EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate D
D4 – Substances of Human Origin and Tobacco Control

Brussels, 17 July 2012

MINUTES OF THE MEETING
BETWEEN THE COMMISSION AND SNOKE GMBH & CO. KG
ON 6 JULY 2012

Participants: Dominik Schnichels, Anna-Eva Ampélas and Isabel Holmquist (DG SANCO)

Prof. Dr. Dr. med. Jürgen Ruhlmann and Benjamin Ruhlmann (SNOKE GmbH & Co. KG)

The main objective of the meeting was to listen to the views/concerns of the electronic cigarette company SNOKE in the context of the on-going revision of the Tobacco Products Directive (TPD) and to clarify some factual questions in relation to the e-cigarette market.

SNOKE and the e-cigarette market

The SNOKE e-cigarette invented by Prof. Dr. Dr. med. Jürgen Ruhlmann is manufactured in Germany according to high quality standards corresponding to those applied for pharmaceuticals. The product was invented to provide smokers with a tobacco free alternative to cigarettes, in particularly considering the difficulty for many smokers to quit smoking. The e-cigarettes currently sold by SNOKE are marketed as leisure products. The SNOKE e-cigarettes are available without nicotine in different flavours. With nicotine (3% or 1.5%) there are actually only tobacco and menthol flavours available.

The German market is estimated to 2 million users of e-cigarettes and further increase of the market is expected, although the market was negatively affected by the recent statement of the German Health Minister of Nordrhein Westfalen that these products are medicinal products and are therefore not allowed on the market unless authorised as such. In a preliminary injunction case the competent Court of Appeal for administrative matters (OVG Münster) declared this statement unlawful (court order dated 23/04/2012 with the file number 13 B 127/12) and concluded that e-cigarettes are not to be considered medicinal products. The main proceedings on the issue are still pending.

E-cigarette Consumers

E-cigarettes are mainly used by established smokers and are sold online and in outlets also selling tobacco products. According to SNOKE, it is important to place the e-cigarettes close to the tobacco products in order to offer smokers a safer alternative. The product is

not presented as a smoking cessation product as it would then fall under the pharmaceutical legislation, but is offered to smokers who wish to reduce their cigarette consumption. SNOKE believes that young people should be prevented from taking up cigarette and e-cigarette use and would support an initiative by public authorities to introduce an age restriction. In any case, SNOKE considers that their products are not attractive for this age range. In SNOKE's estimation, if non-smokers of any age were to try e-cigarettes, they would use a non-nicotine alternative, as they are not addicted to nicotine.

E-cigarettes authorised under the pharmaceutical legislation (not yet available) should be sold in pharmacies.[1] These products should offer a step-wise reduction in nicotine consumption and be sold with a pharmaceutical leaflet.

Health, safety and efficacy

According to its producers, the SNOKE e-cigarette is one of few e-cigarettes available on the EU market which complies with high safety and quality standards. It is also the only product offering its consumer product insurance quality certifications for the hardware and the liquids. Most of the other e-cigarettes sold in the EU are imported from third countries (mainly China) and are lacking in quality. The content of many of these e-cigarettes does not correspond to the information given on the labelling and toxic substances have been found in some products. SNOKE considers that handling of nicotine by the consumer (refill bottles, adding of flavours etc.) involves a health risk and should be avoided. The SNOKE e-cigarettes contain a closed nicotine capsule to avoid direct consumer contact.

According to SNOKE, the lung function improves by 30% for a smoker replacing traditional cigarettes with high quality e-cigarettes after a short time. This physiological function is directly linked to the smoking cessation (body is no longer exposed to harmful products) and not to the use of e-cigarettes as such.

For a smoker, 2-3 puffs on an e-cigarette (or a traditional cigarette) are sufficient to satisfy the nicotine receptors in the body. The e-cigarette nicotine level required depends on the smoker, but lies in the range of 1.5% (corresponding to a "light" tobacco cigarette with 3% nicotine) and 3% nicotine (corresponding to a „standard“ tobacco cigarette with 6% nicotine). There is no need to increase the nicotine level above this. The indicated level corresponds to 3%-6% nicotine in traditional cigarettes ("light"/“standard“). The lower nicotine level in e-cigarettes compared to traditional cigarettes is explained by the different level of inhalation (90% of the nicotine in e-cigarettes is inhaled compared to 50% in traditional cigarettes). A further reduction of the nicotine level in e-cigarettes would be counterproductive, because it would reduce the effect of being a tobacco free alternative for established smokers.

Regulation of e-cigarettes

According to SNOKE, a strict regulation for e-cigarettes is needed, in particular as regards the hardware and the content. Nicotine should be added to the products subject to the same rules as for pharmaceuticals. SNOKE is of the opinion that e-cigarettes marketed as

[1] DG SANCO remark: This is national competence and some Member States allow non prescription medicines to be sold also outside pharmacies.

leisure products do not fit under the pharmaceutical legislation or under the tobacco legislation. Regardless of their classification, the manufacturing of e-cigarettes should be organized with high standards, for example GMP (Good Manufacturing Practice, 2003/94/EG, 1991/412/EWG).