National Heart Forum position paper
on the regulation of nicotine and tobacco and implications for smokeless tobacco products such as snus

May 2008
A. Introduction

Cigarettes and cigars are the only legal products which are lethal when used according to the manufacturer’s instructions. Despite the harm caused by smoking, combustible tobacco products are largely unregulated while medicinal nicotine used as an aid to stop smoking is tightly controlled. Between these two ends of the spectrum are a variety of smokeless tobacco products which differ significantly in terms of their manufacture, storage, harm and availability. Sale of Swedish snus is illegal because it is a form of oral snuff which is banned by the EU (except in Sweden), whilst sale of other more harmful forms of smokeless tobacco, in particular various types of chewing tobacco from South Asia is permitted. The current situation represents an inverse relationship between levels of harm caused by different tobacco products and their accessibility/availability.

The anomalies and inconsistencies around nicotine and tobacco regulation have concerned the tobacco control community over many years, and a repeated recommendation to policy makers has been to establish a dedicated Tobacco and Nicotine Regulation Authority (TNRA).

NHF co-signed a letter to then Secretary of State for Health John Reid in October 2003, calling for a Tobacco Regulatory Authority.

B. Harm reduction

Harm reduction is a widely accepted principle in public health policy. It recognises that in many situations harms cannot be readily eliminated, but that potential dangers and health risks associated with certain behaviours can be mitigated. The International Harm Reduction Association defines harm reduction as: “policies and programmes which attempt primarily to reduce the adverse health, social and economic consequences of all psychoactive substances to individuals drug users, their families and their communities”.

An example of an established harm reduction strategy is needle exchange programmes for intravenous drug users. While providing clean needles does not directly tackle the use of illicit drugs, it can help to reduce associated risks of life-threatening infections. Drawing on the drug use analogy, the cigarette is the equivalent of the ‘dirty syringe’. Dependence on nicotine is the critical factor underpinning tobacco use but it is not the nicotine that causes most of the harm, but the 4,000 or so other constituents of tobacco smoke, of which 60 are known carcinogens. Consideration therefore needs to be given to separating the drug from the delivery system by switching some or all cigarette use to other, zero or reduced harm nicotine delivery systems.

The New Zealand Health Technology Assessment summarized the points of view about harm reduction in tobacco control in its 2007 report to the NZ Ministry of Health as follows:

…Harm reduction is arguably the most complex, controversial and divisive issue in tobacco control today (Chapman 2007). One point that most scientists and commentators agree on is that complete tobacco cessation is the best outcome for smokers and any efforts to make available products safer need to be part of a comprehensive tobacco control strategy aimed at minimising tobacco use through cessation and prevention (Stratton et al. 2001). Comprehensive prevention and cessation programmes have reduced smoking rates dramatically (Vainio and Weiderpass 2003) and promoting snus for harm reduction should not be at the expense
of diverting significant resources away from the public health goal of tobacco elimination (Chapman 2007). Some have argued that it may be better to focus efforts on developing and improving pharmacological therapies than to promote smokeless tobacco (Bullen et al. 2006; Hatsukami et al. 2004; Jorenby et al. 1998). Currently, however, the use of pharmaceutical cessation aids and behavioural support have led to limited success in cessation and it has been argued that means that the majority of current smokers will continue to smoke without acceptable safer alternatives (Britton 2003). Snus and other modified smokeless products may therefore be an additional tool for reducing tobacco related harm when used to target inveterate smokers for whom current cessation programmes have had only limited success (Savitz et al. 2006). Critical to efforts to reduce tobacco-related harm for population net benefit are appropriate regulatory controls which are not stymied by commercial interests aimed at maximising tobacco consumption."

C. Swedish snus

The need for better regulation of nicotine and tobacco products has been brought into renewed focus by the debate surrounding the use of oral snuff, or snus in Sweden. Smoking rates and tobacco-related mortality in Sweden are low compared with other EU countries. Smoking rates in Sweden are 16% compared to 26% in the UK. The gap is even greater for male smokers with just 14% of Swedish men smoking compared to 28% in Britain. Smoking-related deaths are 9% of all deaths in Sweden compared to 19% in the UK."

Recent data from Sweden indicates that habitual smokers and young people experimenting with tobacco products have substituted snus for cigarettes, suggesting that smokeless tobacco is an acceptable smoking substitute for some smokers. The tobacco in Swedish snus is modified so that it is low in nitrosamines and other toxic and cancer causing agents found in tobacco products. Sale of snus is currently illegal in the EU (except in Sweden which has an exemption), but the rules banning the sale of snus in the EU are due to be reviewed under the new Commission which takes over in 2009. It is known that the tobacco companies are lobbying the Commission to lift the ban on snus on the grounds that this would serve to reduce harm from tobacco.

D. The evidence base and policy assessments

There is a significant body of evidence examining the health risks associated with the use of smokeless products, including snus. Recent contributions to the evidence base and policy analysis are summarised below, and some of the difficulties with evaluating the evidence are given in Annex A. It should be noted that in all cases a recommendation is made that bans on snus should remain.

1. Health Effects of Smokeless Tobacco Products. A report by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for the European Commission (February 2008)

The general conclusion of the committee is: “Smokeless tobacco products (STP) are addictive and their use is hazardous to health. Evidence on the effectiveness of STP as a smoking cessation aid is insufficient, and relative trends in progression from STP into and from smoking differ between countries. It is thus not possible to extrapolate the
patterns of tobacco use from one country where oral tobacco is available to other countries."

The report’s conclusions take into account findings reported in 2007 of a follow up to the Bolinder cohort of Swedish men (1994) which suggests that use of Swedish snus increased the risk of death from myocardial infarction (heart attack), but did not increase the risk of myocardial infarction.


This report considers the responsibilities of government, industry, individuals and others in promoting the health of everyone. The Council concludes that the state has a particular duty to help people lead a healthy life and to reduce inequalities and proposes a ‘stewardship model’, which outlines how this can be achieved. The report’s conclusion on snus is:

“Based on our considerations of the stewardship model, the Working Party is not persuaded that snus should be permitted. Although there may be evidence of lower overall health risks compared with cigarette smoking, there is still evidence of harm and addiction. In view of the health risks and the possibility that consumers may be led to believe they are using a relatively harmless product, we are not persuaded that permitting snus or conducting further research on the health risks is a helpful approach. Allowing snus might also carry the risk of increasing health inequalities in the UK as members of certain ethnic groups who already have a culture of chewing stimulants, such as betel nut, might more easily take up snus.”

3. Harm reduction in nicotine addiction: helping people who can’t quit. A report by the Tobacco Advisory Group of the Royal College of Physicians (October 2007)

The report reviews the uses and risks of all sources of nicotine, the current approaches to nicotine product regulation, the ethical considerations of harm reduction and the implications for health policy and regulation.

Summarising the position of the College, the report’s lead author, Professor John Britton said: “The RCP wants to see the entire nicotine market reformed by a new regulatory framework that favours harm reduction, which would include:

- Providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes;
- Encourage the development of innovative, more effective and user-friendly medicinal nicotine substitutes for cigarettes;
- Change nicotine product regulation to make it easier to produce and market medicinal nicotine products;
- Create a nicotine regulatory authority to take control of all aspects of regulation of all nicotine products and reverse the advantage cigarettes have in the marketplace.

The College makes clear that it does not support lifting the ban on snus: “The College has no intention of lobbying for that ban to be lifted. Opening up the EC market to
tobacco companies would invite abuse by allowing them to market to children and through smokeless products also promote smoked cigarette brands.

We want to see research to see how effective it is as a smoking substitute in comparison with medicinal nicotine. If it is effective, and more effective and/or more acceptable to some smokers than medicinal products, we can see grounds for legalization within a reformed nicotine regulatory system to capitalise on the potential for harm reduction that smokeless products can offer smokers.

There are huge potential hazards in legalizing such products without careful monitoring and control. We believe all nicotine products should be regulated by a single authority to encourage all smokers to give up, and for those who can’t, to switch to a safer product. Suggestions that the College’s call for better and less risky smokeless tobacco products means support for making snus and similar products more available is wrong.\textsuperscript{iv}

4. A systematic review of the health effects of Swedish snus. A review carried out by the New Zealand Health Technology Assessment, commissioned by the New Zealand Ministry of Health. (March 2007)\textsuperscript{v}

“The evidence from this review suggests that the harm of using snus, relative to non tobacco use, is significantly less than found for smoking with respect to cancers of the head, neck and gastro-intestinal region, and cardiovascular disease events. While studies were underpowered to detect small increases in mortality risk compared with no tobacco use, results suggested that the product does not lead to significant risks for these outcomes. One older cohort study provided some evidence for a 40 per cent increased risk of death from all causes, and a 40 per cent increased risk of death from cerebrovascular and cardiovascular disease in snus users compared with no tobacco users. However, there was no increased risk for all-cancer mortality. Further research is needed to investigate CVD risks in other populations using low-nitrosamine snus products and to investigate what diseases may have contributed to the increased risk for all-cause mortality, apart from CVD mortality. Single investigations of limited quality did not indicate increased risks in snus users for diabetes, inflammatory bowel disease or malignant lymphoma, and suggested increased adverse effects for snus use in pregnancy. Other known risks associated with snus but not included in studies appraised here are the dependence potential of nicotine and oral effects including snus-induced lesions, oral mucosal changes that apparently are reversible upon cessation, and gingival recessions…

The Ministry of Health in New Zealand is not reviewing the legal status of modified smokeless tobacco products and does not plan to in the near future.
E. What we don’t know

There is incomplete evidence on the effects of snus on cardiovascular and other disease risks. The New Zealand review identified a number of limitations to the evidence (listed at Annex A)

What would be the effect of snus in a new market?

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) considered that the health impacts would “depend substantially on a number of factors, including:

- the extent to which the product is marketed and endorsed as a healthier choice than smoking
- the cultural acceptability of the product
- the extent of abuse of marketing by the tobacco industry to promote smokeless tobacco as a starter product for young people
- price and availability relative to cigarettes and medicinal nicotine products
- the extent to which the product is used as an exit rather than entry stage in tobacco use
- the extent and success of measures taken to maximise health benefits through monitoring and controlling the marketing and use of the product
- the hazard of the STP, used alone or in combination with smoking.”

There is inadequate evidence on the impacts on smoking uptake and quit rates and no evidence to show the effect of introducing snus to a new market. The SCENIHR report notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. Looking beyond snus, the evidence from California is that both the prevalence of smoking and smokeless tobacco use have decreased concurrently.

Modelling effects is difficult owing to unknowable variables such as likely switching behaviour between cigarettes and snus. A modelling study by Gartner et al. (Lancet 2007)xvi suggested that current smokers who switch to using snus rather than continuing to smoke could realize substantial health gains. Snus could produce a net benefit to health at the population level if it were adopted in sufficient numbers by inveterate smokers. The size of the benefit would depend on how many inveterate smokers switched to snus.

What might be the specific pitfalls of introducing snus to new markets?

The SCENIHR report identified the following possible adverse outcomes:

- Increased overall tobacco use without substantial decline in cigarette smoking prevalence
- Impaired tobacco prevention efforts due to ‘mixed messages’ that attempt to advise against any tobacco use, but favour certain forms over others
- Undermining tobacco cessation efforts
- Uptake of smokeless tobacco in populations who would otherwise have not likely used any tobacco product.

**What do the tobacco companies know?**

The motives of the tobacco companies are likely to be complex, including a desire to improve perceptions of corporate social responsibility, to gain access to regulators and develop business opportunities under smokefree regulations. (For example, Lucky Strike Snus is marketed in South Africa under the slogan: ‘Can’t light up, Can Snus’). The development of flavoured snus varieties are believed to have specific appeal to children and women which suggests the tobacco companies do intend snus as a gateway product to nicotine addiction.

**Is harm minimisation a priority for tobacco control, or does this potentially distract from broader goals of cessation and a tobacco free society?**

It is important not to distort global tobacco control initiatives by focusing on one narrow issue such as the ban on snus.

G. Criteria for an NHF policy position and policy goals

In arriving at a position that is clear, ethically principled, united and defensible, it is necessary that the National Heart Forum:

- Approaches this issue from within the premise of primary prevention
- Takes account of the best available evidence
- Takes account the expert and ethical judgements of its members
- Acknowledges the deceitful behaviour of the tobacco companies over the years
- Addresses points of consensus and disagreement
- Adopts a precautionary approach
- Looks ahead and supports policies which are consistent with a tobacco free future
- Keeps the evidence and its position under review.

This draft position and policy goals are intended to be consistent with an ethical position that:

- All policy actions should achieve tighter regulation, not de-regulation of tobacco products;
- There is a moral obligation to explore the potential of harm reduction for inveterate, addicted smokers who cannot quit.
H. NHF position

Nicotine is addictive; therefore all nicotine products should be regulated, including smokeless tobacco products currently used by Asian populations in the UK and which are currently unregulated.

Regulation should be made the responsibility of dedicated, independent Tobacco and Nicotine Regulation Authorities (TNRA) at both national and European levels.

Regulation should be conducted with the aim of moving the market in nicotine towards reduced harm products to help make more effective, medicinal nicotine products available to heavy smokers who can’t quit, and encouraging them to switch.

Any future change to the current ban on snus should only be considered within the context of a reformed regulatory system for nicotine and tobacco as part of a harm reduction strategy.

J. Policy goals

1. The establishment of a tobacco and nicotine regulatory authority, along the lines recommended by the Health Select Committee in 2000\textsuperscript{xvii}. (The HSC recognises that both UK and EU level authorities are necessary along the lines of the UK Food Standards Agency and European Food Safety Authority). The regulatory scope for such a body should include all aspects of product content and marketing. The authority should be accountable to the government, independent of the tobacco industry and the costs should be imposed on the tobacco industry, using mechanisms such as user fees, or earmarking of tobacco excise duties.

2. To assess and monitor how the smoking of tobacco is affected by harm reduction products particularly snus and how this may vary with cultural differences. In particular the impact of the recent introduction of snus to New York, Chicago and other US cities and South Africa should be closely observed. (It is acknowledged that there are ethical concerns about conducting trials of snus and smokeless tobacco, but observational studies should be carefully noted to ensure that the evidence base is kept under review).

3. To define what is intended by ‘harm reduction’, and agree what an appropriate harm reduction strategy would be. (The Department of Health’s Cancer Reform strategy announced that “While recognising that it is crucial to continue to support smokers to quit smoking, the government will consult with stakeholders on measures to reduce the significant harm to health caused by smoking for those who are addicted to nicotine and not able to quit altogether;”\textsuperscript{xviii}).
Annex A

According to the New Zealand reviewers, limitations of the evidence base included the following:

- an emphasis on oropharyngeal cancers and cardiovascular disease health outcomes with investigation of other health outcomes limited to single studies;
- reliance on retrospective, unvalidated self-report of tobacco exposure at study entry;
- potential confounders such as alcohol abuse, illicit drug use, diet, physical exercise, body mass index (BMI), and family history of disease often not suitably controlled or adjusted;
- health risks associated with snus use in ex-smokers, or with dual (smoking and snus) users were rarely measured;
- risk estimates tended to be imprecise and studies underpowered to rule out small to moderate excess health risks associated with snus use;
- in five of the 18 papers appraised in the review, the research, or in one case a researcher, received some financial support from the tobacco industry. This may have introduced subtle biases into the design, conduct and interpretation of the research, although no evidence of systematic differences were observed as a function of funding source.

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1 Royal College of Physicians. Nicotine Addiction in Britain. 2000. RCP
4 www.ihra.net
5 Broadstock, M. Systematic review of the health effects of modified tobacco products. NZHTA Report 2007; 10 (1)
6 WHO Regional Office for Europe. Tobacco Control Database http://data.euro.who.int
12 http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=234
13 UK FAILING HEAVILY ADDICTED SMOKERS, SAYS RCP. RCP press notice. 5 October 2007.
15 See ref. 5. http://nzhta.chmeds.ac.nz/publications/smokeless_tobacco.pdf
19 See reference 5