Ref. Ares(2012)1435576 - 04/12/2012

From: Lars Ramström [mailto:lars.ramstrom@tobaccostudies.com]
Sent: Monday, April 16, 2012 4:04 PM
To: KLAUS Henning (CAB-BARROSO)
Subject: EU Tobacco Products Directive

Dear Mr. Klaus,

The ongoing revision of the EU Tobacco Products Directive involves important questions regarding the scientific evidence that should be the basis for a regulatory system serving the purpose of a high level of health protection. As far as smokeless tobacco is concerned there has been a very rapid advancement of that scientific basis, and last year a group of prominent researchers found it appropriate to elucidate this development in a letter to Commissioner Dalli. Now a Swedish MEP, Mr. Christopher Fjellner, has given me an indication that you may be interested to receive copies of that letter and the response from DG SANCO, and I hereby take pleasure in attaching these documents.

The response from DG SANCO raises concerns about how thoroughly the most recent advancement of science is taken into account. For example, there is no attention given to the evidence pointed out in the researchers' letter about the wide international recognition that the Swedish product, snus, has been beneficial for public health as a contributing factor behind the development making Sweden the European country with lowest level of smoking and all tobacco-related diseases including oral cancer. A revised Directive with status quo regarding ruling on smokeless tobacco would be utterly unscientific by banning the least harmful product while much more harmful kinds of smokeless tobacco are allowed. A Directive combining continued ban of snus with regulation of other kinds of smokeless tobacco would be an even more startling version of negligence of science. A regulation of other-than-snus kinds of smokeless tobacco will mean that the very most harmful products are banned, while at the same time the products allowed for sale would be more harmful than the least harmful one, snus, that in this alternative would be kept under a specific, not scientifically justified ban.

A smart regulation would have to put all kinds of smokeless tobacco products under a

common system that bans the most harmful products and exploits the potential public health benefits of the least harmful ones.

I very much value your interest in these matters and hope that you will find the attached data useful. Please do not hesitate to contact me if you would need further details.

Sincerely,

Lars M Ramström Ph.D.

Director and Principal Investigator
Institute for Tobacco Studies
Stockholm, Sweden

www.tobaccofindings.org

Mr. John Dalli
European Commissioner for Health and Consumer Protection
European Commission
B-1049 Brussels, Belgium

Sir,

A group of researchers from eight countries in three continents would like to draw your attention to the advancement of the scientific basis for the revision of the EU Tobacco Products Directive. As coordinator of the group I hereby take pleasure to convey to you, as an attachment to this mail, a letter where we develop a number of important points.

All signatories have by email to me approved of the wording of the letter.

Yours sincerely,

Lars M Ramström PhD

Director and Principal Investigator
Institute for Tobacco Studies
Stockholm, Sweden

Supplementary hard copy of letter originally sent by email.
(Authors' "signatures" provided as electronic approval messages.)

2011-05-31

Mr. John Dalli,
European Commissioner for Health and Consumer Protection
European Commission
B-1049 Brussels, Belgium

Copy to

Michel Barnier, European Commissioner for Internal Market and Services,
José Manuel Barroso, President of the European Commission
Máire Geoghegan-Quinn, European Commissioner for Research and Innovation
Marianne Klingbeil, Deputy Secretary General, Secretariat General, European Commission
Cecilia Malmström, European Commissioner for Home Affairs
Antonio Tajani, Vice- President of the European Commission
European Commission B-1049 Brussels, Belgium

The advancement of the scientific basis for the EU Tobacco Products Directive

Sir,

As a group of scientists whose research is targeted towards minimizing tobacco-induced diseases we very much welcome your statements that a tougher stance is needed on smoking as a major health threat. We are convinced that the current revision of the EU Tobacco Products Directive can strengthen the effectiveness of the directive to ensure a high level of health protection. But, we are also aware that an optimal result cannot be achieved unless particular attention is given to the advancement of the scientific basis.

We have noticed that the ongoing general discussion around the revision contains various examples of suggestions that are not completely in line with latest scientific evidence. Therefore we would like to highlight both some corner-stones of tobacco science and some recent advances that would constitute essential parts of an appropriate scientific basis for the revision.

From a scientific perspective the provisions of the Tobacco Products Directive should take into account that different tobacco and other nicotine delivery products vary substantially in their health risk and addictiveness. Nicotine is an addictive substance but plays a minor role in causation of tobacco-induced diseases which are mainly caused by the combustion products that accompany the nicotine in tobacco smoke. Consequently, combusted tobacco products represent the most risky nicotine products and non-combusted products are lower in risk. Among the non-combusted nicotine products there is also a wide spectrum of health risk, ranging from highly toxic South-East Asian and Sudanese tobacco products to American snuff, Swedish Snus and non-tobacco nicotine products.

The most logical kind of tobacco product regulation for health protection would be to ban all combusted products and subject combustion-free tobacco/nicotine products to strict regulation according to risk level. An immediate ban of cigarettes and other combusted tobacco products is not feasible, but the possibility of successively phasing out these products over the long term deserves consideration. In the short term, establishing a regulatory framework for all tobacco products is much more feasible and could assist the eventual phasing out of combustible tobacco (Royal College of Physicians, 2008; Le Houezec et al., 2011). Proposals for the design of such regulation are readily available in the third report of the WHO study group on tobacco product regulation (WHO, 2009).

The WHO Framework Convention on Tobacco Control, FCTC, points out (in Article 1) that tobacco control means a range of supply, demand and harm reduction strategies. The "harm reduction strategies" deserve particular attention here, since there is evidence suggesting that such strategies can yield substantial health benefits in tobacco control, if smokers are encouraged to use less harmful nicotine products in appropriate ways (Royal College of Physicians, 2007; European Monitoring Centre for Drugs and Drug Addiction, 2010). The products with the greatest potential for use in tobacco harm reduction are non-tobacco nicotine products and low-toxicity combustion-free tobacco, such as Swedish Snus. It has been estimated that for total mortality, the median relative risks for individual users of such products were 9% and 5% of the risk

associated with smoking for those aged 35 to 49 and ≥50 years, respectively (Levy et al., 2004). Another study has elucidated comparative health risks by calculating the shortening of life expectancy due to different patterns of tobacco use. Those who after quitting smoking use snus are estimated to have almost equally small shortening of life expectancy as those who quit all nicotine use (Gartner et al., 2007). There are no corresponding data for non-tobacco nicotine products, but it could be assumed that their effects are similar.

It should further be noticed that switching to a combustion-free tobacco/nicotine product may also be a stepping-stone to subsequent nicotine-free status so as illustrated by analyses of snus use in Sweden (Ramström & Wikmans, 2011).

All disease-specific health risks are much smaller for low-toxicity combustion-free tobacco/nicotine products than for cigarettes. "Complete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking." (SCENIHR 2008; p. 113). "It is therefore reasonable to draw a conservative conclusion that substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%." (SCENIHR 2008, p. 114). As far as oral cancer is concerned combustion-free tobacco/nicotine products from South-East Asia and Sudan, incur serious risk, while no such association has been found for Swedish snus (Luo et al., 2007). Some earlier studies suggested a possible association between snus and pancreatic cancer (although weaker than the association with smoking). However, the most recently published study, co-authored by one of the authors of the old study, is now rejecting the older conclusions (Bertuccio et al., 2011).

Evidence from Sweden has been summarized by saying: "In Sweden, the availability and use by men of an oral tobacco product called snus, one of the less hazardous smokeless tobacco products, is widely recognised to have contributed to the low prevalence of smoking in Swedish men and consequent low rates of lung cancer. " (Royal College of Physicians, 2008; p. 4), or, "Thus in Sweden, where there has apparently been substantial transfer from smoking to snus, the availability of snus may have been beneficial to public health." (SCENIHR, 2008; p. 117). A recently published study has further illustrated how the use of snus in Sweden has contributed to the decline of smoking in the 1990s (Stenbeck et al., 2009).

Low-toxicity combustion-free tobacco/nicotine products may be beneficial for public health by serving as smoking cessation aids that are easily available for large scale unassisted smoking cessation in the real world outside clinical settings. This is the context in which smoking cessation plays its major role as a public health tool (Chapman & MacKenzie , 2010). Some Swedish studies suggest that Snus may be the most effective aid for self-help quitters and among men the most commonly used one (Ramström & Foulds, 2006; Ramström & Wikmans, 2011). Recent studies in Norway equally found that quit attempts with snus have yielded a higher success rate than other methods thereby demonstrating that the validity of the Swedish findings is not limited to Sweden with its specific traditions (Lund et al., 2010; Lund et al., 2011). The combination of high usage and high efficacy that has consistently been found in the Scandinavian studies suggest a high level of efficiency of low-toxicity combustion-free tobacco products as smoking cessation aids in unassisted smoking cessation in the real world. Further, a recent short term randomized study found that Camel snus produces abstinence rates at least equivalent to 4 mg nicotine gum (Kotlyar et al., 2011).

In the discussions regarding public health aspects there have been concerns that there could be a risk of unintended negative side-effects. For example, products like snus might be a gateway to subsequent initiation of smoking in non-smoking adolescents. However, several studies have found that this has not occurred in Sweden (Furberg et al., 2005; Ramström & Foulds, 2006; Galanti et al., 2008). Most but not all corresponding studies in the US show results consistent with the Swedish findings in that they do not show that youth smokeless use causes an increased subsequent use of smoked tobacco (O'Connor et al., 2005; Timberlake et al., 2009). There are also concerns that dual use of cigarettes and combustion-free tobacco might weaken the motivation to quit smoking or that switching from cigarettes to snus might strengthen nicotine dependence. However, recently published studies have not found support for these concerns (Frost-Pineda et al., 2010; Ramström & Wikmans, 2011). The risk of all these potential negative consequences could also be minimised through appropriate regulation of all tobacco products.

We have a vision of a tobacco-free society, but along the road towards that goal we must help minimise the health burden of remaining tobacco use through appropriate regulation of all tobacco/nicotine products based

on their level of health risk. We hope that the revised EU Tobacco Products Directive will be an effective part of such efforts.

Yours sincerely,

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, Professor, The Cancer Council Victoria, Australia.

, Professor of , University of Nottingham. UK.

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, Professor, The University of Queensland Centre for Clinical Research, Brisbane, Australia.

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, Emeritus Professor of Health Psychology, University College, London. UK.

, Professor, School of Public Health and Health Professions, University at Buffalo, State University of New York. NY, USA.

, Univ.Prof., Institute of Social Medicine, ECDC (European Centre for Disease Prevention and Control), Centre of Public Health, Medical University Vienna, Austria.

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Lars Ramström, Principal Investigator, Institute for Tobacco Studies, Stockholm, Sweden.

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Ref. Ares(2011)680958 - 24/06/2011

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Director

Brussels,
D4/AR/AA D(2011)

Dear Mr. Ramström,

Subject: **The advancement of the scientific basis for the EU Tobacco Products Directive**

Thank you for your e-mail of 31 May 2011 to Commissioner Dalli regarding combustion-free tobacco/nicotine products. As Director responsible for tobacco control, I have been asked to reply to you.

Oral tobacco was banned in the EU as early as 1992 to ensure a proper functioning of the internal market and take as a base a high level of health protection. At that stage, three Member States had already banned oral tobacco.

The harmful health effects of all smokeless tobacco were confirmed by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in February 2008. The Committee concluded that all smokeless tobacco products contain nicotine and carcinogenic tobacco specific substances, even if at different levels. Therefore, all those products are addictive and can cause cancer.

It is true that the health risks might be smaller for some of the combustion-free products, but this does not mean that these are safe or harmless products at all. Products with lower levels of carcinogenic tobacco-specific nitrosamines have been on the market for too short time for any convincing support in favour of the presence or absence of a lower cancer risk.

We are aware of Swedish data not supporting the hypothesis that smokeless tobacco is a gateway to future smoking. The SCENIHR opinion, however, stresses that it is not possible to extrapolate future patterns of tobacco use across countries due to societal and cultural differences.

Mr. Lars M Ramström
Director and Principal Investigator
Institute for Tobacco Studies
Stockholm, Sweden

e-mail: lars.ramstrom@tobaccostudies.com

In conclusion, we consider that the SCENIHR opinion calls for a very cautious approach as regards all smokeless tobacco. When we speak about prevention and the cost of the health systems we cannot at the same time support action that would allow for the marketing of a new product that is essentially harmful to health.

Yours sincerely

Andrzej Rys

c.c.: CAB DALLI

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