Ares(2013)3459064

[redacted]

Subject: FW: request for a meeting

From: SCHNICHELS Dominik (SANCO)
Sent: Friday, November 08, 2013 8:20 PM
To: [redacted]
Cc: [redacted] (SANCO); [redacted] (SANCO); [redacted] (SANCO); [redacted] SANCO)
Subject: RE: request for a meeting

Dear Mr [redacted]

Many thanks for this information. Whilst not satisfactory in every aspect I consider it adequate for the time being. Please contact CECCM and agree on a new meeting date with my secretariat ([redacted] or [redacted] in copy).

Kind regards

Dominik Schnichels

From: [redacted]
Sent: Friday, November 08, 2013 6:37 AM
To: SCHNICHELS Dominik (SANCO)
Cc: [redacted]
Subject: RE: request for a meeting

Contains confidential information the disclosure of which would undermine the protection of commercial interests of Philip Morris International Inc.

Dear Mr. Schnichels,

Thank you for your email of November 6. At the outset I would like to reaffirm our continuing desire to cooperate with the Commission's services, both generally and in relation to the important and complex regulatory decisions the Commission, the Council and the Parliament are now addressing in the TPD revision process. Further, I fully appreciate your desire to obtain information in order to facilitate your consideration of the appropriate regulatory regime for e-cigarettes and other non-medicinal nicotine containing products.

[redacted]

However, in an effort to assist you further, I am taking this opportunity to share with you on a confidential basis information regarding our current thinking on the development of non-tobacco nicotine containing products as well as our perspectives on the appropriate form and content of regulation for nicotine containing products. Indeed, the commercial plans we might ultimately pursue will need to take account of and reflect the regulatory framework that emerges in the coming months and years.

Product Development, Assessment and Commercialization

Our strategy for developing a range of products that smokers will accept as satisfying alternatives to conventional cigarettes involves three distinct stages. First, there is the product development phase. Next, our prototype products undergo extensive assessment which can include chemical characterization, non-clinical and toxicological assessment (including confirmation that the prototype does not introduce any new toxicological hazards), and, if necessary, clinical studies as well as consumer research. Manufacturing of such products will take place according to stringent quality standards. Finally, depending on regulatory, commercial and other considerations, the products will be offered to consumers in the commercialization phase. One of our prototype products – which we internally refer to as "Platform 1" – has passed through the development phase and is now undergoing assessment in a series of clinical trials and consumer acceptance testing. We currently expect to be in a position to commercialize this product between 2016 and 2017.

We have nicotine containing prototype products in the development phase which do not contain tobacco. One such product is based on nicotine pyruvate delivery technology acquired in May 2011 by PMI from Professor Jed Rose (the inventor of the nicotine patch) and his co-inventors. The operating principle of this technology is the reaction of pyruvic acid with nicotine in the gas phase, to produce nicotine pyruvate in the form of a respirable aerosol. [redacted]

[redacted]

From time to time, as with the acquisition from Professor Rose and his co-inventors described above, we supplement our internal development work with the acquisition of externally developed technology.

Regulation

As noted above, our commercialization plans for nicotine containing products in the EU are largely dependent on the regulatory framework and environment. As evidenced by the differing views of the Council and the European Parliament, we do not yet know the form or content of the regulatory regime in the EU. From our perspective, emerging technologies merit an appropriately tailored regulatory regime: this is a complex area that does not fit readily into the existing tobacco or pharmaceutical regimes, which of course predate and did not necessarily envision the product categories that are now emerging and will continue to evolve.

We believe that, at a minimum, the resulting regulation should achieve the following broad objectives.

1. Safety and quality standards applicable to e-cigarettes and other nicotine containing products should be proportionate to the health risks of the product so that they prudently enable innovation in the field of tobacco harm reduction.

2. Nicotine containing products should not be sold to minors.

3. Nicotine thresholds should be set at a level that meets consumer demand. If consumers are not satisfied with the products they will not switch away from conventional cigarettes, a result at odds with the goal of harm reduction.

4. Consistent with the public health goal of harm reduction, there is a need to alert consumers to the availability and characteristics of nicotine containing products and to ensure that products that meet applicable safety standards are readily accessible to adults through a wide range of retail outlets. Product advertising, communications and sales channels should be regulated accordingly. Brands, too, could have an important role to play in persuading adult consumers to switch away from conventional cigarettes and for that reason regulators should avoid a *per se* ban on the use of any category of brands

5. There should be mandatory warnings that are consistent with the risk profile of the products.

6. Any claims of risk or exposure reduction associated with such products should be scientifically substantiated.

I very much hope that this additional information is of assistance to DG Sanco in its consideration of the appropriate regulatory regime for nicotine containing products. We are also looking forward to hearing your views on potential solutions to the apparently conflicting views of the European Parliament and the Council relating to the regulation of nicotine containing products. I remain at your disposal for any further information you may require and look forward to our continued dialogue on this important topic.

Best Wishes,

[redacted]

From: Dominik.Schnichels@ec.europa.eu [mailto:Dominik.Schnichels@ec.europa.eu]
Sent: 06 November 2013 20:25
To: [redacted]
Cc: [redacted]
Subject: RE: request for a meeting

Dear Mr[redacted]

Thanks for your mail. Once we have received the requested information on electronic cigarettes from your company we are happy to include PMI in the meeting. If your company decides not to provide the requested information – which is your right – we will limit the meeting to the companies that decided to cooperate with the Commission services.

The reasons to ask for this information are: as you surely know the EP intends to regulate e-cigarettes differently than the Council. Also in recent months there were reports that the tobacco industry is entering the electronic cigarette market. The requested information is therefore considered necessary/relevant for our reflection on how to regulate electronic cigarettes.

I would kindly ask you to let us know until tomorrow evening whether we can expect the requested information from PMI (and if yes by when). In case I do not hear from you, I assume that you decided not to provide the requested information and I will draw the necessary conclusions.

Kind regards

From: [redacted]
Sent: Wednesday, November 06, 2013 7:09 PM
To: SCHNICHELS Dominik (SANCO)
Cc: [redacted]
Subject: RE: request for a meeting

Dear Mr. Schnichels,

I refer to your email of November 4 informing CECCM and PMI of your decision to "postpone" the meeting scheduled for November 5 and to your email of this morning asking whether we "opt out" of the meeting.

I must admit to be being rather perplexed by the content of your emails because we have provided the information which you requested, *to the extent we are in a position to do so*. We have advised you that we do not sell e-cigarettes (please see my email of November 4). In our summary of October 31 we said that "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." We are not in a position to provide DG Sanco with any further details regarding nicotine containing products (other than tobacco products) because our commercial plans are not yet finalized. We have communicated to our shareholders and investors that we aim at commercializing our Product 1 in 2016-2017. Product 1 contains tobacco and therefore does not fall under the definition of nicotine containing products. We also outlined, as requested, our views on the "the safety and quality standards to be applied", in the October 31 summary noting that "the TPD should ensure oversight on appropriate safety and quality controls for e-cigarettes".

Further, It is not clear to me why DG Sanco now proposes to cancel, or postpone or exclude PMI from, a meeting at which information regarding commercial plans for nicotine containing products could not be discussed (your email of October 29 appropriately recognizes the need for confidentiality). Nor do I understand why you propose to take such action, thereby closing off an important opportunity for dialogue between the Commission and the regulated industry, on the basis that you claim to have insufficient information relating to one of three topics on the agenda, particularly given that DG Sanco had already agreed to a meeting to discuss Articles 6 and 14 before you asked to add Article 18 to the agenda (your email of October 23).

I would very much appreciate your clarification of DG Sanco's position and hope that you will reconsider your decision at least so that the meeting can proceed to discuss Articles 6 and 14 as originally agreed.

Best Wishes,

[redacted]