From: [redacted] who [redacted]]
Sent: Wednesday, June 13, 2012 6:40 PM
To: [redacted] (SANCO)
Cc: NIKOGOSIAN, Haik; [redacted] SCHNICHELS Dominik (SANCO); [redacted] (SANCO); MAUNU Antti (SANCO)
Subject: COP5 Paper on Electronic Nicotine Delivery Systems

Dear [redacted],

Thank you for your comments on the paper on electronic nicotine delivery systems (ENDS).

As Haik has already noted in his note to you, we would like to include in the paper the following material from the NCP background section, and we would be grateful to receive citations for these statements as soon as possible for inclusion in the paper (for ease of reference, I have also highlighted them in yellow in your e-mail below):

(1) "The EU **electronic cigarette** market is growing rapidly and the total value has been estimated to 400-500 mEUR in 2011."

(2) "For example, in 2009, Niconovum AB was purchased by Reynolds American Inc and Kindconsumer has agreed a marketing and distribution agreement with Nicoventures Limited, a company within the British American Tobacco Group."

(3) "As for the demand side, the current use of NCP is growing quickly. 7% of EU citizens have reported in the latest Eurobarometer that they have at least tried electronic cigarettes. In the UK an increase in the number of electronic cigarette owners has been estimated from a small number in 2006 to over 1 million by 2013."

(4) "Electronic cigarettes are widely advertised on the internet. A study monitoring Google search queries from January 2008 to September 2012 reported that online interest in electronic cigarettes has surpassed that of oral tobacco (snus) and nicotine replacement therapies."

In addition, we have included the six points you have raised in the 'problem definition' section as a summary paragraph at the end of the paper – all of these issues are mentioned in the paper, but this paragraph will serve as a way to frame the issues prior to the COP's discussion of them. Since the COP requested a report based on the experience of the Parties, the Parties' responses to the questionnaire had to be the starting point for the paper, and this summary paragraph will bring together those points highlighted by Party experience as received in the responses to the questionnaires.

For our other comments, I have included them in green below at appropriate points in your original message.

Please let me know if you have any questions.

We look forward to receiving citations for the four points noted above (which we will rephrase to avoid duplicating your materials).

Best regards,

[redacted]

[redacted]
Convention Secretariat
WHO Framework Convention on Tobacco Control

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From: [redacted]ec.europa.eu [redacted]
Sent: Tuesday, June 12, 2012 03:19 PM
To: NIKOGOSIAN, Haik
Cc: Dominik.Schnichels@ec.europa.eu <Dominik.Schnichels@ec.europa.eu>; Anna-[redacted]ec.europa.eu [redacted] Antti.Maunu@ec.europa.eu <Antti.Maunu@ec.europa.eu>
Subject: RE: draft paper on e-cigarettes

Dear Haik,
thanks for giving us the time and please find below our comments on the draft e-cigarette paper.
best regards from the whole team in SANCO
[redacted]

The scope:
In our view the borderline between ENDs and nicotine containing non-electronic cigarettes (smokeless cigarettes like "Similar") and NRTs (nicotine replacement therapies approved for cessation) should be made more clear, in order to well frame the issue of ENDs.

We limited our review to 'electronic' nicotine delivery systems, based on the COP4 mandate (of course, the discussion at COP5 can certainly include the non-e-versions), and we believed that discussion of NRTs would enter into a policy discussion that might be premature (and could result in a mischaracterization of all ENDS as acceptable NRTs). Our discussion of cessation aids was limited to reference to Article 14 and its guidelines, and to the UK in Annex I. Again, Parties are most welcome to raise these other issues at COP5, which may arise naturally from the paper in any event, in reference to those Parties that responded that they regulated ENDS with health or therapeutic claims.

The problem definition:
The paper would benefit from a clearer problem definition already in the beginning. In our view, this section should more in detail describe (1) the different product

categories (with tobacco and without, with nocitine and without, with cartridge or single use, battery driven or chargeable) (2) market development (significant increase in recent years), (3) the legal complexity/uncertainty and that Parties regulate the products differently, (4) health and safety concerns (that many products are put on the market without any prio control and that content is often unclear), (5) that products are sometimes subject to heavy marketing, including towards young people (e.g. flavours) and (6) ENDS unclear role in smoking cessation or on the opposite risk as starting product or dual use (keeping up nicotine addiction). P 18-20 appear to fit more under the introductory part describing the work of Tob Reg.

See our comment above in terms of incorporating these 6 points in a summary paragraph at the end, to draw out the principles mentioned in the paper before requesting the views of the COP.

Regulation of ENDS in Parties:
In our view, it would be appropriate to conclude up front that it is difficult to get an exact overview of how ENDS are regulated in Parties, in particular as the regulatory status sometimes is based on an assessment product by product, e.g. to consider if a product is a medicinal product or not. The conclusions on the link between regulation as pharmaceuticals and market autorisation in p 22 and 23 is a bit unclear. As far as EU is concerned, ENDS can be considered pharmaceuticals either by presentation (i.e. they are presented as smoking cessation aid) or by function (i.e. because of their physiological functions). The paper seems to focus on the first category, which is in our view the easier part of the problem. Because even if a Party considers ENDS marketed with health claims as pharmaceuticals, ENDS without such claims might be marketed in these Parties without market autorisation (p 22). Only in countries where all ENDS (with or without claims) are considered pharmaceuticals there is a requirement of prior autorisation, including risk/benefit assessment, before putting a product on the market. But even in those countries it is possible that ENDS are sold on the markets simply because the regulatory framework is not respected. The Commission is not aware, at this stage, of any ENDS authorised as pharmaceuticals in the EU, but at least one application has been issued.

Again, part of the problem in drafting this paper was that the COP4 mandate required us to use the experience of the Parties as a starting point. Having said that, we feel that all of the points set out in this paragraph are, in fact, elicited through the Parties' responses, and can, of course, be enlarged upon during the discussion at COP5.

The potential role of ENDS in smoking cessation:
This aspect is missing in the document. However, it appears important considering that many Parties have reported that they regulate some or all ENDS as pharmaceuticals. This aspect was also highlighted by the WHO study group in its report of 2009.

Smoking cessation is included at least implicitly in reference to those Parties that regulate ENDS on the basis of health or therapeutic claims, and explicitly in the reference in the paper to Article 14 and its guidelines for implementation (and the emphasis on medications that have been shown by scientific evidence to increase the chances of cessation). Annex I also makes reference to this issue in terms of the UK's regulation of ENDS.

ENDS and WHO FCTC:

We would suggest starting with a sentence stressing that FCTC primarily targets tobacco products, i.e. products containing at least partly tobacco. From that starting point, the paper tries to find reasons why ENDs could actually fall under the FCTC. However, the conclusion drawn from the different FCTC Articles mentioned in p 32-35 is a bit unclear and in particular the relevance of Article 12, 13 and 8 need to be clarified further as it is not evident that ENDS would promote tobacco products by their pure ressemblance. Articles 5.2b, 16.1c and 14 appear more relevant, but it is very likely that some Parties would argue that ENDS are totally outside the scope of the FCTC. It is suggested that tan argument is added that nicotine in most cases is derived from the tobacco plant and therefore would fall under the FCTC. But it is true that this argument falls short as regards non-nicotine containing ENDs.

A number of Parties responded that they have already banned ENDS as a tobacco product or as an imitation tobacco product. The paper simply attempts to explore all intersections between ENDS and the WHO FCTC both in terms of the definition of tobacco products, and in broader terms of the overall goals and guiding principles of the WHO FCTC.

Ban:
By suggesting a **ban** of these products (p 32), the paper goes much further than the recommendations of the WHO study group (2009) recommending ENDS to be regulated as combination drugs and medical devices. Regulation as a tobacco and medical product is suggested as a second alternative (p 36), but without describing how such a regulation could look like. In p 37 the statement that if a Party categorises ENDS as tobacco, all FCTC provisions would apply, is not clear. In p 38, again, regulation as pharmaceuticals is not limited to ENDS making health claims, but could also be the case for ENDS without claim due to their physiological function (i.e. by function). The last sentence of p 38 is misleading, because if ENDS are regulated as pharmaceuticals, they would not be sold to maintain a nicotine addiction, but rather to assist people in quitting smoking (getting rid of their addiction). This again brings to light that ENDs without claim (but with the dual use of NRTs or nicotine products for continued use) are not subject of the analysis.

ENDS have already been banned by some Parties, and it would not have been possible to report on Parties' experiences without noting that some have simply banned the products. In addition, a complete policy analysis cannot ignore that allowing the sale of ENDS and regulating them (as contrasted with banning them) give the products a certain legitimacy that they have not enjoyed to date (unlike tobacco products, which already had a great deal of commercial and social legitimacy before they were regulated domestically and through the Convention). Of course, that is not to suggest that a ban is the right option – just that it is one of the options, as demonstrated by the actions of some Parties. Further, the last sentence of para. 38 has been slightly adjusted, and moved to another paragraph so as to accommodate your concerns.

We appreciate that this is a very complex area and we also have our dificulties with it !

You might want to have insight into some of the **market analysis and background** which we have collected for our **Impact Assessment.**
If you use any of the data, it would be important that you do not copy and paste the content, to avoid any problems for us later on (this document will only be published once the legislative proposal is published ie in November 2012). However, if you

wanted to use and reformulate or take it as inspiration/verification/double checking, this is very welcome.

Market Description and Regulation

The NCP market is an emerging market estimated at around 400-500 mEUR in 2011. Electronic cigarettes did not exist when the current TPD was adopted in 2001. In the absence of EU legislation, NCP are subject to a **heterogeneous and complex legal situation**. About half of the Member States have reported that they would consider them as medicinal products by function, even if the electronic cigarettes are not presented as smoking cessation aid but rather as alternative to cigarettes (leisure products). One third have no specific regulation in place which means that the General Product Safety Directive applies and a minority of the Member States have chosen to ban these products or subject them to the tobacco legislation. So far, no electronic cigarette has been authorised in the EU under the pharmaceutical regulation, but at least one application has been submitted and others are foreseen. The increasing market volume and cross-border trade together with the different legislations in Member States prevent NCP from moving freely on the internal market and require manufacturers and distributors to comply with many different legal systems. Member States have expressed an urgent need for orientation from the Commission as to which legislation applies to electronic cigarettes. Electronic cigarettes Industry Trade (**ECITA**) representing vendors of electronic cigarettes in the UK has argued that these products do not need to be further regulated.

The current fragmented situation is a result of various efforts in Member States to respond to **health concerns** associated with NCP. The Commission has, so far, received six **notifications** concerning (refill) liquids for electronic cigarettes via the RAPEX system, indicating serious health risks for consumers. The serious health risks were due to the toxicity of nicotine and misleading presentation, for example labelling referring to fruit.

Nicotine is a toxic and addictive substance. Acute nicotine poisoning has occurred in children who accidentally ingest nicotine and safety of heavy or long terms use are not known. Cartridges are sometimes sold in containers with minimal protection against tampering, opening by children etc. Ingestion of a single replacement cartridge is very likely to be lethal and users have reported leakage when replacing cartridges, suggesting that the quality of cartridges themselves is highly variable. A study of five different brands of electronic cigarette also found that most brands' cartridges were poorly constructed and leaked.

Cartridges generally contain up to 20 mg nicotine compared to a maximum level of 1 mg of nicotine in traditional cigarettes marketed in the EU. Studies of the nicotine content of cartridges have shown significant differences between labelled and true levels of nicotine cartridges and refill solutions. Analyses of electronic cigarette samples conducted by the US Food and Drug Administration (FDA) have shown detectable levels of known carcinogens and toxic chemicals; including diethylene glycol, tobacco-specific nitrosamines and tobacco specific impurities.

Some NCP also appear to be subject to **vivid and innovative marketing, which could attract younger people in particular**. This is the case, for instance, for a new e-cigarette brand available on the US market, which produces e-cigarettes in a range of flavours, including coffee and cherry, and is introducing a "smart pack" that

vibrates and flashes a blue light when a user is within 50 feet of someone with another pack.

Under the current situation, where NCP are presented as consumer or leisure products and without any prior testing, they can **circumvent national measures of tobacco cessation.** The products are often promoted as alternative to smoking which keeps up nicotine addiction in situations where smoking is prohibited. There is also a risk that they become a starter/re-starter product attractive to young people or former smokers. On the other hand, many consumers appear to use the products with the purpose to quit smoking (see above section 2.1.3) which would suggest that NCP could have a potential role in smoking cessation. Nicotine has a long tradition of use in authorised medicinal products to reduce craving and help people stop smoking. On the other hand, more studies of the efficacy of **electronic cigarettes** as smoking cessation aids are still needed. All nicotine containing medicinal products (NRTs) have to undergo pharmaceutical authorisation. Allowing electronic cigarettes to be put on the market without such authorisation undermines reaching a level playing field.

And background:

Nicotine Containing Products (NCP)

In addition to the traditional tobacco market, recent years have seen the emergence of new nicotine containing products (NCP) and other novel and niche products marketed primarily as consumer/leisure products. Electronic cigarettes appear to be the most commonly available of this type of product in the EU followed by herbal cigarettes.

The EU **electronic cigarette** market is growing rapidly and the total value has been estimated to 400-500 mEUR in 2011. The EU market is mainly composed of distributors rather than manufacturers and dominated by small enterprises, although there is a growing interest from bigger cigarette manufacturers (including the big four FMC producers) to enter into the market. For example, in 2009, Niconovum AB was purchased by Reynolds American Inc and Kindconsumer has agreed a marketing and distribution agreement with Nicoventures Limited, a company within the British American Tobacco Group.

Most of electronic cigarettes are produced in China. Once imported into the EU, they are subject to significant cross-border trade. For example, in the Netherlands vendors of electronic cigarettes operate as a hub, reselling most of the electronic cigarettes they import from China to the rest of Europe. There are around 20 vendors in the Netherlands operating with a turnover of 4-6 million EUR per year. Around 20% of their sales are internal to the Dutch market, while around 60% are sold to German vendors and the remaining 20% to vendors in Denmark, Spain, France, Austria and Switzerland.

As for the demand side, the current use of NCP is growing quickly. 7% of EU citizens have reported in the latest Eurobarometer that they have at least tried electronic cigarettes. In the UK an increase in the number of electronic cigarette owners has been estimated from a small number in 2006 to over 1 million by 2013.

Electronic cigarettes are widely advertised on the internet. A study monitoring Google search queries from January 2008 to September 2012 reported that online interest in electronic cigarettes has surpassed that of oral tobacco (snus) and nicotine replacement therapies.

Electronic cigarettes are most often marketed as an alternative to FMC rather than a smoking cessation aid. There are limited data available at this stage why people use electronic cigarettes. However, according to a recent survey among electronic cigarette **users** in Poland, most used the product primarily to quit smoking or to reduce harm associated with smoking (both 41%). An online survey of more than 3500 e-cigarette smokers found that the vast majority of respondents were using e-cigarettes to quit smoking or reduce their smoking (92%) and a large proportion felt these products were less toxic than traditional tobacco products (84%). A recent Polish survey also found that one in five young people had tested electronic cigarettes. As explained in subsequent sections of this report, the regulatory framework for electronic cigarettes and other nicotine containing products is complex and varies between Member States and a number of health and safety concerns are associated with the products.

Other NCP appear, at this stage, to be less common on the EU market. Some products containing neither tobacco nor nicotine, including herbal products for smoking and nicotine-free electronic cigarettes are also available on the EU market.

Some of these products are particularly targeting teenagers and young adults and are explicitly advertised as a means to consume nicotine in smoke-free places.