EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C6 – Health Law and International

Meeting with stakeholders on the study "Assessing the Impacts of Revising the Tobacco Products Directive" prepared by RAND Europe

Summary record

Meeting date: 20 October 2010, 9.30
Brussels, Rue Froissart 101, 08/120

1. Welcome and introduction

The Chairman welcomed the present representatives and there was a short presentation of the participants.

2. Adoption of the draft agenda

The draft agenda was adopted without amendments.

3. Presentation of the RAND report

The Commission gave a short presentation on the study "Assessing the Impacts of Revising the Tobacco Products Directive" prepared by RAND Europe and explained the ongoing work consisting of;

1. A public consultation with the objective to get the views of all stakeholders on the problem definitions and policy options for addressing these problems effectively was launched on 24 September. The Chairman announced the extended deadline for the public consultation until 17 December 2010.

2. An assessment of the impact of the proposed changes, resulting in an impact assessment report from the Commission. The RAND report will be one of the sources of information used when working on the Impact Assessment.

The Chairman underlined that the RAND study is independent, and that it does not express the views of the Commission. As the RAND study will be used for the Commission's Impact Assessment further comments from all stakeholders on the RAND report are very important.

The Chairman invited the participants to send comments not only rejecting certain data, but also proposing alternative data as it is crucial that the Commission uses accurate data for its Impact Assessment. All comments sent in before the end of the year will be taken into consideration.

4. Discussion

The present representatives were invited to comment on the RAND report. The Chairman asked for constructive comments specifically on the scope of the directive, and the impact of pictorial warnings and labelling measures.

4.1 Baseline scenario and employment

- The calculation in the baseline scenario is on the low side. Accurate figures will be submitted.
- A UK study including an impact assessment will be submitted.
- It is very hard to assess the impact of going from tobacco to nicotine products. Example from Australia.
- Is there a co-relation between a decrease in consumption and employment?
- Production can drop quite a lot before there is an effect on employment. There are other factors which affect employment.

4.2 Online reporting systems

- Could there be security-problems with respect to trade secrets if submissions/reports to authorities are made electronically?
- Today all documents are sent trough e-mails. The authorities will use the data in the same way irrespectively if it is submitted electronically or by regular mail.
- Electronic submissions lower the administrative burden, and digitalization makes it easier to keep track of things.

4.3 Scope

- Products such as e-cigs are currently in the grey zone between tobacco products and pharmaceuticals and consequently not covered by any regulation. There is no common approach in this area.
- Nicotine products should be separated from tobacco products.

The Chairman asked for comments on how this could be achieved. Non-tobacco products could either be classified as pharmaceuticals, or there would have to be e a safety net in the Tobacco Products Directive (TPD) which includes nicotine products. Different opinions were shared.

- It was suggested that non-tobacco nicotine products should be put more firmly into the medicinal area and consequently fall into the scope of pharmaceutical regulation. It should then be made clear through the definition of products in the TPD that non-tobacco products do not fall within its scope, and there should be a reference to regulation in the medicinal area.
- There is confusion about nicotine among doctors; some think nicotine is the problem in cigarettes. Mixing non-tobacco nicotine products with tobacco products might cause an even bigger confusion.
- If nicotine products are not included in the pharmaceutical area there is no requirement for clinical approval. This may lead consumers into thinking that these products are less dangerous than they are. It might however be possible to put some safety criteria in the TPD.
- E-cigarettes will be more difficult to market if they are considered as pharmaceuticals. In Canada different parts of the e-cigarettes are regulated through different areas of regulation; tobacco, medicine and medical device.
- Nicotine products could be included in the scope of the TPD, as products including nicotine should not be considered as medicines.
- There is a difference between how manufacturers and consumers look at nicotine products. If these products help to cease smoking, could they be seen as medicines? Harm reduction products can be included in the medicinal regulation.

4.4 Harm reduction

There was a discussion on how to reach the smokers who don’t believe they can quit. This group of people could possibly be helped by nicotine therapy, which would work as a "one step at the time" harm-reduction with the aim to become nicotine free in a long term perspective.

- UK consultation on harm reduction has been finalized and will be published. A link to the consultation will be submitted.
- Smoking addiction should be seen as a disease which should be treated through medicine (for example nicotine products). There has to be a clear distinction between tobacco products and non-tobacco nicotine products.
- Can smokeless tobacco be used as a harm reduction product?
- Smokeless tobacco could possibly be used for harm-reduction. There is however still question marks. How safe is safe enough? Why make smokeless tobacco available when there are nicotine products available?
- Can existing products such as e-cigarettes be used for harm reduction or is there a requirement for new products?
- It has to be acknowledged that the current products are not ideal for harm reduction. There are ongoing product development programs so this might be taken into account for the future.

4.5 Labelling

- The Chairman asked for comments on administrative burdens on industry to change labels. Could there be a comparison with figures from pharmaceutical industry?
- The regulatory procedures are very different for pharmaceuticals, this means it might be hard to compare. Control of packages is rigorous in the pharmaceutical sector – these costs are probably higher than the costs involved with changing a label.
- In the pharmaceutical sector there are different package formats in different countries. Costs for production of packages are very high, among others because of the required control of the list of contents.
- The focus should not only be on why to quit – also positive messages (solution) on how to quit; such as numbers to quit lines and recommendations such as "speak to your doctor".

4.6 Concluding remarks

- Health warnings are a good way to decrease smoking prevalence.
- Those selling cigarettes should also be required to provide information on cessation.
- In the US there are posters which say: "have you considered quitting" at cigarette points of sale. This could also be considered for Europe.
- A study on additives will be submitted.

Annex I – List of Participants

Paharmaceutical Industry

Glaxo Smith Kline consumer Healthcare
Novartis
Johnson&Johnson
Pfizer European Government Affairs
European Federation of Pharmaceutical Industries and Associations (EFPIA**)**

Commission services:

Mr Antti Maunu	DG SANCO C6 (Chair)
Ms Terje Peetso	DG SANCO C6
Ms Anna Eva Ampelas	DG SANCO C6
Ms Anna Jassem-Staniecka	DG SANCO C6
Ms Magdalena Ahlberg	DG SANCO C6
Ms Rossella Chiodo	DG SANCO 02
Ms Mathilde Reynaldi	DG SANCO 02
Mr Dalibor Mladenka	DG SANCO 02