From: WATSON John (SG)
Sent: Monday, May 03, 2010 3:25 PM
To: IGLESIA GOMEZ Maria (SANCO)
Cc: KLINGBEIL Marianne (SG); SCHARRENBORG Robertus (SG)
Subject: Meeting on revision of tobacco products directive

Maria,

For info.

Marianne and I just had a short meeting with Philip Morris (Antoine Lefranc and Kristof Doms - Marianne had met AL recently at a conference in London and he asked to meet her here).

We had a general discussion on IA and then on two specific points related to the revision of the tobacco products directive:

1. follow-up to a meeting they had in SANCO in December on a report done by RAND. They sent comments in January and wondered if they will be able to comment again before the report is finalised. We weren't able to confirm that, but said that even if the report is now published in final form, they are free to send SANCO any additional comments they might have.

2. the roadmap: they very much welcomed the publication of the roadmap on the tobacco directive and the transparency it brings. They asked if they could provide comments on it (they wondered, for example, if AGRI and TAXUD would be part of the interservice group). We said that they could as the idea of the roadmaps, as indicated in the IA Guidelines, is to allow stakeholders to be involved early in the process.

John

From: WATSON John (SG)
Sent: Tuesday, June 15, 2010 12:30 PM
To: KLINGBEIL Marianne (SG)
Cc: GREMMINGER Michael (SG); SCHARRENBORG Robertus (SG); MCCOLM Helen (SG)
Subject: RE: Tobacco ....

Marianne
I met Antoine Lefranc for coffee. I repeated what I said in the telephone conversation. No new elements although he gave me some documents which I will pass on Helen. He will write to the DGs of Trade and Sanco to express his concerns on the inconsistency of the Commission's approach to tobacco issues in the WTO and the WHO, and the lack of a scientific basis for the WHO recommendation on tobacco additives, which apparently the Commission will sign up to.
I assume I will get the other side of the story at the Smoke Free Partnership event at the end of June .....
John

From: WATSON John (SG)
Sent: mercredi 9 juin 2010 16:17
To: KLINGBEIL Marianne (SG)
Cc: GREMMINGER Michael (SG); SCHARRENBORG Robertus (SG); MCCOLM Helen (SG)
Subject: Tobacco ....

Marianne
given the sensitivity of our relations with the tobacco world and to ensure full transparency ..... I had a call from Antoine Lefranc of Philip Morris (we met him with a colleague a month or so ago). He wanted to discuss an issue on the revision of the tobacco directive, and an apparent inconsistency of approach between SANCO (on public health issues) and TRADE (on WTO related issues). I told him I did not know enough of the detail to comment, but suggested he contact the experts in the DGs, or ultimately write to the respective director generals to raise his concerns. He asked to meet for a coffee on 15 June which I have pencilled in, but will confirm later. ..... I have explained this to Maria Iglesia in DG SANCO.
John

PHILIP MORRIS
INTERNATIONAL
CORPORATE AFFAIRS, EUROPEAN UNION OFFICE

Mr. Watson
Head of Unit Better Regulation and Impact Assessment
European Comission
Rue de la Loi 200
1049 Brussels

July 5, 2010

Dear Mr. Watson,

Further to our meeting in the spring on the subject of the upcoming review of the Tobacco Products Directive, we take the liberty to attach a commentary we prepared on an "Annotated Bibliography" which was recently distributed to all the Member States. Philip Morris International was requested to comment on this document by several Member States.

The "Annotated Bibliography" was distributed in the context of discussions on the FCTC Guidelines, where there is a proposal to ban the use of all ingredients in tobacco products. It was understood by Member States to provide the necessary scientific evidence to support such a ban.

As this issue is also likely to arise in the context of the review of the Tobacco Products Directive, we are bringing this to your attention in order to respectfully ask the necessary standard of objective evidence be reflected in the impact assessment related to that review.

As said in our meeting, we welcome the up-coming review of the Tobacco Products Directive and welcome a review of the use of ingredients in tobacco products. However, any such review must be based on the best evidence available, should be scientific and objective.

We hope our comments are useful and will be happy to provide you with any further information on this issue.

Yours Sincerely,

Kristof Doms
Vice President EU Affairs

CC: Ms. Patricia Brunko, DG SANCO Health Law and International

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EUROPEAN COMMISSION
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Directorate C
SG-C-2
Better Regulation and Impact Assessment

Brussels,
SG C2/HM/ec
Ares(2010)429981 and 429926

Mr Kristof Doms
Vice President EU Affairs
PHILIP MORRIS INTERNATIONAL
Rue Montoyer 51
1000 Brussels

Dear Mr. Doms,

Thank you for your letter of 5 July and for the three enclosed documents, namely the *'Annotated Bibliography: Additives in Tobacco Products'* prepared by the Key Facilitators of the Working Group, the commentary by your organisation and the commentary by Professor Alfred Kuss.

I have taken note of this information and retained it for future reference.

Yours sincerely,

John Watson
Head of Unit

C.c.: M. Klingbeil, H. McColm, R. Scharrenborg (SG)
Patricia Brunko (DG SANCO)

PHILIP MORRIS
INTERNATIONAL

CORPORATE AFFAIRS, EUROPEAN UNION OFFICE

Mrs. Marianne Klingbeil
Mr. John Watson
EU Commission, Secretariat General
Better Regulation, Evaluation and Impact Assessment,
B-1049 BRUXELLES

Brussels, October 25, 2010

Re: Final RAND Report "Assessing the Impacts of Revising the Tobacco Products Directive"

Dear Mrs. Klingbeil,
Dear Mr. Watson,

Further to our meeting earlier this year where we discussed the on-going work on the revision of the Tobacco Products Directive, we take this opportunity to provide you with a copy of a submission we have recently presented to DG SANCO.

As you may be aware, DG SANCO requested RAND Europe to prepare a study to support DG SANCO's Impact Assessment on a revision of the Tobacco Products Directive.

The Final RAND Report has now been published and DG SANCO invited stakeholders to provide their commentary. DG SANCO also organized a stakeholder consultation meeting last week to listen to the views of tobacco manufacturers, tobacco growers, retailers, unions and employers' representatives, suppliers and consumer representatives. That meeting revealed the deep concerns of all stakeholders regarding the quality of the RAND Report, including the inaccuracy of the data presented, the faulty and non-transparent methodology used by RAND, and the fact that RAND completely ignored readily-available published research and data.

We enclose an executive summary of our submission and a CD-ROM which includes our entire submission, including the Annexes where we provide copies of all of the studies we reference.

We believe the Commission's final impact assessment must address these very real shortcomings if it is to be used as a basis to support the Commission's eventual proposals to revise the Tobacco Products Directive.

With best regards,

Kristof Doms
Vice President EU Affairs

Cc: Mrs. Catherine Day, Secretary General, EU Commission, Secretariat General

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Executive Summary

Submission of Philip Morris International of 20 October 2010 on RAND Europe's Final Report "Assessing the Impacts of Revising the Tobacco Products Directive"

This Final RAND Report examines various options which DG SANCO is considering regarding revision of the existing Tobacco Products Directive (TPD) and is intended to support DG SANCO's eventual Impact Assessment.

We believe the RAND Report is so fundamentally flawed that it cannot be used as the basis for the Commission's Impact Assessment, or as the basis for any public policy decisions.

First, RAND's speculation that various policy options will reduce smoking prevalence by 0.5% is a baseless over-estimate. As we show in **Section II** of our submission, this key 0.5% estimate, at the heart of RAND's impact assessment model, is based on a series of past projections about unrelated measures which were forecast but never verified by the UK Department of Health. Moreover, in RAND's own words, the 0.5% estimate is an "*overestimation*" and is well within the margin of error of RAND's "*blunt*" and "*imprecise*" model. It would be a mistake to base such far-reaching proposals as plain packaging and oversized health warning labels on such a flimsy foundation.

Second, RAND has simply ignored the impact any of the policy options will have on illicit trade and the implications rising illicit trade would have on prices, tax revenues and smoking prevalence, particularly amongst youths. As we show in **Section III.A** of our submission, illicit trade – which is larger in size than the French legal market and costs €10 billion in tax losses annually – is given barely half-a-page in the 344-page Report. RAND's failure to assess the impact of illicit trade is all the more disappointing since all have agreed it must be a critical component of any analysis of tobacco control options.

Third, RAND's "rapid review" of the evidence overlooks key evidence. In its Interim Report, RAND said that as a next step, its research team would conduct systematic literature reviews for each area of change. However, as we show in **Section III.H** of our submission, RAND did not conduct such systematic literature reviews for each policy option, but instead, simply carried out "*rapid reviews*" of the data. As RAND itself admits, the data it relied on were of very poor quality.

RAND's rapid reviews completely overlooked relevant, readily available information. For example, RAND ignored data published by Eurobarometer which shows that smoking prevalence increased in Belgium and the UK following the introduction of pictorial health warnings. Instead of looking at those actual data from Member States, RAND's assessment of health warnings was based on a 1991 study from the US and a 2004 study from Canada. How can those be considered more relevant or more robust than actual data from the EU? Because it consistently relied upon speculative studies instead of robust data, the "evidence" in the Final RAND Report is completely unreliable.

Fourth, because its data are inaccurate, RAND's conclusions are questionable, as we show in **Section III** of our submission. Even some of the most basic facts – such as the number of people employed in the tobacco sector – are completely inaccurate. For example, as we show in **Sections III.D and III.F** of our submission, RAND underestimates the numbers employed in the wholesale and retail sectors by at least one million, and completely ignores hundreds of thousands of tobacco farmers.

As we show in **Section III.C** of our submission, RAND fails to accurately report the historical tax revenue data for the EU Member States, which should be a fairly straightforward exercise of simply copying tables produced by DG TAXUD. In Table 4.12, RAND completely leaves out France and Poland – which together account for nearly 13 billion Euros – but does manage to report on 27 countries by including Switzerland and Norway. In fact, the Table put forward by RAND only manages to get the figures right for just two of the Member States.

As we show in **Section III.A** of our submission, RAND fails to accurately describe the serious level of illicit trade already present in the EU. RAND says that Member States lost revenues of 230 million Euros in 2007 due to smuggling – but it only counts losses from the seized products. This is simply wrong. In 2007, the Commission estimated total losses from illicit trade at around 6 billion Euros. More recently, the Commission put the figure at 10 billion Euros. RAND underestimated the size of illicit trade by more than 9.5 billion Euros.

These are just a few examples of the inaccurate data and mistakes made in the RAND Report. RAND's carelessness in gathering the underlying data to assess the economic and health impacts of different policy options presented to it is reason enough to reject the Report.

Fifth, and perhaps most importantly, neither RAND nor DG SANCO has carried out the most critical threshold analysis of the various options. As we discuss in **Section III.G** of our submission, neither RAND nor DG SANCO has provided any assessment of the impact on the functioning of the internal market of any of the options, even though this should have been a key part of RAND's analysis. Neither RAND nor DG SANCO has carried out an assessment of whether the EU is even competent to enact any of these options, nor addressed the fundamental issues of subsidiarity and proportionality. One wonders why both stakeholders and the public are being consulted on these options before this fundamental analysis has been undertaken. This calls into question not just the credibility of the RAND report, but also the integrity of the entire consultation process.

In sum, the RAND Report contains seriously inaccurate data, is based on poor and unreliable evidence, puts forward misleading and meaningless estimates, ignores many key impacts and fails to explain the underlying methodology.

PMI continues to support meaningful regulation which promotes the public policy objective of reducing the harm caused by tobacco products. In order to achieve this objective, such regulation must be based on an informed, thorough and rigorous analysis of the impacts of any proposed measures. The RAND Report fails to provide that.

As a result, relying on RAND's incomplete and inaccurate analysis could lead EU regulators to enact laws which they believe will promote a health policy objective, but which will, in fact, have the opposite effect. An increase in illicit trade, an increase in smoking prevalence, an increase in youth smoking is not on anyone's agenda – but that will be the real impact of many of these proposed options.

We are hopeful that DG SANCO will respond to these very serious concerns and provide us and other stakeholders with meaningful opportunities to further contribute to this process in order to provide EU regulators with a realistic impact assessment.

EUROPEAN COMMISSION
SECRETARIAT-GENERAL

Directorate C
SG-C-2
Better Regulation and Impact Assessment

Brussels, 17 November 2010
SG C2/HM/ec

Mr Kristof Doms
Vice President EU Affairs
PHILIP MORRIS INTERNATIONAL
Rue Montoyer 51
1000 Brussels

Dear Mr. Doms,

Thank you for your letter of 25 October and for the enclosed CD-ROM containing the extensive submission that you recently presented to DG SANCO.

I have taken note of this information and retained it along with the material you sent earlier this year for future reference.

Yours sincerely,

Michael Gremminger
Acting Head of Unit

C.c.: M. Klingbeil