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From:
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15 February 2013

Dear Mrs Larsson

Re: Tobacco Products Directive and Sweden's unique responsibility and opportunity

We are writing to you as independent public health specialists as the new Tobacco Products Directive begins its passage through the European Parliament and Council. We write to express our hope that you will take a positive approach to one of Sweden's great health successes. That success is the widespread use of low-risk oral tobacco (snus) to quit smoking and as an alternative to high-risk cigarettes. Despite the unambiguous contribution to better public health in Sweden, the proposed directive continues with unjustified and counterproductive restrictions on this product. Recognising that many member states will not wish to lift the ban on oral tobacco, we would like to propose a politically pragmatic way forward in this letter.

Sweden's unique health success. There has been a remarkable success for public health in Sweden that deserves more recognition by policy-makers. According to the most recent *Eurobarometer* survey, adult smoking prevalence in Sweden is just 13%. That is far lower than the EU average of 28% and the next closest member state at 23%. 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 smoking, this has resulted in substantially reduced burdens of tobacco-related disease (cancer, cardiovascular disease, emphysema) compared to other member states. Today's low rates of smoking will translate to significant health benefits in future, relative to other member states.

Sweden's proof of 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, but today more than one in four adults in the European Union still smokes, and the WHO still predicts one billion premature deaths from tobacco in the present century. Sweden 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 to restrict them in the ways envisaged in the proposed directive. We wish to draw your attention to three particular weaknesses and our three proposed alternative approaches.

Problem 1. Outside Sweden snus would remain banned and smokers will be denied options to reduce their risk

- *The ban on oral tobacco (outside Sweden) has no scientific basis:* the evidence points to significant net health benefits 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 potential snus users in Northern Europe and amongst Swedish 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 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 approach to problem 1. 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. 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 German government has a standard that could be broadly applicable and adopted into the directive.
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.

Problem 2. By banning characterising flavours, the directive will make smokeless tobacco less attractive relative to cigarettes

The ban on characterising flavours in tobacco products (Article 6.1) would apply to smokeless tobacco available throughout the EU as well as to smoking tobacco, such as menthol cigarettes. It is disputed whether it would apply to snus sold in Sweden, but if it did it could put at risk Sweden’s great health success.

- Characterising flavours are particularly important in smokeless tobacco, which does not have the strong flavours of tobacco smoke. The best selling snus in Sweden for example is flavoured with the herb bergamot, and many other flavours are in use in over 60% of products by volume.
- The danger of banning characterising flavours in smokeless tobacco is that these much safer products could become less appealing for some users. It therefore carries the risk they would revert to smoking, or never switch to smokeless tobacco in the first place.

Proposed approach to problem 2. We believe the right approach is to ban characterising flavours for smoking tobaccos only. If greater safeguards were thought necessary for smokeless tobacco (we do not think they are), then a schedule of approved or prohibited flavours could be drawn up.

Problem 3. Misleading messages designed to alarm rather to inform better health choices

Smokers know they are at great risk, but many do not have a clear sense of how much less risky smokeless tobacco would be (95-99% less risky). The directive presents an opportunity to communicate risk much more effectively. Article 11.1 requires the following message is placed prominently on smokeless tobacco products: *"This tobacco product can damage your health and is addictive"*. Whilst this is technically correct, it is an incomplete and misleading communication with a smoker, who may benefit from switching to smokeless tobacco.

Proposed approach to problem 3. A more credible, health promoting message would be: *"This product contains nicotine and may be addictive, but presents substantially lower risks to health than cigarettes"*.

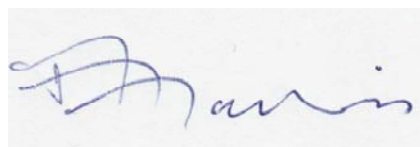
The draft directive as formulated will deny citizens in other member states access to a much lower risk alternative to smoking. Furthermore, it threatens to undermine significant health gains that have been made in Sweden. There is no scientific, ethical or legal basis to do this, and we hope that you 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.

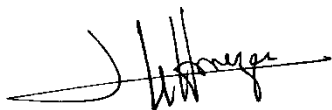
Yours sincerely



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