From: Ch arles Hamshaw-Thomas [Charles@e-lites.co.uk]
Sent: 14 June 2013 13:53
To: FLORENZ Karl-Heinz; RIES Frédérique; CALLANAN Martin; SCHLYTER Carl; ROSSI Oreste; ANDERSON Martina; GROOTE Matthias
Cc: MCAVAN Linda; ROMANO Emilia
Subject: electronic cigarettes and Article 18 of Draft Tobacco Products Directive: compromise amendment proposal - maximising public health benefits and tobacco harm reduction
Attachments: Art 18 TPD Compromise Amendment Proposal - Maximising Public Health Benefits and Tobacco Harm Reduction.pdf

Dear Karl-Heinz, Frederique, Carl, Martin, Oreste, Martina and Matthias

As you are aware the e-cigarette industry, e-cigarette consumers and public health advocates, who believe in harm reduction as a solution to the public health impact of tobacco, agree Article 18 as proposed by the Commission would eliminate small and medium sized enterprises from the category (and correspondingly discourage innovation), make e-cigarettes less available (to the benefit of large pharmaceutical companies) and less affordable for consumers and ultimately seriously reduce consumer uptake (to the benefit of large tobacco companies and pharmaceutical companies) ….. and be to the detriment of wider public health.

We recognise a number of amendments have been tabled and have sought, based on the principles outlined in our earlier communication, to identify a workable solution. Based as closely as possible on Amendment no.1250 tabled by Linda McAvan, please find attached a draft proposal which we're confident can maximise public health benefits and tobacco harm reduction, which has been presented to Linda's office today.

Please do let me know if you have any questions on the draft and/or if there's further information you'd like.

With thanks and kind regards
Charlie

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From: Charles Hamshaw-Thomas
Sent: 29 May 2013 18:45
To: linda.mcavan@europarl.europa.eu
Cc: karl-heinz.florenz@europarl.europa.eu; frederique.ries@europarl.europa.eu; carl.schlyter@europarl.europa.eu; 'martin.callanan@europarl.europa.eu'; oreste.rossi@europarl.europa.eu; martina.anderson@europarl.europa.eu; matthias.groote@europarl.europa.eu; ROMANO Emilia
Subject: electronic cigarettes and Article 18 of Draft Tobacco Products Directive

Dear Linda

While we welcome the recognition that Article 18 as tabled by the Commission requires substantial amendment, your proposed *'simplified procedure'* for the regulation of e-cigarettes will:

- **make it harder to sell e-cigarettes than cigarettes**
- **make e-cigarettes far less attractive to consumers than cigarettes and stifle continuing product innovation** and
- **hamper, rather than enhance, the European single market in terms of harmonisation of rules for the functioning of the internal market**

With e-cigarette sales already displacing +2.5 billion cigarette sales in the EU annually, these are detrimental outcomes for public health across the EU.

Please note, as per my earlier email of 6 May, we remain committed to working collaboratively with you – using the three principles re-stated below - to agree how e-cigarettes are regulated for the benefit of smokers and wider public health across the EU.

With thanks and kind regards

Charlie

1. *Electronic cigarettes shall not carry any claims that they are a smoking cessation aid unless they have authorisation to do so under the relevant legislation*

2. *All electronic cigarette products must comply with all relevant national and EU legislation, rules & regulations relating to product quality and safety; electronic cigarette products that do not make medicinal claims are not medicinal products and they are not tobacco products, so we acknowledge the need for harmonised regulation of the quality and safety of electronic cigarettes that allows them to compete with cigarettes across the EU and would like the Commission to review that need and propose further specific and proportionate legislation*

3. *All electronic cigarette products shall carry an appropriate health message and the sale of electronic cigarettes shall be restricted to adults and/or those over the legal age for smoking*

These principles are shared by a very large number of e-cig suppliers, a number of the different e-cig trade associations and a collection of senior public health experts - all of whom would support amendments to the EU Tobacco Products Directive guided by these principles.

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Article 18 Compromise Amendment Proposal - Maximising Public Health Benefits and Tobacco Harm Reduction

Introduction

This proposal is an attempt to find common ground for an proportionate approach to regulation of e-cigarettes or nicotine containing products (NCPs). The aim is to ensure the products are safe, properly labelled and packaged, accurately described and marketed fairly, but without imposing disproportionate burdens, costs and restrictions that would make it less likely that smokers will switch and so protect the cigarette category from competition from much less harmful products.

The points below set out what the amendment aims to achieve. It is based as closely as possible on the amendment (1250) proposed by the ENVI rapporteur, Linda McAvan MEP, and EPP shadow rapporteur, Karl Heinz Florenz.

1. NCPs where a health claim is made would be subject to regulation under the medicines directive;
2. A 'simplified procedure' would apply for all other NCPs;
3. The simplified procedure requires each manufacturer or importer to submit an 'independently audited compliance report'. This has some similarities with the regulatory approach taken to cosmetics in Regulation 1223/2009, which requires each product to undergo a safety assessment, creation of a product information file and notification of a competent authority.
4. The audited compliance report would provide evidence that:
    a. they meet all applicable safety, packaging and labelling, consumer protection and marketing legislation;
    b. full disclosure of product detail, with safeguards for commercial confidentiality;
    c. they have a complaint handling and risk management regime.

    This goes considerably beyond what is required of consumer product vendors, as it requires them to provide proactive evidence of compliance.
5. The simplified procedure also requires warnings and appropriate information are placed on the packaging, and that members states address other aspects of the regulation of e-cigarettes;
6. Products would be removed from the market if:
    a. Regulators considered there was evidence from the compliance reporting that the products did not comply with the general safety requirement of other law
    b. The compliance reports were not produced or were incomplete;
    c. The products did not meet the requirements laid down for warnings etc
7. After five years, a Commission review, informed by scientific advice, of the working of the directive would take place to examine its effectiveness and propose amendments if necessary;
8. A suitable lead in time would be needed for compliance reporting, but not as long as envisaged for an authorisation process. This could give faster results and produce results sooner while the industry is still in a rapid growth phase.

The proposed amendment

Article 18 a (new, replacing COM Article 18 Proposal)

Text proposed by McCavan / Florenz – amendment 1250	*Amendment*
Article 18 a	**Article 18a**
Nicotine-containing products	**Nicotine-containing products**
	1. (a) 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.
	(b) This Directive shall not apply to nicotine containing products authorised pursuant to paragraph 1a.

Justification

Establishes that any health claims made for NCPs must be made subject to medicines regulation – the language 'treating and preventing disease' is from the definition of a medicine in 2001/83/EC, so this is legally watertight. Where a product is medicinally licenced, then this Directive does not apply to avoid overlaps.

1. Nicotine-containing products may only be placed on the market if they ***are authorised pursuant to***:	***(c)*** Nicotine containing products ***which are not authorised pursuant to paragraph 1a*** may be placed on the market if they ***comply with applicable European Union safety and consumer protection legislation and with*** the ***simplified*** procedure as set out in paragraphs 2 and 3
(a) Directive 2001/83/EC, or	
(b) The ***simplified*** procedure as set out in paragraph 2 and 3.	

Justification

All other NCPs are to be regulated under this directive – thus providing clarity and proper approximation of laws. It asserts the applicability of directives and regulations covering: general product safety; electrical safety; classification labelling & packaging of hazardous preparations; weights and measures; fair commercial practices; and data protection – and the use of the simplified procedure to show that they are compliant.

Simplified **procedure**	***Simplified*** **procedure**
2. Under the ***simplified*** procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit ***an application for a marketing authorisation,*** which shall contain the following:	2. Under the ***simplified*** procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit ***an independently audited compliance report,*** which shall contain the following:

Justification

This places a requirement on the manufacturers and importers to demonstrate they meet legislation in force. This is a non-trivial undertaking involving an audit and detailed assessment of products and processes.

a) Evidence that the product ***is manufactured in accordance with the principles and guidelines of Good Manufacturing Practice;***	a) Evidence that the product ***meets the general safety requirement and other applicable legislation in force;***

Justification

This establishes a broader obligation to demonstrate safety and consumer protection compliance that goes beyond the narrow specification of the manufacturing process.

From Commission web site*: A safe product is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable in view of maintaining a high level of protection for the health and safety of persons. A product is deemed safe once it conforms to the safety provisions provided in European legislation, or, in the absence of such rules, if it complies with the specific national regulations of the Member State in which it is being marketed or sold. [more]*

Applicable legislation includes directives covering general safety, electrical safety, labelling and packaging of hazardous preparations, weight and measures, fair marketing practices, on-line marketing and data protection. These could also be listed in an annex and member states required to report on implementation and enforcement.

b) A detailed description of the product in question, including all ingredients and quantities thereof, ***as well as information on emissions;***	b) A detailed description of the product in question, including all ingredients and quantities thereof, ***with appropriate protection for proprietary information***

Justification

The requirement for measuring emissions is impractical given the different designs of e-cigarettes and NCPs and the absence of standardised 'smoking' regimes. An emissions testing regime could be developed in future. Some safeguards are needed to protect manufacturers' proprietary information, recipes etc so this disclosure will need commercial confidentiality protection

c) A Risk-Management Plan, including a system for monitoring and recording any adverse reactions;	c) A Risk-Management Plan, including a system for ***reporting*** and recording ***faulty or unsafe products***, any adverse reactions ***or other complaints***;

Problems will only come to light if there is a system for reporting, and the system should cover a broader range of concerns

Member States shall be entitled to charge a fee for ***processing the application***. They	Member States shall be entitled to charge a fee for ***assessing compliance reports***.

may also require manufacturers or importers to ***carry out additional tests or*** submit additional information. Each Member State shall take due account of ***authorisations previously granted by*** another Member State.	***Where necessary to establish compliance with paragraph 1,*** they may also require manufacturers or importers to submit additional information. Member State shall take due account of ***compliance reports submitted in another*** Member State.

Justification

This allows member states to demand certain standards of evidence, but limits it to establishing compliance with the regulation in force – ie. demonstrating they meet existing standards. Manufacturers would be responsible for compiling reports.

3. For products ***authorised*** under the ***simplified*** procedure, Member States shall ensure that the following conditions are fulfilled:	3. For products ***compliant*** under ***paragraph 1(c) and*** the ***compliance*** procedure, Member States shall ensure that the following conditions are fulfilled:
a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;	a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;
b) each unit packet and any outside packaging shall carry the following health warning:	b) each unit packet and any outside packaging shall carry the following health warning:
This product is intended for use by existing smokers ***aged 18 or over*** as an alternative to tobacco cigarettes. It contains nicotine which is ***a highly*** addictive substance. ***Consult your doctor if you are pregnant, breast feeding, allergic to nicotine or propylene glycol, or have high blood pressure.***	This product is intended for use by existing ***adult*** smokers as an alternative to tobacco cigarettes. It contains nicotine, which is ***an*** addictive substance.

Justification

Provides appropriate warnings. These may need further refinement, and technical committee to amend or specify in more detail. Note that 3c below reflects the different ages are specified in member states, so rather than specify 'aged 18 or over' this uses 'adult'. Note that other warnings may be required under other directives or regulations (eg. CLP regulation) – for example the presence of allergens, nuts residues etc. E-cigarettes are less addictive than cigarettes, and no addictiveness warning is included in the Commission's proposal. The addiction warning for smokeless tobacco just uses 'addictive'. The warning should avoid giving partial medical advice and needs to leave space for other mandatory warnings arising from packaging and labelling legislation.

c) flavourings shall not be allowed;	***Deleted***

Justification

NCPs without flavourings would not be viable – all use some sort of flavouring, and a ban on flavourings would be a de fact ban on e-cigarettes. Flavourings are important in making e-cigarettes appeal to smokers and persuading them to switch and in retaining smokers as NCP users rather than relapsing. If there were concerns about certain flavours having harmful effects they could be considered under safety legislation or as part of the review proposed in paragraph 4 when more information was available. Options for later review include: restriction to a positive list; prohibition of a negative list; prohibition of a category of flavours (eg. confectionary); prohibition of flavours aimed a target group (like young people. But some care is needed – users can always mix their own liquids using whatever flavours they choose, so banning commercial flavoured products may simply stimulate mixing, which has risks too.

d) the sale of the product shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;	***c)*** the sale of the product shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;
e) the products shall be available ***to be sold outside pharmacies***;	***d)*** the products shall be available ***for general sale, subject to paragraph c***
f) advertising and promotion shall be appropriately regulated;	***e)*** advertising and promotion shall be appropriately regulated

Justification

Clarifies scope and ensures that e-cigs are not competitively disadvantaged relative to cigarettes. There is no case for restricting e-cigarette sales to pharmacies or any other class only. Available for general sale is consistent with internal market principle of free movement of goods, with the only qualification (para c) related to age.

	[new] 3a. Nicotine containing products that do not comply with paragraph 1, 2 and 3 may not be placed on the market.

Justification

This gives the directive some force. It requires manufacturers and importers to meet existing law, and to prove that they do, and to prove it in a way that satisfies the authorities. If the authorities believe they are non-compliant based on the information received, then they should remove the products from the market using the powers in the existing directives. It also means that vendors that do not provide audited compliance reports of an acceptable standard (ie. like the ISE) would have their products removed from the market. However, the default is the products are allowed onto the market until a case against them is made. An authorisation process bars them from the market until a case for them is made.

4. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence, the	4. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence ***and***

Commission shall report back to the European Parliament and the Council 5 years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary.	***independent scientific advice***, the Commission shall report back to the European Parliament and the Council 5 years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary.

Justification

This requires the Commission to assess development take appropriate scientific advice (for example from SCENIHR) and return with amendments if necessary. These could include broader applicability of medicines regulation; a bespoke regulatory framework for NCPs (as has been devised for cosmetics); specific standards for e-liquids or e-cigarettes; or no change.