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17 June 2013

From:

Dear Mrs Krag,

Re: Tobacco Products Directive and snus - Denmark's potential role

We are writing to you as independent public health specialists as the Tobacco Products Directive continues its passage through the European Parliament and Council. We write to express our hope that you personally will take a positive approach to oral tobacco ('snus') in forthcoming discussions in the European Health Council. We were greatly encouraged by the reasoned opinion of Denmark's parliament and hope that Denmark will play a positive role in overturning more than two decades of the highly counterproductive ban on snus throughout the European Union outside Sweden. This would be a victory for public health, consumer rights and common sense.

Health potential of snus in Denmark and the rest of Europe. There has been a remarkable success for public health in Sweden that deserves more recognition by policy-makers in other member states. According to the most recent Eurobarometer survey¹, adult smoking prevalence in Sweden is just 13%, half the level of Denmark and far lower than the EU average of 28%. The reason for this is perfectly clear: it is that, in Sweden, snus has been widely used to quit smoking or as an alternative to cigarettes. Given that the risks associated with snus use are of the order of 95-99% lower than for smoking², this has resulted in substantially reduced burdens of tobacco-related disease (cancer, cardiovascular disease, emphysema). The rate of lung cancer mortality in Sweden is half that of Denmark according to the most recent figures available from the World Health Organisation³. Sweden also has significantly lower levels oral cancer mortality.

The tobacco harm reduction concept. Throughout Europe starting in the 1960s there have been steadily increasing efforts to reduce smoking through controls on marketing and branding, health warnings, taxation, restrictions on smoking in public places, information campaigns and support for smoking cessation. Smoking rates have reduced considerably, and impressively in Denmark, but today more than one in four adults in Denmark still smokes, and the WHO still predicts one billion premature deaths from tobacco worldwide in the present century. The experience of wider snus use points the way to a new and additional strategy – tobacco harm reduction. This means helping the many people who are unable or unwilling to give up nicotine or tobacco to use it in ways that cause

them dramatically reduced harm. Snus and the new nicotine products, such as e-cigarettes, meet this important need and there is no case – scientifically or ethically - to restrict them in the ways envisaged in the proposed directive. That point was made sharply and correctly in the Danish parliament's reasoned opinion⁴:

The majority cannot therefore support a ban on the marketing of 'snus', regardless of how it is packaged. The majority furthermore notes that 'snus' is less harmful to health than conventional cigarettes and does not lead to passive smoking".

We would like to summarise the problem and propose a pragmatic solution.

Problem. Under the proposed directive, snus would remain banned outside Sweden and smokers will be denied options to reduce their risk – this is detrimental to public health in Denmark

- The ban on oral tobacco (outside Sweden) has no scientific basis: the evidence points to significant <u>net health benefits</u> from snus use due to reduced smoking with no evidence of significant 'gateway effects' or other unintended and undesirable consequences;
- It is deeply unethical: in our view it is an abuse of authority to deny any tobacco or nicotine user access to products that may greatly reduce their individual risk there are many existing potential snus users among Northern Europe citizens moving freely in the European Union;
- There are no precedents: we cannot identify any other product where a much less hazardous alternative (snus) to the dominant high-risk product (cigarettes) is banned. While cigarettes are widely available in the EU, there can never be a case for banning a vastly safer alternative;
- The ban is unlawful: both common sense and professional legal opinion suggest a ban on an arbitrarily defined sub-category of smokeless tobacco is discriminatory and disproportionate and certainly does not contribute to a 'high level of health protection' within the single market;
- There is no internal market logic: the ban protects the cigarette category from competition and penalises businesses and employees that make a significantly less damaging tobacco product.

Proposed solution. We believe this is politically achievable and would create a more rational approach to oral tobacco / snus in Europe.

- 1. Replace the ban with a regulatory framework for all smokeless tobacco that would limit the toxic contaminants that potentially cause harm. That approach is already used voluntarily for snus in Sweden and Denmark. This could remove from the market some of the more dangerous smokeless tobacco products that would otherwise remain on sale under the proposed directive. The WHO's expert group on smokeless tobacco recommended exactly this⁵, and the approach is supported by the UK Royal College of Physicians and many experts.
- 2. If a complete lifting of the ban is politically impossible, then the decision to ban oral tobacco should become a matter for each member state reflecting the diverse cultural traditions in tobacco use and the different attitudes to harm reduction. However, it would use community competence to create harmonised rules in an effective single market in those member states that decide to permit sales of oral tobacco. This would in effect extend the concession made to Sweden at its accession to other EU member states that wished to adopt it. It would not require it. Even those countries that do not wish to exercise the option now, may value the right to exercise it in the future without requiring a new legislative proposal.

The draft directive as formulated will deny citizens in other member states access to a much lower risk alternative to smoking. Furthermore, it threatens to undermine significant health gains that have been made in Sweden. There is no scientific, ethical or legal basis to do this, and we hope that you will speak frankly and act decisively for public health as the directive completes its passage. We realise this is difficult, and that it can appear to be supporting a tobacco product. In reality, it is supporting better health and challenging the dominance of cigarette smoking, which is the most harmful and addictive form of tobacco and nicotine use.

If you would like to pursue these arguments, we would be pleased to provide you with more detailed information. If you would find it useful to meet, we would welcome the opportunity to discuss these issues with you in person at your convenience. Meanwhile, I hope you will be able to consider our suggestions, and confirm your support for our proposed approach.

Yours sincerely

Clive Bates Former Director

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Notes

¹ European Commission, Special Eurobarometer 385, Attitudes of European Citizens to Tobacco, March 2012

² Phillips CV, Rabiu D, Rodu B. Calculating the comparative mortality risk from smokeless tobacco versus smoking. *Am J Epidemiol* 2006; 163: S189.

³ WHO / International Agency for Research on Cancer: Cancer mortality database. The most recent figures for Denmark are 2006, but these trends change slowly as they represent years of accumulated smoking. Lung cancer also has poor survival rates so difference are unlikely to be due to difference in treatment. Lung cancer is a good marker for all smoking related diseases as it is mostly (c. 85-90%) attributable to smoking

⁴ Opinion of the Danish Parliament on the Commission proposal for revision of the Tobacco Products Directive - COM(2012) 788 [link]

⁵ WHO study group on tobacco product regulation (2009). Report on The Scientific Basis Of Tobacco Product Regulation: third report of a WHO study group. WHO technical report series; no. 955. WHO, Geneva. [Link]