Zweiter Vorentwurf zum Tabakproduktesgesetz / Second preliminary draft Tobacco Products Act

We write as eighteen experts in the field of tobacco control and public health. We wish to provide some brief comments on the second preliminary draft Tobacco Products Act\(^1\), which is currently open for consultation. We welcome the proposed legalization of trade in alternative products such as e-cigarettes and snus and specific regulation of these products. This will greatly expand the lawful opportunities for smokers to quit smoking. Our focus in this letter is the intention to permit the marketing of oral tobacco in Switzerland. We welcome this proposal and regard it as a valuable departure from the European Union’s ethically and scientifically unjustified ban on oral tobacco.

E-cigarettes and vapour products

The case for permitting and regulating e-cigarettes has been made extensively. We recommend three key evidence and policy reviews: Public Health England\(^2\); the Royal College of Physicians (London)\(^3\) and the U.S. National Academies of Science, Engineering and Medicine\(^4\). Each of these reports combined with the rapid declines in adult and teenage smoking in the United Kingdom and United States make a powerful case for allowing consumers to access a regulated low-risk alternative to cigarettes as a harm reduction strategy for those who cannot or do not wish to quit use of nicotine. There appear to be few if any material negative consequences.

Oral tobacco and snus

Where oral tobacco is available in Europe, it has had a highly beneficial effect on health by displacing smoking with a much lower risk product. We provide a brief review of public health data before looking at the experience of oral tobacco in several countries.

1. **Oral tobacco is much less harmful than smoking**

The Federal Bureau of Public Health acknowledged that the risks of oral tobacco would be lower, but raised concerns about residual risks. This is a legitimate concern, but what matters is the approximate magnitude of such residual risks. Because there is no combustion and therefore no harmful products of combustion, prolonged regular snus use is *much less harmful* than cigarette smoking. There is extensive epidemiology that demonstrates that compared to smoking, snus poses

\(^1\) Federal Office of Public Health (BAG) Second preliminary draft Tobacco Products Act, Switzerland, 8 December 2017 [link]
\(^3\) Tobacco Advisory Group, Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016 [link]
far lower risk (if any) of all forms of cancer, including oral cancer and pancreatic cancer. There are minor risks associated with nicotine exposure and these apply to oral tobacco use. However, nicotine exposure through use of nicotine replacement therapy (NRT) is permitted for adolescents from age twelve and for pregnant women in the UK because nicotine poses only a small and weakly-established risk compared to smoking and because NRT use can prevent smoking.

On the basis of a thorough review of the available epidemiology, it is likely that the risks of snus use are close to negligible and no more than 1% of the risks of smoking.

I concluded that snus use is clearly much safer than smoking, and that any effects of snus use on the risk of cancer or [circulatory disease], if they exist, are probably no more than 1% of that of smoking. I also noted that switching to using snus should improve the health prospects of those smokers unable or unwilling to relinquish nicotine, and that there is no good evidence that introducing snus into a population would encourage smoking initiation or discourage cessation.

2. Oral tobacco has had a highly beneficial public health impact

The Federal Bureau of Public Health (BAG) also expressed concerns that oral tobacco availability may lead to more tobacco use, not less. Again, there is a theoretical possibility that this could happen, but there is no evidence to support that concern and considerable evidence that the opposite effect is more likely – a displacement of smoking.

3. Sweden

There is clear data showing the patterns of snus in Europe use result in lower burdens of smoking-related cancer and cardiovascular disease, most notably in Sweden. Where available, snus has displaced smoking – both by increased smoking cessation and reduced smoking initiation - leading to significant population health improvements. According to the pan-European Eurobarometer survey, this effect is large. Sweden has by far the lowest rate of smoking in the European Union with an adult smoking prevalence of 7 percent compared to the EU-28 average of 26 percent and 17 percent in the UK, as measured in this survey. In Northern parts of Sweden, smoking has almost been completely displaced by snus use and it is likely that some who would otherwise have become smokers use snus from the outset.

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7 Lee PN. Summary of the epidemiological evidence relating snus to health. Regul Toxicol Pharmacol. 2011;59(2). [link]
4. Norway

These positive effects are not confined to Sweden. Norway has also benefitted from reduced smoking rates\textsuperscript{13} by remaining outside the European Union and securing an exemption from the snus prohibition in its European Economic Area agreement. Snus use appears to displacing smoking at all ranges in the Norwegian population, but the effect is especially pronounced in young adults, where smoking among under-25 has fallen to one percent among women and five percent among young men. These are very low levels by any standard.

![Smoking and snus use in Norway 2008 - 2017](image)

Source: Statistics Norway\textsuperscript{14}


\textsuperscript{14} Statistics Norway, Smoking Habits, 18 January 2018 - overview [link] – in depth [link]
The charts show that smoking can approach very low levels with alternative nicotine products, and not just in Sweden—the 2017 EU average for adult daily smoking is 24 percent\(^\text{15}\). The charts also show significant change over a relatively short period—suggesting changes \textit{within} the pattern of use of nicotine products may be more rapid than between nicotine use and complete cessation. Snus in Scandinavia and Nordics provides a ‘proof of concept’ for tobacco harm reduction, but in other countries it may be different products that provide the beneficial effects. The policy imperative is to have the availability of as many of the alternatives to smoking as possible.

5. Finland

In contrast, when Finland joined the European Union in 1994, the snus ban was imposed and the rate of decline in Finnish smoking slowed. Finland provides a cautionary message about the harmful impact of banning safer alternatives to smoking. It has been estimated that Finland has a materially higher smoking rate as a result, and hence higher rates of disease and premature death than would otherwise have been the case\(^\text{16}\):

\begin{quote}
In the post-ban period, smoking was 3.47 percentage points higher in Finland relative to what it would have been in the absence of the ban.
\end{quote}

It is important to recognize at least the possibility that there can be harmful effects arising from denying smoker access to much lower risk alternatives to smoking. While there may be concerns raised about snus or e-cigarettes, policymakers should also have concerns about not allowing these products on to the market or imposing excessive restrictions on them. The precautionary principle demands consideration of the impacts of both non-intervention and intervention.

6. United States

In 2015, the Food and Drug Administration of the United States evaluated eight Swedish Match snus products through its arduous ‘Pre-market Tobacco Application’ (PMTA) process, and concluded that the products are \textit{“appropriate for the protection of public health”}\(^\text{17}\):

\begin{quote}
Under the PMTA pathway, manufacturers must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products.
\end{quote}

7. The European Union

The import, manufacture and sale of oral tobacco is prohibited in the European Union under the 2014 Tobacco Products Directive\(^\text{18}\). The case for lifting the ban on snus has been set out by the

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\(^{17}\) U.S. FDA, FDA issues first product marketing orders through premarket tobacco application pathway, 10 November 2015 [link]  
\(^{18}\) The ban was introduced in 1992, and reaffirmed in Article 17 of the Tobacco Products Directive 2014/40/EU of April 2014 [link]
expert community in numerous communications: to the European Commission in May 2011\textsuperscript{19}; to the Government of Sweden and European Council in February 2013\textsuperscript{20}; to the European Parliament in September 2013\textsuperscript{21} to UK government in October 2013\textsuperscript{22} and to the Directorate General For Better Regulation in June 2017\textsuperscript{23} arguing that the European Union prohibition of snus is unjustified and damaging and should be lifted. A detailed critique of the Commission’s proposal to retain this prohibition was provided to the Commission and widely shared in March 2013\textsuperscript{24}. There is no equivalent body of argument that supports the case for the prohibition. The EU ban on oral tobacco is deeply irrational, banning the product that is both responsible for Sweden’s anomalously low smoking prevalence and tobacco-related mortality – see charts below.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{chart1.png}
\caption{EU Smoking Prevalence - percentage of adults - March 2017}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{chart2.png}
\caption{Death rate per 100,000 attributable to tobacco - all causes of death, men 30 and older}
\end{figure}

\textsuperscript{19} Letter to Commissioner Dalli: Advancement of the scientific basis for the EU TPD, May 2011 [link]
\textsuperscript{20} Letter to Maria Larsson, Minister for Health, Government of Sweden 15 February 2103 [link] copied to Working Party on Public Health - Health Attachés, Brussels on 15 February 2013 [link]
\textsuperscript{21} Letter to Martin Schulz, President of the European Parliament, copied to MEPs 23 September 2013 [link]
\textsuperscript{22} Letter to Rt. Hon. Jeremy Hunt MP, Secretary of State for Health (UK/England), 7 October 2013. [link]
\textsuperscript{23} Letter to Frans Timmermans, Lifting the unjustified European Union ban on oral tobacco or “snus” in the light of ongoing legal action, 1 June 2017 [link]
\textsuperscript{24} Bates CD, Ramström L. Proposed revision to the Tobacco Products Directive: a critique of the scientific reasoning supporting the proposed measures relating to oral tobacco, 18 March 2013 [link] and Covering letter to Commissioner Borg 18 March 2013 [link]
The current challenge to the legality of this European Union prohibition (European Court of Justice case C-151/1727) is based on the violation of the principle of proportionality and principle of equal treatment and non-discrimination and the violation of human rights. We can see no ethical justification for denying a smoker an alternative product that is much lower risk than cigarettes and has proved successful in reducing smoking at a population level.

The government of Switzerland would be right to avoid the mistakes made in the European Union over many years and to allow oral tobacco products onto the market to compete with cigarettes.

We believe the approach proposed approach is well founded in science, ethics, public health and law.

We hope these views are useful.

Your sincerely,

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27 Court of Justice of the European Union, Case C-151/17 24 March 2017 [link]
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