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From: Bureau CACE [bureau.du.cace@gmail.com] Sent: Wed 9/4/2013 4:16 PM

To:

Cc:

Subject: TPD electronic cigarette - Collectif des acteurs de la cigarette électronique

Attachments:

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Dear President,

In the context of the current debate on regulating the use of electronic cigarettes under the TPD Directive, I wish to alert you, in my capacity as Chairman of the CACE (Collectif des acteurs de la cigarette électronique), about the public health and economic prejudices that would be caused by the adoption of its status as a medicinal product on a European scale.

A public health issue:

1/ The electronic cigarette is a viable alternative to tobacco for smokers. The e-cigarette is not a tobacco weaning product but it responds to the needs of millions of smokers wishing to reduce the risks linked to the use of traditional cigarettes while retaining the pleasure and feel of the smoking experience.

2/ The electronic cigarette is considerably less harmful than the traditional cigarette. The vapour released contains up to 400 to 1 000 times less toxic substances than the smoke from a tobacco cigarette. The e-cigarette contains no carbon monoxide which, when absorbed – even from secondhand smoke – promotes lung cancer and cardiovascular diseases. It causes no second- hand smoke emission.

The real potential of the electronic cigarette as an ultimate replacement of the traditional cigarette relies on several criteria:

- Retention of the feel and behaviour;
- Presence of aromas;
- Existence of various nicotine levels enabling the vaper (e-cigarette user) to modulate the intake

of nicotine and reduce it down to zero, unlike the traditional cigarette delivering a constant nicotine content;

- Freedom of consumer use;
- Access to the product.

Consequently:

The electronic cigarette should not be classified as a medicinal product

· No scientific study has proven that the e-cigarette is a medicinal product (no evidence of curative or preventive properties) and to date nicotine is not regarded as a medicinal product as such,

· The electronic cigarette cannot be regarded as a tobacco weaning product due to the retention of the smoking behaviour and presence of nicotine,

· Classifying the electronic cigarette as a medicinal product would disqualify it as a smoking replacement product: its access would become more restricted due to the monopoly of pharmacists; and the pleasure aspect would be reduced due to the elimination of aromas.

The electronic cigarette must not be classified as a tobacco product

· The lower harmfulness of the e-cigarette justifies that it should not be stigmatised as a tobacco product,

· Tobacconists should not sell this product as they are unable to inform and advise consumers about it (time spent with the customers, staff at hand …)

· Tobacconists expose e-cigarette users to traditional tobacco cigarettes and other additive products.

In this context, we propose to contribute to the establishment of a regulation that would take into consideration the reality of the sector and its challenges for the benefit of consumers.

CACE proposes to create a specific regulation on the electronic cigarette that will guarantee quality products and comprehensive information to consumers regarding the consequences of nicotine consumption.

We are in favour of a minimum regulation on the EU scale.

· Applicable laws in EU Member States are very different.

· Harmonisation would be discriminatory for the French economic players in view of French laws applicable to the monopoly of pharmacists and tobacconists.

· Nicotine-containing products claiming to have curative properties should solely be regulated under the Medicinal Products Directive.

· For all other nicotine-containing products, it would be advisable to:

- Guarantee the ban of triglyceride,

- Clearly label the product with: nicotine content, user's notice, side effects and detailed information about the manufacturer,

- Label the product with the following legal mention: "This product is intended for users of legal age to smoke as a tobacco replacement product. It contains nicotine, a highly addictive substance. Consult your physician if you are pregnant or nursing, if you are allergic to nicotine, to propylene glycol, or if you have high blood pressure. "

- Regulate advertising on e-cigarette products: ban advertising targeted to minors, ban any advertising claiming any prestige in the use of e-cigarettes,

- Require studies on the electronic cigarette for the purpose of securing reliable scientific data on the product.

Our proposals to regulate the sector on a national scale, and subsequently on the EU level:

Implement a standardisation of e-liquids related to common protocols for importing, creating, assembling (chemical tests), filling and labelling, applicable to all players in order to enhance monitoring controls.

Professionalize the distribution channels:

• The e-cigarette is a sensitive product requiring comprehensive information to consumers and the seller's ability to advise consumers. Accordingly, the CACE has created a training centre

dedicated to the sale of e-cigarettes. Its purpose is to combine within a single dedicated learning structure the corpus of knowledge indispensable to fully inform and advise the consumers and therefore professionalize the electronic cigarette retail sector.

• Our proposal is to make such training mandatory in France and ultimately at the EU level, and to authorize the distribution of electronic cigarettes only in specialized stores or via channels authorized under a license granted by the national government.

An economic challenge

In France alone, the CACE represents 46 members (manufacturers, assemblers, retailers), with nearly 125 specialized shops and 12,800 sales outlets, together accounting for more than 2000 jobs and 1.5 million consumers.

The adoption of a medicinal product status would be a fatal blow to this emerging business.

I wish to thank you in advance for your attention to this letter, in view of the urgency of the situation.

Best regards,

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