



Philip Morris International

Mrs. Marianne Klingbeil  
European Commission  
Secretariat General  
B - 1049 Brussels

SG - DSG 2
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Brussels, 21 May 2012

Dear Mrs. Klingbeil,

Further to an earlier meeting we had and following your advice to always come back to you in case of important new developments, I take the liberty to draw your attention to new facts regarding the pending Tobacco Products Directive (TPD) revision. It pertains to the development of products that have the potential to reduce the risk associated to smoking, also often called "next generation products" or "NGPs". I would like to kindly request a meeting with you to share progress in this matter.

In general, we would like to emphasize the importance of reducing the risk for those who continue to use tobacco, which has become an area of intense interest in the public health, regulatory and public policy communities over the last ten years. Neither current pharmaceutical regulations nor the TPD in its current form or anticipated revisions to it appropriately regulate these products. Recital 8 of the current TPD remains true today: *"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 by the manufacturers."*

PMI believes that the TPD should be revised to incorporate this important public health concept and specifically provide for the adoption of a science based regulatory framework for the assessment of reduced risk products and related product claims. Since we are making progress every day in the development of modified risk products, we would like to ensure that in a way the Impact Assessment on TPD would reflect these key aspects. We have shared specific views with DG SANCO (Unit D4) on 8 March 2012, as well as with the Cabinets of Commissioners Tajani and Geoghegan-Quinn, and we would welcome the opportunity to share our thoughts with you directly.

With best wishes,

Kristof Doms

Enclosures:

- Minutes of the meeting between DG SANCO – PMI 8 March 2012



EUROPEAN COMMISSION  
SECRETARIAT-GENERAL

Deputy Secretary General

Brussels, 25 JUIN 2012  
SG C2/PD/ec Ares(2012)

Mr. Kristof Doms  
Philip Morris International  
EU Office  
Rue Montoyer, 51  
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Dear Mr. Doms,

Thank you for your letter of 21 May 2012 requesting a meeting to discuss the ongoing review of the Tobacco Products Directive.

I am glad to learn that you have already directed your comments to the lead service for this initiative, DG SANCO, as well as to a number of other colleagues.

From my perspective, I regret to inform you that I would not be in a position to take any action. As Chair of the Impact Assessment Board, I must ensure its objectivity and independence. It would, therefore, not be appropriate for me to discuss substantive issues that relate to an impact assessment in preparation.

Yours sincerely,

Marianne Klingbeil