

Subject: Re: request for a meeting
Attachments: PMI Summary.pdf

From: [REDACTED]
Sent: Thursday, October 31, 2013 4:04 PM
To: SCHNICHELS Dominik (SANCO); [REDACTED] (SANCO)
Cc: [REDACTED]
Subject: RE: request for a meeting

Dear Mr. Schnichels,

Please find enclosed the requested information. We kindly ask you to treat this information as confidential, and look forward to our meeting next week.

With best wishes,
[REDACTED]

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From: Dominik.Schnichels@ec.europa.eu [<mailto:Dominik.Schnichels@ec.europa.eu>]
Sent: 29 October 2013 12:25
To: [REDACTED] antonella.pederiva@ceccm.eu
Cc: [REDACTED]

Subject: RE: request for a meeting

Dear Ms Pederiva, Dear [REDACTED]

I would also like to recall that we are still waiting for the one page summary to be sent by each company separately (to ensure confidentiality) about current and envisaged (next five years) activities regarding electronic cigarettes. This information should be received until Friday, 1/11. If we do not receive the information, we will postpone the meeting until the information is received from all companies concerned.

In order to facilitate the tasks for the companies I recommend to cover the following issues: 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.

We are looking forward to meeting you.

Kind regards

Dominik Schnichels

From: [REDACTED] (SANCO)
Sent: Tuesday, October 29, 2013 11:54 AM
To: 'Antonella Pederiva'
Cc: [REDACTED]
[REDACTED] SCHNICHELS Dominik (SANCO);

[REDACTED]
[REDACTED]
Subject: RE: request for a meeting

Dear Mrs Pederiva,

Thank you for the email and the names of the seven attendees. You have mentioned the number of the participants during our telephone conversation yesterday.

On Tuesday, just before 3.30 pm - once you are in DG SANCO, please ask the reception desk to contact either [REDACTED] or [REDACTED] so as to let us know that you have arrived. In case the two previously mentioned colleagues are not available, please ask the reception to call [REDACTED]
[REDACTED]

Kind Regards

[REDACTED]
DG SANCO

From: Antonella Pederiva [mailto:antonella.pederiva@ceccm.eu]

Sent: Tuesday, October 29, 2013 10:47 AM

To: [REDACTED] (SANCO)

Cc: [REDACTED] SCHNICHELS Dominik (SANCO);
[REDACTED]

Subject: RE: request for a meeting

Dear Mr [REDACTED]

Thank you for your mail confirming the meeting scheduled for the 5th of November 2013 at 3.30 pm in SANCO's offices.

From our side, the delegation would be:

[REDACTED] (BAT)
[REDACTED]
[REDACTED] (BAT, expert for Article 14)
[REDACTED] (JTI, expert for Article 6)
[REDACTED] (JTI)
[REDACTED] (ITG)
Antonella Pederiva (CECCM)

I hope this is acceptable.

Best regards

Antonella Pederiva

Secretary General of CECCM
Av Louise 125
B - 1050 Brussels
Tel ++ 32 2 541 00 34
Fax ++ 32 2 541 00 45

Confederation of European Community Cigarette Manufacturers (CECCM) AISBL, registered number 0879 438919 ceccm@ceccm.eu

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From: [REDACTED]
Sent: lundi 28 octobre 2013 3:13
To: Antonella Pederiva
Cc: [REDACTED]
[REDACTED] Dominik.Schnichels@ec.europa.eu
Subject: RE: request for a meeting

Dear Mrs Pederiva,
I would like to confirm that the meeting is going to take place on Tuesday 5 November 2013 at 15.30, in DG SANCO (Rue Froissart 101, 1040 Brussels).

Kind Regards

[REDACTED]
DG SANCO

From: SCHNICHEL Dominik (SANCO)
Sent: Friday, October 25, 2013 3:47 PM
To: 'Antonella Pederiva'
Cc: [REDACTED]
[REDACTED]
Subject: RE: request for a meeting

Dear Ms Pederiva,

Many thanks for your mail and the clarifications regarding participation.

Obviously we understand that CECCM represents the interests of the large tobacco manufacturers (excluding PMI). Still I would ask that your members send us – before the meeting – a one page summary of their current and future activities for the e-cigarettes market. Also we will invite the companies represented in the meeting to comment on the two legislative options that are currently on the table. As suggested by you, please fix the details of the meeting with my PAs

Kind regards

Dominik Schnichels

From: Antonella Pederiva [<mailto:antonella.pederiva@ceccm.eu>]
Sent: Friday, October 25, 2013 3:42 PM
To: SCHNICHEL Dominik (SANCO)
Cc: [REDACTED]
[REDACTED]
Subject: RE: request for a meeting

Dear Dr. Schnichels,

Thank you for your e-mail dated 23.10.13.

I would like to confirm that it would be a joint CECCM PMI meeting. We thank you for the opportunity to comment on the minutes before they are published.

We note that you would like to add Article 18 to the agenda and we are happy to listen to the Commission's views on this topic and to make comments of a general nature. I hope that you appreciate that e-cigarettes are not in the scope of CECCM (which is exclusively a tobacco association) and therefore we will not be able to address this in detail at the meeting. Individual companies may get in touch with you separately to provide their comments or share their activities in the e-cigarette market.

As suggested, we will revert to your secretariat early next week on the date (5 or 6 of November?) and the proposal for our delegation.

We hope this is acceptable to you and we look forward to the meeting.

Yours sincerely,

CECCM & PMI

Antonella Pederiva
Secretary General of CECCM
Av Louise 125
B - 1050 Brussels
Tel ++ 32 2 541 00 34
Fax ++ 32 2 541 00 45

Confederation of European Community Cigarette Manufacturers (CECCM) AISBL, registered number 0879 438919 ceccm@ceccm.eu

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

Sent: mercredi 23 octobre 2013 1:19

To: Antonella Pederiva

Cc: [REDACTED]

Subject: RE: request for a meeting

Dear Ms Pederiva,

Thanks for your mail.

Do I understand you correctly that you are asking for a joint meeting CECCM and PMI. If yes, fine. If not, I would kindly ask for a declaration from PMI that do not wish to meet.

Please note that we intend - like last time - to publish minutes of the meeting on the internet. I trust that this is acceptable to you. Obviously you are given an opportunity to comment prior to publication.

An area that we would like to add to the agenda is Art. 18 (nicotine containing products). In preparation of the meeting we ask the members of CECCM as well as PMI to send us separately (to ensure confidentiality) a one page summary of your current activities regarding electronic cigarettes as well as your intentions/plans for the next five years.

Due to the upcoming school holidays a meeting can only take place as of 4/11. Please arrange the details with my assistants in copy.

Kind regards

Dominik Schnichels

From: Antonella Pederiva [antonella.pederiva@ceccm.eu]
Sent: 22 October 2013 11:15
To: SCHNICHELS Dominik (SANCO)
Cc: [REDACTED]
Subject: request for a meeting

Dear Mr Schnichels,

Further to our earlier exchange of mails, we would like to request a meeting with you to discuss the recently adopted EP amendments on Articles 6 and 14 on the Revision of the Tobacco Products Directive.

Please note that this request is coordinated with PMI and that [REDACTED] is copied in on this mail.

I thank you in advance for considering our request

Best regards

Antonella Pederiva

Secretary General of CECCM
Av Louise 125
B - 1050 Brussels
Tel ++ 32 2 541 00 34
Fax ++ 32 2 541 00 45

Confederation of European Community Cigarette Manufacturers (CECCM) AISBL, registered number 0879 438919 ceccm@ceccm.eu

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PMI Summary

1. Public health experts, including in Member States, recognize that e-cigarettes can help reduce the harm caused by tobacco use.

- The best way to reduce the harm caused by smoking is to prevent initiation and encourage cessation. However, despite the well-known health effects of tobacco use, many people continue to smoke and use other tobacco products.¹
- Nicotine replacement therapies have not meaningfully improved smokers' long-term chances of successfully quitting smoking.²
 - Tobacco control experts attribute that to the fact that NRTs fail to replicate the sensory experience and ritual of smoking.³
 - An additional limitation is *"the fact that no available licensed nicotine-containing product mimics the pharmacokinetic nicotine delivery characteristics of the cigarette."*⁴
- Public health experts have therefore embraced the policy of tobacco harm reduction – i.e., encouraging smokers to use less hazardous forms of nicotine instead of cigarettes. *"Harm reduction provides an option for these smokers to substitute cigarettes, preferably completely, with a less hazardous nicotine source."*⁵
- In order to be effective at reducing harm, e-cigarettes and other alternatives *"need to be acceptable to smokers as substitutes for cigarettes, and available at a price and with marketing and health messages necessary to encourage smokers to substitute them for tobacco smoking."*⁶

2. PMI is working to develop reduced risk alternatives to cigarettes.

- PMI is developing a range of products that (1) smokers will accept as long-term alternatives to cigarettes and (2) are scientifically substantiated as reducing risk of smoking related disease in smokers who switch to them.
- We are currently focusing on three products, including both tobacco-based products and products that do not contain tobacco, and products that use electronics and products that do not. We are continuing to explore other possibilities as well over the short- and longer-term.

3. The new Tobacco Products Directive needs to regulate and encourage less harmful alternatives to cigarettes. Regulation should also apply to e-cigarettes.

- Recital 8 of Directive 2001/37/EC notes that *"[a] revision of the regulatory framework needs to evaluate evidence-based claims for tobacco products designed and/or marketed to 'reduce risk', or for which harm reduction is claimed..."* Similarly, Article 11 of the Directive calls for special attention to developments in scientific and technical knowledge with regard to *"tobacco products which may have the potential to reduce harm."*

- We concur with the view that the new TPD should “*create an ‘enabling framework’ for ... new, much less risky, alternatives to smoking to enter the market in a way that gives consumers confidence in switching from smoking.*”⁷
- Unfortunately, the Commission’s proposal does not recognize that certain tobacco or nicotine containing products may constitute reduced-risk alternatives to conventional tobacco products. A comprehensive regulatory framework should be established including rules and standards for the assessment, evaluation and commercialization of such reduced risk alternatives. Such framework should encourage and incentivize companies to innovate in a direction that advances harm reduction and public health.
- In particular, the TPD should ensure oversight appropriate safety and quality controls for e-cigarettes and continued availability of consumer-acceptable e-cigarettes and other potential forms of nicotine-containing products as alternatives to combustible tobacco products.

¹ 28% of the EU population continues to smoke, despite the fact that over 60% have tried to quit over the past four years. Special Eurobarometer 385, 2012 – Attitudes of Europeans towards tobacco.

² See, for example, Alpert, H., Connolly, G. and Biener, L., A Prospective Cohort Study Challenging the Effectiveness of Population-Based Medical/Intervention for Smoking Cessation, Tobacco Control, 2012; Ferguson, J. et al., Effect of Offering Different Levels of Support and Free Nicotine Replacement Therapy via an English National Telephone Quitline: Randomised Controlled Trial, BMJ 344:e1696, 23 March 2012.

³ UK Centre for Tobacco Control Studies, Response to Consultation, MLX 364: Regulation of Nicotine Containing Products, available at: <http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf>.

⁴ UK Centre for Tobacco Control Studies, Response to Consultation, MLX 364: Regulation of Nicotine Containing Products, available at: <http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf>.

⁵ John Britton, Ann McNeill, Nicotine Regulation and Tobacco Harm Reduction in the UK, The Lancet, June 2013.

⁶ Royal College of Physicians, Harm reduction in nicotine addiction: Helping people who can't quit. October 2007, p. 223.

⁷ Clive Bates, European Union making bad policy on nicotine – five ways to make it better, December 5, 2012, available at: <http://www.clivebates.com/?p=697>.