Ares(2013) 3615675

Subject: RE: Dear Dr Schnichels - in reference to 'request for a meeting'
Attachments: Kantar Research data 30112013.pdf; DRAFT Nicoventures Product Standards 30112013.pdf

From: henrik_brostrom@nicoventures.co.uk [henrik_brostrom@nicoventures.co.uk]
Sent: 30 November 2013 16:25
To: SCHNICHELS Dominik (SANCO)
Subject: RE: Dear Dr Schnichels - in reference to 'request for a meeting'

Dear Dr Schnichels,

Thank you for your email and I fully understand your time constraint with regards to a meeting.

Earlier this year we commissioned Kantar Research to conduct a multi-country survey for us covering 8 markets out of which 6 within the EU. The total sample size of respondents in the European markets was 12 000. I have attached extracts from the study which I hope will address the specific information you requested. I hope you appreciate that this data is the property of Nicoventures and that you respect the confidential nature of the information provided.

I have seen the recent Article 18 proposals that appeared on this website (http://nicotinepolicy.net<http://nicotinepolicy.net/>) I hope you don't mind if I take the opportunity to comment on certain elements which I fear may limit the appeal of e-cigarettes for smokers and therefore the harm reduction potential:

(i) Restricting the refillable cartridges or bottles (referred to as Modular in the attached slides) would be to outlaw the fastest growing segment of this category and ultimately driving it underground. The issue of lack of control of composition and use of liquids can be adequately dealt with by proper product standards.

(ii) The proposed restriction of the use of certain flavours is arguably counterproductive to the harm reduction potential of the category as research tells us that flavours are key for the category appeal and growth.

(iii) The proposal to reduce the nicotine threshold from 30mg/ml to 20mg/ml or 10mg/unit will effectively ban the majority of exiting nicotine containing e-cigarettes. The intent may be to limit the nicotine content of e-cigarettes to that amount available from cigarettes. Please note however that all available PK studies show a much slower and lower nicotine uptake compared to cigarettes, regardless of nicotine strength of e-liquid. Lowering the 30mg/ml threshold would move e-cigarettes even further away from cigarettes in terms of performance and thereby reducing the likelihood of smokers switching from cigarettes to e-cigarettes.

Finally, I learnt from Ronan Barry that you may be interested in getting a more detailed account of the product standards, Therefore, I took the liberty of attaching our draft standards in this document. Once you have read them, I hope you recognise that we appreciate and support your efforts to introduce the issue of safety and quality into the Directive. However, in our view the introduction of product standards requires significant input and consultation. For example, greater clarity is needed in relation to standards for design and manufacture, appropriate quality management systems and standards for safety assessment etc. Arguably it might be more appropriate and effective to provide the Commission with the powers to introduce product standards by way of delegated or implementing act, rather than trying to introduce them into the Directive as such.

I hope you consider our draft products standards in the light of our best intention to ensure the continued growth of the e-cigarette category while providing regulators and smokers with the reassurance that products on the market meet appropriate criteria with regards to quality and safety. NB these standards have been developed by our pharmaceutical inhalation experts currently involved on our other technology referred to in previous

correspondence. If you would like to speak to any of our experts for clarification or further elaboration, please don't hesitate to contact me.

Although I do not have all of the data you are looking for, I think that the attached does go some distance towards addressing your information needs and that you find our draft product standards helpful.

The research referred to above also includes some interesting data on smokers switching/quitting patterns, away from cigarettes and into e-cigarettes. If you are interested, I would be more than happy to provide you with a few slides summarising this. Please let me know if you are interested.

Best reg and please don't hesitate to call if you have questions

Henrik

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From: <Dominik.Schnichels@ec.europa.eu>
To: <henrik_brostrom@nicoventures.co.uk>
Cc: <SANCO-CONSULT-D4@ec.europa.eu>
Date: 28/11/2013 20:13
Subject: RE: Dear Dr Schnichels - in reference to 'request for a meeting'

Dear Mr Brostrom,

Many thanks for the mail. At this stage we are rather pressed with time, but you could help us a lot with information on the following issues (ideally for UK and EU; if you do not have the information, please provide your best estimate):

1. the market share of electronic cigarettes in % (in terms of sales), which are refilled/refillable (i.e. consumer puts e-liquid into the device) and which are non-refillable (i.e. use single use cartridges or disposable e-cigarettes). Main players on the market.
2. the market share of electronic cigarettes with the following flavour varieties - i. tobacco, ii. mint, iii. other candy flavours like chocolate, lakrits, iv. fruit, v. other – please specify - in % (in terms of sales) and any consumer preferences for any of these flavours (young people, non-smokers, established smokers)
3. the market share of electronic cigarettes in % (in terms of sales) according to the nicotine concentration - i. 0-15 mg/ml, 15-20 mg/ml, 20-30 mg/ml, 30-45 mg/ml, above 45 mg/ml.

If you have information on commonly used cartridge sizes (including market share), this would also be helpful. Many thanks for your help, highly appreciated.

Kind regards

Dominik Schnichels

From: henrik_brostrom@nicoventures.co.uk [mailto:henrik_brostrom@nicoventures.co.uk]
Sent: Thursday, November 28, 2013 12:42 AM
To: SCHNICHELS Dominik (SANCO)
Subject: RE: Dear Dr Schnichels - in reference to 'request for a meeting'

Dear Dr Schnichels,

I hope the summary information I provided earlier met your needs with regards to the requested pre-read material in advance of your meeting with the CECCM members. I was also informed that the meeting took place earlier today and that although Art 18 was not the focus of the meeting, it was briefly discussed.

I appreciate that it is potentially late in the process and that you have already consulted with the appropriate stakeholders with regards to the Art 18 of the review of the Tobacco Products Directive. However, I hope you don't mind me reiterating my sincere request for an opportunity to discuss the regulatory aspects with regards to e-cigarettes in the context of the TPD.

Based on the reasoning above and since I understand your potential time constraint, I fully respect if you if you don't accept or find time for a short meeting. Having said than, I hope you respect the reason why I feel obliged to address the opportunity for a potential meeting to discuss Art 18 in more detail.

Best regards
Henrik

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Date: 03/11/2013 22:25
Subject: RE: Dear Dr Schnichels - in reference to 'request for a meeting'

Dear Mr Brostrom,

Many thanks for the information provided.

Could you please clarify whether within the BAT group Nicoventures is the only company active in the area of e-cigarettes. If not please ensure complete reply by BAT [redacted]

In my email to [redacted] had asked for the following information regarding BAT's activities in the area of e-cigarettes (covering the next five years):

current brands on the market, envisaged product launches, nicotine content per brand/product (if too many introduce categories), pending or envisaged marketing authorisations (under pharmaceutical legislation), use of tobacco brand names for electronic cigarettes, the safety and quality standards to be applied and the use of flavours.

Could I kindly ask you/BAT to complete the requested information until Monday, 5/11 cob.

Kind regards

From: Henrik Brostrom [henrik.brostrom@nicoventures.co.uk]
Sent: 01 November 2013 08:54
To: SCHNICHELS Dominik (SANCO)
Subject: Dear Dr Schnichels - in reference to 'request for a meeting'

Dear Dr. Schnichels,
I have been referred to you by [redacted] BAT), Western European Region. I understand that you are interested in learning more about our e-cigarette endeavours.
For a long time, BAT has been committed to harm reduction and as part of this approach BAT in 2011 established a standalone business, called Nicoventures, to focus on the development and sale of inhaled nicotine products. Nicoventures has recently launched an e-cigarette brand called Vype in UK. In parallel we are awaiting a Market Authorisation from the MHRA (Medical and Healthcare products Regulatory Agency) for our licensed breath activated pulmonary inhaler. Once approved, we are planning a launch in UK in Q2 2014. In addition, we have recently submitted an application for a market authorisation for an e-cigarette to the MHRA. Our ambition is to launch this product once the market authorisation has been granted to us.

With regards to the review of the TPD, we believe that there are benefits as well as some concerns with each of the two options currently on the table. In relation to the European Parliament's Amendment 170 to Article 18, we believe the need for proper product standards should be addressed under the GPSD option in order to fully realise the potential for these products to offer smokers a safer and more viable alternative to cigarettes. Appropriate Product Standards would ensure that products on the market meet relevant criteria with regards to quality and safety. These would include standards related to e-liquid content, aerosol content, product stability, content labelling, device safety and child proofing.

In relation to the Council Position on Article 18, the application of the medicines regime would clearly deal with the need for product standards. However, the harm reduction potential of this new category could be undermined by

the restrictions on distribution inherent in the medicines regimes of many EU member states. If this route is followed, consideration should be given in this directive to promoting the exercise by Member States of flexibility in this area.

We trust the above top line views are of assistance. However, if you require any more information, Nicoventures are more than happy to meet and discuss Art 18 with the Commission, and in particular to explore ideas about what an appropriate Standards regime under Amendment 170 could look like.

Best Regards
Henrik

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DRAFT

November 22, 2013

nicoventures

NICOVENTURES PROPOSED PRODUCT STANDARDS FOR E-CIGARETTES

BACKGROUND:

E-cigarettes are battery-powered electronic devices that do not contain tobacco but rather deliver a nicotine aerosol (or 'vapour') to users. The vapour is generated from a liquid formulation (or 'e-liquid') containing nicotine, excipients such as water and glycerol, and sometimes flavours. The battery heats up a coil that vaporises the e-liquid and the vapour is inhaled just like cigarette smoke.

It is scientifically well established that it is the combustion of tobacco, not the nicotine, that is the cause of most smoking-related diseases and it is for that reason that many respected public health professionals believe that e-cigarettes may be a significantly less harmful, effective alternative to conventional cigarettes, and therefore an important element of a comprehensive tobacco harm reduction approach.

THE NEED FOR PRODUCT STANDARDS:

Although policymakers and regulators are also increasingly acknowledging the role of e-cigarettes as potential cigarette substitutes, many are expressing concerns about the safety and quality of some of the products currently available in the marketplace and are therefore adopting a precautionary approach to the regulation of e-cigarettes. This has resulted in the adoption of regulations in many places that err on the side of restricting the growth of the category out of an abundance of caution as to the safety and quality of the products on the market. If appropriate product standards are introduced which can give regulators comfort on the safety of the category they will be more likely to introduce related regulations which promote the overall growth of the category and thereby the larger harm reduction agenda.

Product standards are also key from a consumer perspective. Although the category is expanding rapidly today there are nevertheless still many consumers who are unsure about the safety of e-cigarettes. Suitable product standards would give these consumers the necessary assurance thereby encouraging an increase in the current rate at which smokers are switching to e-cigarettes.

For e-cigarettes to realise their true public health potential, regulators and smokers need to be assured that the products are made to such standards that ensure smokers' safety.

OUR APPROACH TO PRODUCT STANDARDS:

Our approach in proposing these standards recognises that:

i. consumer safety is of utmost importance, and given that these are inhaled products, the product standards require strict maximum allowable limits for any impurities and contaminants that could occur as a result of how the products are designed, manufactured and used; however,
ii. the comparator is a conventional cigarette and meeting any proposed standards should not be so onerous as to make the category cost prohibitive and unattractive vis-à-vis conventional cigarettes for manufacturers and consumers alike.

We propose the following Product Standards for incorporation into national regulations so as to maximise the harm reduction potential of e-cigarettes whilst assuring consumer safety.

PROPOSED PRODUCT STANDARDS

PRODUCT ATTRIBUTE	PROPOSED STANDARD	RATIONALE
Content labelling		
Nicotine concentration	Nicotine concentration to be +/- 10% of label claim	To provide accurate information to consumers on the strength of the formulation
Total nicotine content (per unit)	Total mass of nicotine contained in unit to be +/- 15% of label claim	To provide accurate information to consumers on the total nicotine in one unit. The nicotine content will be a function of both nicotine concentration and unit fill volume, thus the range is wider than for concentration alone.
e-liquid content		
Quality of the sourced nicotine	Nicotine used in the e-liquid should be pharmaceutical grade	To ensure safety for the consumers by minimising risk of toxicant exposure, as non-pharmaceutical grade nicotine may contain carcinogens such as tobacco specific nitrosamines in quantities that would expose the consumer to an unacceptable level of risk.
Excipients	Excipients used in the e-liquid should be pharmaceutical grade.	To ensure safety for the consumer by minimising risk of toxicant exposure
Flavours	• Flavours which will lead to generation of unacceptable levels of toxicants in the aerosol may not be used. • To make this determination a risk assessment of all flavours must be undertaken • The risk assessments must be documented and maintained for scrutiny by the regulator	Flavours may be required to make e-cigarettes an attractive alternative to cigarettes for smokers; however their inclusion should not expose smokers to more risk than that of smoking. As it is not practical to specify limits for all possible flavours the onus is on manufacturers to perform appropriate analysis to ensure consumer safety. Retaining records of this analysis will be proof of compliance.
Quality	All liquid should be manufactured	Requiring manufacture

management System	according to [cGMP]	according to cGMP will ensure that products consistently meet the relevant standards. Having standards without an accompanying QMS significantly undermines consumer and regulator confidence that products will consistently meet the require standards
Controlling contamination		
Microbial contamination	All products should meet the European Pharmacopoeia standard for a non-sterile inhalation product.	Safety for the consumers (risk of airway infection)
Foreign particulate matter in the emitted aerosol	• Foreign particulate matter in the aerosol must be as low as reasonably practical. • Foreign particulate matter levels must be tested and documented to demonstrate compliance.	Safety for the consumers (e.g. choking hazard, irritation of the airways, long term deposition, risk of toxicant exposure)
Aerosol constituents		
Organic and inorganic impurities measured in the aerosol	• For integrated products where devices and liquids are sold together (eg disposables and rechargeables), the chemistry profile of the aerosol of each product must be tested to GLP standards • For constituents listed in the Appendix A, levels should not exceed limits set out in appendix • For all other constituents which are above the ICH Q3B threshold for impurities, maximum acceptable levels for that constituent in the aerosol should be determined, based on an appropriate risk assessment • The risk assessments should be documented and maintained for scrutiny by the regulator. • For devices where a consumer can buy e liquid from a number of different suppliers , such devices shall be required to show that when used with a liquid conforming to the liquid standards ,the resulting aerosol complies with the aerosol standards in this	Overall risk to the consumers should be significantly less than that from the cigarette. For toxicants that are known to be found in e-cigarettes' aerosol, it is possible to set specified limits. However, if other constituents are found above ICH Q3B threshold levels, the onus is on the manufacturer to perform the appropriate analysis to ensure consumer safety. Retaining records of this analysis will be proof of compliance.

	section.	
Quality Management System	All devices shall be manufactured in accordance with ISO 13485	Requiring manufacture according to ISO 13485 will ensure that products consistently meet the relevant standards. Having standards without an accompanying QMS significantly undermines consumer and regulator confidence that products will consistently meet the require standards
Stability over the claimed lifetime of the product		
Expiry date and in-use expiry period	The product shall remain within specification throughout its claimed shelf life	Accurate consumer information and consumer protection.
Device Safety		
Device safety	The device shall meet relevant EU standards (or equivalent standards outside the EU) for electrical and equipment safety, including drop testing, contact temperature, EMC testing. (relevant EU Directives are set out in Appendix B)	Consumer safety during consumption, storage and recharging of the product.
Labelling		
Pack labelling	(i) All products shall comply with EU Classification, Labelling and Packaging (CLP) regulations (or equivalent regulations outside the EU). (ii) All products should carry a clearly visible and legible sign specifying the legal age limit for purchase of the product. (iii) Unless otherwise specified by other regulations, all products shall carry the warning: "This product may be hazardous to health and contains nicotine which is addictive".	Meets regulatory expectations, informs consumers of the risks and protects underage populations.
Child Proofing		
Child proofing	All products shall comply with child proofing standards in accordance with ISO 8317	To protect against accidental underage consumption

ENSURING COMPLIANCE WITH THE STANDARDS:

Implementing legislation should provide for a suitable body to oversee compliance with these standards who would have the following powers/obligations:

(1) To provide a simple method for consumers to register concerns/complaints,
(2) To establish a system for products on the market to be tested to ensure that they comply with product standards. Any such tests should be carried out at laboratories working to Good Laboratory Practice standards,
(3) To audit manufacturers to establish compliance with the standards. In respect of such audits manufacturers would have the burden of proving compliance and would be expected to produce relevant documentary evidence (e.g. product test results), and evidence of appropriate quality management systems to demonstrate compliance,
(4) To take off the market products not in compliance with the standards and to impose fines for non-compliance.

APPENDIX A

The following toxicants have been measured in a range of e-cigarettes, and so are suggested as toxicants that limits should be set for:

Toxicant	Aerosol Limit
(1) Formaldehyde	[ ]
(2) Acetaldehyde	[ ]
(3) Butyraldehyde	[ ]
(4) Crotonaldehyde	[ ]
(5) Acetone	[ ]
(6) Methylethylketone	[ ]
(7) Acrolein	
(8) Metals & silicates (list TBD)	[ ]
(9) Other toxicants (TBD)	[ ]

[The limits for all the above toxicants TBD].

APPENDIX B

- **Directive 2011/65/EU** on the restriction of the use of certain hazardous substances in electronic equipment (**RoHS**) [Imposes restrictions on chemical content in certain electrical and electronic equipment (e.g. lead, mercury). Also imposes obligations in relation to documentation (technical file) and labelling (CE mark). Also has recall and authority notification obligations]
- **Directive 2006/95/EC** on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (**Low Voltage Directive** or **LVD**) [This regulates the safety of electrical equipment. Similar to RoHS it imposes obligations in relation to documentation and labelling]
- **Directive 2004/108/EC** on the approximation of the laws of the Member States relating to electromagnetic compatibility (**EMC**) [This regulates the electromagnetic compatibility of equipment to ensure it does not interfere with the operation of other equipment and can itself operate without interference. Similar to RoHS and LVD it imposes obligations in relation to documentation and labelling]
- **Directive 2006/66/EC** on batteries and accumulators and waste batteries and accumulators (**Batteries Directive**) [The Batteries Directive is similar to the WEEE Directive in that it seeks to reduce the amount of waste batteries going to landfill. It also imposes restrictions on batteries containing certain hazardous substances (e.g. mercury, cadmium). It also stipulates information and labelling requirements and provides for "take-back" obligations]