EUROPEAN COMMISSION

Brussels, 17th January 2013

MEETING WITH THE TOBACCO VAPOR ELECTRONIC CIGARETTE ASSOCIATION (TVECA)

Participants:
TVECA: Dac Sprengel, Holger Schwemer, Ray Story, Catherine Longeval, Reshad Forbes
SANCO: Dominik Schnichels, Anna-Eva Ampelas, Marcus Klamert, Matus Ferech

Date: 17 January 2013

Summary

SANCO gave a brief summary of the revision of the Tobacco Products Directive and how it regulates nicotine containing products (NCP). SANCO stated the wish to hear stakeholders, as it has also done in the past, in a fully transparent manner.

TVECA expressed its satisfaction that SANCO welcomes input from stakeholders, even though the proposal is now "out of its hands". It expressed concern that the proposal were biased towards the pharmaceuticals industry, and that the thresholds foreseen in the proposal for NCP would de facto eliminate electronic cigarettes from the market (99% of electronic cigarettes currently sold on the EU market would contain nicotine exceeding the threshold). On the first point, SANCO stressed allegations of an undue policy influence by the pharmaceutical sector are not founded.

TVECA made a power point presentation, claiming to represent all existing vendors' associations including in Italy, France, Greece, Germany and the Netherlands, but stating that it would no longer represent ECITA (UK). TVECA wished to distinguish itself from ECITA by its not for profit nature, and by accepting the need to regulate electronic cigarettes, in view of the current divergent regulatory treatment in the Member States.

TVECA claimed that the proposal would fail to differentiate between Nicotine Replacement Therapies (NRT) for smoking cessation on the one hand and electronic cigarettes on the other hand. Whereas NRTs would be presented as smoking cessation products, and regulated as medicinal products, electronic cigarettes were not or no longer marketed as smoking cessation aids or tobacco replacement in most countries. Manufacturers of electronic cigarettes want to compete with traditional cigarettes rather than with NRTs and they would only target current smokers.

TVECA mentioned that electronic cigarettes without nicotine was of little interest for consumers (current smokers) and that the market share of such products would only

amount to around 5-6% of the total electronic cigarette market in the EU, and even less in the US. It was also stressed that the maximum amount of nicotine in electronic cigarettes were only half the amount in traditional "light" cigarettes. TVECA stated that it would not and could not claim that electronic cigarettes are a healthy/healthier alternative to cigarettes, but that they were a less harmful product. For this reason, electronic cigarettes could and should not be subject to the requirement of authorisation as medicinal products. Upon inquiry by SANCO, TVECA also confirmed that it would not have objections to the health warnings required under the proposed Directive for NCP below certain thresholds.

TVECA noted that nicotine does not have a distinct taste and that for this reason flavours would have to be added to the products. TVECA stressed that nicotine contained in electronic cigarettes would have a scientifically proven low addictive potential compared to tobacco cigarettes.

TVECA argued that electronic cigarettes have been the focus of over 20 studies, including an FDA study, that they would not contain a single chemical or toxin at any levels harmful to humans, and that they would cause no third party harm. SANCO stressed the addictiveness of nicotine and the toxicity in high quantities. SANCO – without taking position in substance - also wondered whether the statement is correct. Moreover SANCO mentioned that some Member States have already prohibited the use of electronic cigarettes as part of their smoke-free environments legislation.

TVECA presented its analysis why the proposal for the revision of the Tobacco Products Directive would violate EU law on different grounds. In this context, TVECA stated that electronic cigarettes do not fit under the definition of medicinal products and could therefore never be authorised and placed on the market as such. TVECA pointed to the fact that in the US a lawsuit was brought successfully against the FDA to prevent it from regulating electronic cigarettes as a drug delivery device requiring pre-authorisation. Also a judgment in the Netherlands would confirm that electronic cigarettes are not to be considered as medicines.

TVECA made suggestions for amendments to the proposal. As a preferred option, TVECA suggested regulating electronic cigarettes as tobacco products, while exempting them from the ban of characterising flavours, but not from the labelling (health warnings) requirements and other provisions of the Directive. SANCO stated that it would carefully study the considerations presented by TVECA, expressing reservations however about whether TVECA had really fully considered the implications of submitting electronic cigarettes to the regime foreseen for tobacco products under the proposed Directive. As an alternative option, TVECA suggested a distinction between electronic cigarettes and other nicotine containing products in the proposal, allowing electronic cigarettes containing no more than 3.6% nicotine to be placed on the market subject to labelling and packaging requirements.