

From:

Henrik Brostrom <henrik.brostrom@nicoventures.co.uk>

Sent: To:

04 November 2013 16:29

Cc:

SCHNICHELS Dominik (SANCO)

Subject:

RE: Dear Dr Schnichels - in reference to 'request for a meeting'

Categories:

TO REGISTER

Dear Dr Schnichels,

With reference to your email of the 3rd of November and with regards to the additional questions raised, I can confirm that Nicoventures is the only company within the BAT Group that is active in the e-cigarette business. Our key focus is Vype® and the products we have submitted to the MHRA for market authorisation. We also have a few products under the Intellicig brand name which we acquired through the acquisition of CN Creative earlier this year.

The Vype® product range consists of two unflavoured products that come in different strengths and one menthol flavoured variant. The Intellicig products variants are unflavoured. The nicotine content of these product ranges from 12.5mg (3%v/v) to 18.6 mg (4.5% v/v). The volume of the nicotine formulation in each of these products is 0.4ml

We do not use or intend to use any tobacco brands for an e-cigarette product, as it is our understanding that it is illegal in most countries to use tobacco brands for non-tobacco products.

As mentioned earlier, Nicoventures is currently waiting for a Market Authorisation from the MHRA (Medical and Healthcare products Regulatory Agency) for our licensed breath activated pulmonary inhaler. We are anticipating launching this product in UK in Q2-Q3 2014. Recently, we also submitted an application for a market authorisation for an e-cigarette to the MHRA. It is our ambition to launch this product once the market authorisation has been granted.

Finally and with regards to products standards for e-cigarettes, we are giving this a lot of thought at the moment and we would like to reiterate our desire to meet and discuss these in more detail with the Commission.

I hope this satisfies your need for additional information following our previous email correspondence

Best regards Henrik

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From: Dominik.Schnichels@ec.europa.eu [mailto:Dominik.Schnichels@ec.europa.eu]

Sent: 03 November 2013 22:26

To: henrik.brostrom@nicoventures.co.uk

CC

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 ecigarettes. If not please ensure complete reply by BAT via Ronan Barry.

In my email to Mr Barry I 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

(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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