogue process (~22 November 2013)

Disclosure: I have no competing interests. I was previously Director of Action on Smoking and Health and a civil servant. The views stated here are not necessarily those of previous employers.

Appendix 1: Basis for suggested further scrutiny

Does the UK position prior to Council first reading justify further scrutiny?

In the body of my letter to the Chairman, I stated the following:

1. Given this important aspect of the proposal is radically different to the Council's General Approach, should the Commons and Lords European scrutiny committees examine this again before the government takes a position at the Council's first reading, which is most likely in December? The Cabinet Office guidance and Lords procedural guidance suggests that they should.

House of Commons Standing Order 143 gives the Committee a broad purpose to consider legislative documents or 'related matters'.

> c) to consider any issue arising upon any such document or group of documents, or related matters.
> The expression 'European Union document' […] means
> (i) any proposal under the Community Treaties for legislation by the Council or the Council acting jointly with the European Parliament;
> http://www.publications.parliament.uk/pa/cm200809/cmstords/2/body.htm#BABBAAHFA

Cabinet Office guidance on European scrutiny shows that scrutiny is not limited to formal texts and that scrutiny of substantial modifications should be expected. The guidance states at para 1.15:

> 1.15 However, where a proposal is subsequently modified in the course of Council discussion, for example under the ordinary legislative procedure (OLP) procedure (previously codecision), further EMs may be submitted, even if no new text can be deposited, in the light of which the scrutiny reserve resolutions apply again and the Scrutiny Committees may re-open their consideration of the proposal
> http://europeanmemoranda.cabinetoffice.gov.uk/files/content/parliamentary-scrutiny-overview-1306.pdf

The Lords guidance embodies the same approach – see Companion to the Standing Orders and Guide to the Proceedings of the House of Lords in Annex L p 258.
http://www.publications.parliament.uk/pa/ld/ldcomp/compso2010/compso.pdf

Does the amended draft legislative act need to be sent to national parliaments?

In the body of my letter to the Chairman, I stated the following:

2. Given the significant amendment, should the European legislature have circulated amended text to national parliaments for scrutiny and with the option to provide further reasoned opinions on the new proposal. The EU's Protocol on the Application of the Principles of Subsidiarity and Proportionality suggests that they should.

This Protocol is an important text in the governance of the EU legislative process and it requires amended texts to be sent to national parliaments.

> **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.
> http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0201:0328:EN:PDF

I doubt the intention is to require resubmission to national parliaments of every changed word, but in this case the amendment is substantial, amounting to a new legislative proposal. It is common sense too – if national Parliaments should scrutinise original proposals of the EU institutions, they would logically scrutinise any fundamental changes.

The Protocol also establishes due process to facilitate scrutiny – including evidence-based justification and impact assessment, neither of which has been produced:

> **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.

… and requires legislative proposals to be subject consultation.

> **Article 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.

There had in fact been no consultation on the Article 18 proposal to regulate e-cigarettes as medicines, let alone the new detailed regulatory proposals.

Appendix 2: Article 18 Commission Proposal (19 December 2012)

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:
(a) products with a nicotine level exceeding 2 mg per unit, or
(b) products with a nicotine concentration exceeding 4 mg per ml or
(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.

3. each unit packet and any outside packaging of nicotine containing products below the thresholds set out in paragraph 1 shall carry the following health warning:
"This product contains nicotine and can damage your health".

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:
(a) be printed on the two largest surfaces of the unit packet and any outside packaging;
(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

[**note**: almost all e-cigarettes would be covered by paragraph 1 alone]

Appendix 3: Article 18 Council General Approach (21 June 2013)

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:
(a) products with a nicotine level equal to or exceeding 1 mg per unit, or
(b) products with a nicotine concentration equal to or exceeding 2 mg per ml

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 where this is necessary based on scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

> This product contains nicotine which is an addictive substance and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 8(4). In addition, it shall:
(a) be printed on the two largest surfaces of the unit packet and any outside packaging;
(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That size shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the wording of the health warning in paragraphs 3 based on scientific and market developments.

5a. The provisions of paragraphs (3) to (5) of this article shall be without prejudice to the application of Directive 2001/83/EC.

6. Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months]

Appendix 4: European Parliament Amendment 170 to Article 18 at first reading (8 October 2013)

1. Nicotine-containing products may only be placed on the market in accordance with the notification procedure set out in Article 17 of this Directive.

Member States shall ensure that nicotine-containing products comply with all relevant Union legislation, and in particular with Directive 2001/95/EC on general product safety.

2. Nicotine-containing products that are presented as having properties for treating or preventing disease may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

3. As regards nicotine-containing products to be placed on the market in accordance with paragraph 1, Member States shall ensure that:
(a) nicotine-containing products with a nicotine level exceeding 30 mg/ml are not placed on the market;
(b) manufacturers and importers of nicotine-containing products submit to the competent authorities a list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof, as well as any changes. Member States shall then ensure the dissemination of this information on a website with due regard to the protection of trade secrets. Manufacturers and importers shall also report to the authorities about national sales volumes by brand name and type;
(c) nicotine-containing products with additives listed in Article 6(4) are not placed on the market;
(d) the unit packet of nicotine-containing products includes a leaflet with instructions for use, including that the reference that the product is not recommended for use by non-smokers, contra-indications, warnings for specific risk groups, reporting of adverse reactions, place of manufacture and contact details of the manufacturer or importer;
(e) each unit packet and any outside packaging of nicotine-containing products carry the following health warning:

> "This product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance";

(f) the sale of the product is restricted in line with the legal age for sale of tobacco products in the relevant Member State; in any case it should not be allowed under the

age of 18;
(g) the products are available to be sold outside pharmacies;
(h) flavourings are allowed in the products;
(i) the limitations on advertising, sponsorship, audiovisual commercial communication and product placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC shall apply to nicotine-containing products;
(j) cross-border distance sales of nicotine-containing products are regulated in accordance with Article 16;
(k) tobacco trademarks, brand names and symbols are not used on nicotine-containing products.

4. The health warning referred to in paragraph 3(e) shall comply with the requirements specified in Article 10.

5. Member States shall monitor the development of the nicotine-containing products market, including any evidence of gateway use among young people and report their findings to the Commission. Based on the evidence submitted as well as scientific studies the Commission shall submit a report to the European Parliament and the Council on nicotine-containing products five years after entry into force of this Directive. The report shall assess if amendments to this Directive or any further legislation are necessary.

Appendix 5: Commission 'suggested text' for Article 18 from trilogue process (~22 November 2013)

Note: not including amended recitals

[Scope]
1. Electronic cigarettes are a tobacco related product. They can be placed on the market as a tobacco related product if they comply with the relevant provisions of this Directive and all other relevant Union legislation.
Electronic cigarettes can be classified as medicinal product by presentation pursuant to first subparagraph 2a of Art. 1(2) of Directive 2001/83/EC if they are presented as having properties for treating or preventing disease in human beings. They cannot be classified as a medicinal product by function pursuant to the second subparagraph 2b of Article 1(2) of Directive 2001/83/EC.

[Notification]
2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A new notification shall be submitted for each substantial modification of the product.
The notification shall include at least the following information:
a. name and contact details of the manufacturer and, if applicable, the importer into the EU;
b. list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof;
c. toxicological data available to the manufacturer or importer regarding these ingredients;
d. information on nicotine dosing when used under reasonable and foreseeable conditions; and
e. description of the components of the electronic cigarette.
Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

[Safety and quality]
3. Member States shall require manufacturers and importers of electronic cigarettes to

bear full responsibility for the quality and safety of electronic cigarettes placed on the market when used under reasonable and foreseeable conditions.
Member States shall require that manufacturers and importers of electronic cigarettes to establish and comply at least with the following manufacturing requirements:
a) design and manufacture in accordance with the safety requirement set out in this article;
b) procedures in place for series production to remain in conformity with the safety requirement;
c) a safety assessment prior to placing on the market, with information on the composition of the product, microbiological quality, impurities and traces, toxicological profiles, and adverse effects;
d) a legal or natural contact person within the European Union.
Member States shall require manufacturers and importers of electronic cigarettes to ensure that electronic cigarettes deliver the nicotine doses uniformly and consistently.
Member States shall ensure that electronic cigarettes with refillable cartridges or tanks are not placed on the market. Only single use cartridges can be placed on the market.

[Restrictions/limitations and information to consumers]
4. Member States shall require manufacturers and importers to ensure that:
a) Electronic cigarettes do not contain nicotine in excess of 20 mg/ml and 10 mg/unit;
b) Electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market;
c) Only flavours which are authorized for use in nicotine replacement therapies can be used in electronic cigarettes, unless such a flavour is particularly attractive to young people and non-smokers;
d) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes;
e) Unit packets of electronic cigarettes include a leaflet with information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, and contact details of the manufacturer or importer;
f) Unit packets and any outside packaging of electronic cigarettes:
i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose;
ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content;

iii. do not use tobacco trademarks, brand names and symbols;
iv. carry the following health warning:
"This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers."
g) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

5. Member States shall ensure that:
a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;
b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of Directive 98/34/EC;
c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio;
d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited;
e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;
f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes;
g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.

[Reporting and monitoring obligation]
6. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.

7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.
Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

8. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If an operator considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operators shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operators, for example on safety and quality aspects or any adverse effects.

[Re delegated acts]
9. The Commission shall also be empowered to adopt delegated acts to adapt the wording of the health warning in paragraph 4 (f) iv.
The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2.

Amendments to other articles
Article 2
[definition of Electronic cigarettes]
Electronic cigarette means a product, or any components thereof including cartridges and the device without cartridge, that can be used for consumption of nicotine containing vapour via a mouth piece.

Article 20

[on cooperation of competent authorities]
The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.

Article 21a new
[on designation of competent authorities and change title into "Committee procedure and competent authorities"]

Member States shall designate the competent authorities within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the identity of the competent authorities responsible for enforcement of obligations provided for in this Directive. The Commission shall publish that information in the Official Journal of the European Communities.

Article 23
[to add in paragraph 2]
market developments in electronic cigarettes considering, inter alia, information received under Article 18;