Submission in response to a letter to the Committee from the Secretary of State regarding oral tobacco

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I write in response to a statement provided to the Committee by the Secretary of State for Health and Social Care, published on 20 February 2018. The statement provides background on the government’s approach to the prohibition on oral tobacco products, often known as ‘snus’, and the ongoing legal challenge to this ban in which the UK is a defendant. The import, manufacture and sale of oral tobacco is prohibited in the European Union under the 2014 Tobacco Products Directive.

1. The government’s position on oral tobacco / snus

The Secretary of State argues in favour of retaining the European Union ban on oral tobacco in order to ensure “the appropriate application of proportionality and other legal principles to the relevant facts” and because, if the prohibition on snus is lifted on proportionality grounds, “there is a risk that this could undermine the implementation of other tobacco control measures, in particular, the UK implementation of Standardised Packaging of Tobacco”. The government claims it is supporting the prohibition on snus in the European Court of Justice “not to secure the continued prohibition of snus, but to seek to protect the principle of proportionality on which it is based”.

The Committee should reject the Secretary of State’s position and reasoning in its entirety. The proportionality principle is an important foundation of the EU treaties and UK policy-making, but it cannot be defended by arguing that a measure that is manifestly disproportionate conforms to the proportionality principle and therefore that the principle can be used to defend any measure, no matter how disproportionate or vulnerable to challenge. The government’s approach drains this important principle of all meaning, and the wider implications of such tactical behaviour are disturbing. The case for lifting the ban on snus is overwhelming from a scientific, legal and ethical perspective, and opposing a sound policy change to defend measures for which there is little supporting evidence cannot be considered good or acceptable practice.

2. The dispute over the prohibition of oral tobacco / snus

The current challenge to the legality of this prohibition (European Court of Justice case C-151/17) brought by a producer (Swedish Match) and a consumer group (New Nicotine Alliance) provides a timely opportunity to reassess this policy and implement genuinely better regulation. That would mean lifting the prohibition of snus and regulating this form of smokeless tobacco no differently to the other forms of smokeless tobacco that have always been permitted in the European Union.

The case for lifting the ban on snus has been set out by the expert community in numerous communications: to the European Commission in May 2011; to the Government of Sweden and

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1 Letter from the Secretary of State, Department of Health and Social Care (ECG0095), Oral-use tobacco products, February 2018 [link]
2 The ban was introduced in 1992, and reaffirmed in Article 17 of the Tobacco Products Directive 2014/40/EU of April 2014 [link]
3 Court of Justice of the European Union, Case C-151/17 24 March 2017 [link]
4 Letter to Commissioner Dalli: Advancement of the scientific basis for the EU TPD, May 2011 [link]
Written evidence submitted by Clive Bates (ECG0096)

European Council in February 2013⁵; to the European Parliament in September 2013⁶ to UK government in October 2013⁷ and to the Directorate General For Better Regulation in June 2017⁸ 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 2013⁹. There is no equivalent body of argument that supports the case for the prohibition.

Whatever justification may have prompted the original prohibition in 1992, there was no basis for extending it in 2014 and there is no basis for continuing to defend it in 2018. The European Union, with the support of the UK, is dogmatically clinging to a decision made more than 25 years ago that no longer has any evidential foundations, if it ever did.

The position of the UK government and the European Union violates important European Union principles, including: (1) the principle of proportionality; (2) the principle of equal treatment or non-discrimination, and; (3) the guidance on application of the precautionary principle. Each of these principles is discussed in this submission following a sort overview of the health evidence.

3. The factual basis on health impacts of oral tobacco / snus

The health impacts of snus have been studied extensively and over many decades. There are two key findings that should underpin the UK and European Union policy approach.

1. **Oral tobacco is much less harmful than smoking.** Because there is no combustion and therefore no harmful products of combustion, prolonged regular snus use is much less harmful than cigarette smoking, and it is likely that the risks approach negligible10 11. There is extensive epidemiology that demonstrates that snus poses far lower risk (if any) of all forms of cancer, including oral cancer12 and pancreatic cancer13, than smoking. There are minor risks associated with nicotine exposure and these apply to oral tobacco use. However, it should be recognized that 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 a small and weakly-established risk compared to smoking and because NRT use can prevent smoking.

2. **Oral tobacco has had a highly beneficial public health impact.** There is clear data showing the patterns of snus in Europe use result in lower burdens of smoking-related cancer and

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⁵ 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]
⁶ Letter to Martin Schulz, President of the European Parliament, copied to MEPs 23 September 2013 [link]
⁸ 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]
⁹ 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]
¹⁰ Lee PN. Summary of the epidemiological evidence relating snus to health. Regul Toxicol Pharmacol. 2011;59(2). [link]
¹¹ Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. Harm Reduct J. England; 2013;10(1):36. [link] "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”.
cardiovascular disease, most notably in Sweden. Where available, snus has displaced smoking leading to significant population health improvements\textsuperscript{14 15}. 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\textsuperscript{16}. In Northern parts of Sweden, smoking has almost been completely displaced by snus use\textsuperscript{17} and it is likely that some who would otherwise have become smokers use snus from the outset.

**Norway and Finland.** These positive effects are not confined to Sweden. Norway has also benefitted from reduced smoking rates\textsuperscript{18} by remaining outside the European Union and securing an exemption from the snus prohibition in its European Economic Area agreement. In contrast, when Finland joined the European Union in 1994, the snus ban was imposed and the rate of decline in Finnish smoking slowed. 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\textsuperscript{19}:

*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.*

**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 “appropriate for the protection of public health” and should be placed on the market in the United States\textsuperscript{20}:

*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.*

It is disappointing that the Secretary of State should make such a vague and insubstantial argument about the science or oral tobacco in his letter to the Committee:

*It is worth noting that there are strongly diverging views in terms of the evidence on the health risks of snus – with significant concerns in Norway and Sweden about the impact of the use of snus, particularly by young people and pregnant women.*


\textsuperscript{20} U.S. FDA, FDA issues first product marketing orders through premarket tobacco application pathway, 10 November 2015 [link]
There is in reality no credible dispute about the benefits in both Sweden and Norway. It is surprising that in taking such an aggressive stance in court, that the government does not appear to have its own advice on health risks and public health impact from Public Health England or other neutral experts, and that it overlooks the exhaustive evaluation undertaken by the FDA.

Snus in Scandinavia provides proof of concept for ‘harm reduction’, an idea that the government has latterly embraced in its own 2017 Tobacco Control Plan\(^{21}\). The idea is that people who cannot or do not wish to stop using tobacco or nicotine should be able to access safer consumer nicotine products. There is no obvious reason why the Department should apply this philosophy to vaping products and heated tobacco products, but to deny it is applicable to oral tobacco.

I would now like to turn to the Secretary of State’s argument about the proportionality principle.

4. The principle of proportionality

The principle of proportionality is defined in the European treaties\(^{22}\), and summarised as follows:

*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties*

In the case of the Tobacco Products Directive, which imposes the ban on snus, the objective of the directive and its main legal base is the promotion of *free movement of goods* (the internal market) with a high level of health protection\(^{23}\). It is impossible to reconcile an outright ban on a product with promotion of the free movement of goods in the internal market, especially when the product is responsible for highly beneficial public health impacts where it is in use in Scandinavia. The alternative regulatory strategy of setting standards (e.g. for contaminants, ingredients or for the manufacturing process) is far superior and recommended by WHO’s scientific expert panel\(^{24}\). WHO’s TobReg expert committee argued in its 2010 report:

*Smokeless tobacco products should be regulated by controlling the contents of the products*

The regulatory approach proposed by WHO’s expert committee would comply with the principle of proportionality, and has been recommended for several years by the expert community. But an outright ban does not comply. This is not because it far exceeds the Union action necessary to achieve internal market and health objectives of the treaties, but because it actively works against these objectives. It does this by denying European smokers and would-be smokers access to products that have proved extremely successful for public health where the products are permitted.

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\(^{21}\) Department of Health, Towards a smoke-free generation: tobacco control plan for England, 18 July 2017 [link]

\(^{22}\) Article 5.4 of the Treaty on European Union [link] and Treaty on the Functioning of the European Union - Protocol (No 2) on the application of the principles of subsidiarity and proportionality [link].


5. The principle of non-discrimination or equal treatment

As well as violating the principle of proportionality, the oral tobacco prohibition also egregiously violates another, related, principle of EU policy-making. This principle of non-discrimination or equal treatment. This is famously expressed in European Court of Justice jurisprudence:

*Comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified*

The ban on oral tobacco blatantly violates the principle of non-discrimination in at least three ways.

1. It is self-evidently discriminatory to allow the manufacturing, import and sale of cigarettes in the internal market, but to prohibit a rival consumer nicotine product that is two orders of magnitude lower in risk to users. This comparison shows the government’s policy is not just disproportionate, but *anti-proportionate*: a much more severe regulatory sanction is placed on the much less hazardous product.

2. It is also discriminatory, and absurd, to prohibit smokeless tobacco products that are intended to be *sucked* once placed in the mouth but permit them if *chewed*. There is no basis at all for such a distinction. The Tobacco Products Directive 2014/40/EU provides a labelling regime for smokeless tobacco that is not oral tobacco (i.e. placed in the mouth and sucked) at Article 12.

3. It is discriminatory to ban oral tobacco products but to allow novel tobacco products access to the internal market via a notification procedure set out in Article 19 of the Tobacco Products Directive. When the snus prohibition was challenged in 2004, the Court of Justice relied heavily on an argument that snus products would be ‘novel’ in most EU countries and therefore presented novel risks which could theoretically justify a ban on precautionary grounds. This argument was weak at the time it was made. However, the ‘novel product’ justification is now unambiguously invalid. Article 19 of the Directive provides a route to market for any novel tobacco products, but this is route is denied to snus by the outright prohibition in Article 17.

6. The precautionary principle

The Secretary of State does not invoke the precautionary principle explicitly, but it is implicit in stating the following justification for a ban:

*Where such controversy exists, our view is that a ban constitutes a proportionate response*

There is not a material controversy that justifies this action and the government has not demonstrated there is. But assuming there was a controversy and it was legitimate, that does not mean a ban is an appropriate or proportionate response under the precautionary principle. In fact, the precautionary principle as defined in the European Union does not allow arbitrary or excessive measures or dispense with good policy making disciplines, and establishes the following principles:

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25 For example see Case C-127/07 Arcelor Atlantique et Lorraine and Others v Premier ministre and Others, Judgement of the Court, 16 December 2008 [link] which cites the following at para 23 (see, inter alia, Case 106/83 Sermide [1984] ECR 4209, paragraph 28; Joined Cases C-133/93, C-300/93 and C-362/93 Crispoltoni and Others[1994] ECR I-4863, paragraphs 50 and 51; and Case C-313/04 Franz Egenberger [2006] ECR I-6331, paragraph 33).

26 Court of Justice of the European Union, Case C-210/03 Documentation 2003-04 [link] see paragraphs 5, 7, 8, 37, 49, 51, 55, 65, 67 and finally the conclusion at paragraph 71 of the Court’s judgement).

27 Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2 February 2000) [link][summary]
The precautionary principle shall be informed by three specific principles:

- the fullest possible scientific evaluation, the determination, as far as possible, of the degree of scientific uncertainty;
- a risk evaluation and an evaluation of the potential consequences of inaction;
- the participation of all interested parties in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available.

In addition, the general principles of risk management remain applicable when the precautionary principle is invoked. These are the following five principles:

- proportionality between the measures taken and the chosen level of protection;
- non-discrimination in application of the measures;
- consistency of the measures with similar measures already taken in similar situations or using similar approaches;
- examination of the benefits and costs of action or lack of action;
- review of the measures in the light of scientific developments.

The Secretary of State’s position on oral tobacco fails to address any of these requirements for precautionary action. In particular, it has not weighed the potential harmful effects of the prohibition in denying smokers far safer alternatives that have proved successful elsewhere.

7. The fundamental flaw in the government’s approach

The Secretary of State argues: “there is a risk that this could undermine the implementation of other tobacco control measures, in particular, the UK implementation of Standardised Packaging of Tobacco”. In order to defend a policy for which there is currently little supporting evidence, the government is mounting a faux defence of the ban on oral tobacco with the aim of hollowing out the principles of proportionality and non-discrimination to the point where these have no practical meaning in law and cannot threaten its weakly justified flagship policy. In contrast, there is strong supporting evidence that the prohibition of oral tobacco is harmful, unethical, disproportionate and discriminatory. There is a cost to such crude tactical manoeuvring in terms of harm to smokers, harm to competition and internal market, and yet more damage to the credibility of UK/EU policymaking. The right way to defend a measure like standardised packaging is on its merits, not by distorting the principles that underpin good policymaking to effectively render them meaningless.

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