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EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Substances of human origin and Tobacco control

Dear Mr Gill,

Subject: Request to stop or change Tobacco legislation

Thank you for your submission to the Commission dated 30 March 2014 on the regulation of electronic cigarettes and the Code of Good Administrative Behaviour. As responsible head of unit, I have been asked to reply to you.

Please note that the rules agreed on electronic cigarettes in the revised Tobacco Products Directive (TPD) were a joint decision by the European Parliament and Council. The Commission's role in the trilogue process was to facilitate the negotiations between the co-legislators, but it welcomed the compromises reached, which put an emphasis on the safety and quality of consumer electronic cigarettes to be placed on the EU market.

Regarding the setting of a maximum nicotine concentration level of 20mg/ml, please note that despite differing views on the associated risks, there is consensus that nicotine is not a harmless substance: it is classified as a toxic substance under existing EU law[1]. It is also a highly addictive substance, with which young people and non-smokers may start experimenting, as a number of recent studies/surveys have confirmed.

Furthermore, the concentration limit was widely considered by the co-legislators to be a sufficient dose to satisfy the nicotine requirement of those wishing to give up smoking. It is not expected that this will lead to the consumption of significantly more electronic cigarette liquid.

In light of the above, the co-legislators considered it appropriate to set the maximum nicotine concentration limit in the revised TPD.

Regarding other ingredients of electronic cigarettes, several provisions have been included to ensure maximum safety and quality standards apply. These concern an obligation on manufacturers to submit information and toxicological data on all ingredients, to ensure that ingredients are of high purity and do not pose a risk to human health. Continuous monitoring and reporting are also ensured.

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[1] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

It should also be pointed out that although consumer electronic cigarettes may not be sold at nicotine concentrations above 20 mg/ml, this does not preclude products authorised as pharmaceuticals from being sold with higher nicotine concentrations.

In the light of the above, we believe that the Commission adhered to its obligations and respected the principles of good administration and respect for human rights.

Best regards,

Dominik Schnichels
Head of Unit