EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Substances of human origin and Tobacco control

Brussels, 25 November 2013

MINUTES OF THE MEETING

Participants: Dominik Schnichels, Ingrida Pucinskaite-Kubik, Patricia Murray, Isabel Holmquist and Chiara Bortoluzzi (DG SANCO)

Catherine Longeval (Van Bael & Bellis representing TVECA), Renato F. Addis (EPPA representing TVECA) and Peter Beckett (ECITA)

Date: 22 November 2013

The main objective of the meeting was to listen to the views/concerns of the electronic cigarette industry regarding the Article 18 of the Tobacco Products Directive under revision.

The Commission representatives underlined that they would be in listening mode, given the current phase of the legislative process (trilogue negotiations).

Regulatory framework

TVECA and ECITA stated that the electronic cigarette industry advocates the creation of an appropriate regulatory scheme for electronic cigarettes. However, TVECA was of the opinion that the pharmaceutical products' regime proposed by the Commission would not be an appropriate approach taking into account that electronic cigarettes would be subject to stricter regulation than conventional cigarettes. They also mentioned a series of national court cases which had ruled against the qualification of electronic cigarettes as pharmaceutical products.

TVECA and ECITA supported amendment 170 of the European Parliament to the extent that it subjects electronic cigarettes to consumer products legislation but suggested that there could be improvements, *inter alia* to the quality and safety requirements. TVECA and ECITA handed over their position paper with accompanying annex on quality, safety and purity outlining such improvements. They explained that in their view the vote in the Parliament was not just the "result" of industry lobbying but the success of a "social movement" of those who want to have free access to electronic cigarettes and were concerned that pharmaceutical requirements would make the product almost unavailable on the market. They warned of the

potential risk of an illicit market if electronic cigarettes would be regulated as pharmaceuticals.

Safety and quality

The associations indicated that there are still quality and safety issues with some products, and that not all producers of electronic cigarettes were 'responsible' manufacturers. They, therefore, presented a proposal for a strengthening of the Parliament amendment 170 which would require the manufacture of electronic cigarette liquids to produce according to good manufacturing practices and European Pharmacopeia. They also proposed that Member States should test notified products to ensure that they were compliant with the provisions of Article 18. They also advocated that 'clean room' production standards be verified through inspections. The industry mentioned that there are a large number of EU regulations that already today apply to electronic cigarettes, including rules on general product safety, labelling of nicotine, and standards for electronic devices.

The Commission asked how the associations view the risk of electronic cigarettes with home-blending, in particular in relation to health risks (e.g. contamination and intoxication), in light of their new requirements for GMP. ECITA indicated that the market share of "home blending", *i.e.*, consumers mixing their own solutions and flavours in their own homes, is limited (less than 5% of the market) and that it is impossible to control what people do in their own home. ECITA also pointed out that acting against refillable units would lead to more home blending of liquids and an unregulated black market. The Commission wondered how refillable units could be reconciled with the call for 'clean room' production standards. The associations stated that there was also always a risk of contamination once medicines were opened and TVECA gave the example of a medicine in powder form which is removed from its capsule and mixed with babyfood. Anyway users want to blend, which should be considered in the legislation in order to increase the switch ratio from conventional smoking to vaping.

Flavours, risk of gateway effect, advertising and health warnings

The Commission asked about the flavours used in electronic cigarettes. The associations estimated that roughly 50% of the products on the market have a tobacco flavour, with the remaining products using a great variety of other flavours. They promised to provide additional information on flavours, including menthol, and any information on user preferences for certain flavour types. The industry underlined that the proposal should make electronic cigarettes attractive to as many existing smokers as possible, and in this light the availability of wide-range of flavours was essential.

The Commission asked whether electronic cigarettes could have the potential to develop into an entry gate to nicotine addiction (if not into smoking). ECITA stated that there was no scientifically sound evidence of a gateway effect into smoking. TVECA stated that the only study mentioned in the Commission's Impact Assessment Report, *i.e.*, a study conducted in Poland, indeed found that about one in five young people in a sample group had tested

electronic cigarettes, but they argued the impact assessment failed to mention that the study says that *"most of them had previously smoked cigarettes"*. According to the associations, this study does not substantiate the "gateway-argument". TVECA also considered that the potential risk of young people taking up electronic cigarettes could be prevented through age restrictions (including age verification mechanisms) and appropriate health warnings highlighting that electronic cigarettes are only aimed at adult smokers.

On advertising for electronic cigarettes TVECA argued that it should not be limited, as electronic cigarettes have the potential to make people switch from smoking to using a less harmful alternative. The same reasoning should also apply to cross-border sales, which should be allowed.

The associations raised concerns about the size of the health warnings, which were not clearly specified in the Parliament amendment. In particular, the current obligation to put the CLP logo (classification, labelling and packaging of substances and mixtures according to Regulation 1272/2008) on packages because of the presence of nicotine, combined with the aforementioned health warnings, would reduce even further the space for brands on e-cigarettes packages to the point where they were larger than for smoked tobacco. This was unacceptable to the associations.

Maximum nicotine content

According to the associations, a large majority of electronic cigarettes have a nicotine concentration below 30 mg/ml (the most common strength in the UK is 18 mg/ml). They argued that concentrations below 30 mg/ml would not be sufficient to meet the nicotine cravings of heavy smokers. They were not aware of any studies substantiating this claim, but would provide further evidence on this point. The right maximum level should be 36 mg/ml and 50 mg/ml according to TVECA and ECITA, respectively. ECITA stated that the most popular cartridges contain approximately 1 ml of nicotine solution.

Information for the Commission

ECITA agreed that they would provide the Commission with some studies and data on flavours currently used for electronic cigarettes, which flavours are more attractive for which age group, cartridge sizes, nicotine concentrations, and nicotine absorption. The associations reiterated their support for a strict but workable regulatory framework for electronic cigarettes and offered any help and support that might be useful for a successful conclusion of the trilogue negotiations.