

Cancer Research UK Policy Statement on Harm Reduction and the Regulation of Nicotine and Tobacco

I. What is harm reduction?

Harm reduction (HR) is a term used in a number of ways in tobacco control, but, in its broadest sense, refers to any measure that reduces the illness and death caused by the use of tobacco. This could mean reducing the availability of, access to, and affordability of cigarettes or switching from more harmful tobacco and nicotine products to less harmful ones. While these measures have differing degrees of impact, not smoking or quitting should always be seen as the ultimate goal. Cancer Research UK supports this broad interpretation of harm reduction because our aim is a decline in tobacco use in all its forms, leading ultimately to a world that is as tobacco-free as possible.

In a more limited sense HR is often used, especially in the USA, to refer to changes in the design and manufacture of cigarettes aimed at reducing certain of the known harmful constituents of tobacco such as nitrosamines. The resulting products are termed Potential Reduced Exposure Products or PREPs¹. There is no clear evidence that the use of PREPs could substantially reduce the harm to health caused by tobacco and they may reduce smokers' motivation to quit². Also, there is likely to be confusion among the public due to some cigarettes being seen as 'safer' (as the tobacco industry would certainly seek to promote them) or 'less harmful', and a risk that the longstanding public health message that cigarettes are harmful could lose credence (see also 4 below).

2. The spectrum of nicotine-containing products

The modern cigarette has been described as a highly chemically-engineered drug-delivery device primarily designed to deliver the drug nicotine³. Nicotine is as addictive as cocaine or heroin⁴ and nicotine addiction is the reason why people smoke and why they find it so hard to quit. However, nicotine in itself carries relatively little health risk. It is the tar in tobacco that is harmful, containing over 4,000 chemicals including at least 69 cancer-causing substances^{5,6}.

Pure nicotine products (nicotine replacement therapy or NRT) have been developed to provide an alternative and much safer source of the drug and come in the form of patches, lozenges, inhalers, nasal sprays and gum. Use of NRT doubles the chances of quitting successfully⁴. It is also increasingly seen as having a role in situations where smoking is not permitted. There is a distinct possibility that people may come to use pure nicotine long-term in place of smoking, especially as more effective or attractive products (e.g. ones that deliver faster 'hits') are developed. Cancer Research UK therefore calls for research into the possible role of long term pure nicotine use and its effect on health and on quitting rates.

Between the most harmful form of nicotine (smoked tobacco) and the least harmful, pure nicotine, lie the various forms of non-smoked (chewed, sucked) or smokeless tobacco. However, for smokeless tobacco there is also a spectrum of harm, with chewed tobacco products such as paan (traditionally used by South Asian communities) carrying a high risk of

¹ Chapman S, Public Health Advocacy and Tobacco Control, Blackwell Publishing, Oxford, 2007

² Shiffman S, Pillitteri JL, Burton SL et al. Smoker and ex-smoker reactions to cigarettes claiming reduced risk. Tobacco Control 2004; 13: 78-84

³ Gray N, Henningfield JE, Benowitz NL et al. Towards a comprehensive long term nicotine policy. Tobacco Control, 2005; 14: 161-165

⁴ Royal College of Physicians, Nicotine Addiction in Britain, RCP, London, 2000

⁵ www.smokeispoison.org

⁶ WHO International Agency for Research on Cancer. Volume 83: Tobacco smoke and involuntary smoking. Lyon: IARC, June 2002. <http://monographs.iarc.fr/htdocs/monographs/vol83/02-involuntary.html>

causing oral cancers⁷. Snus, a form of moist, sucked tobacco used extensively in Sweden, carries a greatly reduced risk of cancers and other tobacco-related diseases⁸. This is due to its method of manufacture, involving pasteurisation and storage at low temperatures, that results in snus containing far lower levels of nitrosamines than other forms of smoked or smokeless tobacco.

All smokeless tobacco (apart from traditional South Asian products such as paan) is currently banned in the EU under Directive 2001/37/EC. Sweden argued for exemption on the grounds of snus being a traditional product there. A recent challenge to the ban by tobacco companies was unsuccessful.

3. The need to regulate all forms of nicotine and tobacco

Cigarettes have until very recently remained virtually unregulated, and the design and constituents of tobacco and of cigarette smoke continue to be within the control of the tobacco companies. Numerous alterations have been made, including early modification of filters, changes to leaf constitution and leaf blends, the addition of upwards of 600 additives, different types of paper and ventilated filters. Many of these changes were aimed at reducing the levels of nicotine and tar, as assessed by standard measuring machines, while continuing to deliver a sufficient dose of nicotine⁹. Much safer pure nicotine products, in contrast, are very highly regulated. The situation whereby the most harmful nicotine delivery products, (cigarettes) and most harmful smokeless tobacco products (e.g. paan) are the least regulated, is clearly anomalous and against the interests of public health (see also 8 below).

4. Potential Reduced Exposure Products (PREPS)

Cancer Research UK does not support the promotion of PREPs for the reasons that: while some toxic constituents may be reduced, others remain or may even be increased ("risk swapping"); smokers may be discouraged from quitting; and while exposure to particular harmful constituents may be reduced in some countries, companies might offload products that fail to meet regulatory standards to other, probably, low income countries ("risk shifting")¹. Therefore Cancer Research UK fully endorses the principles of WHO's TobReg guidelines¹⁰. These include: setting maximum limits for specific toxic constituents (especially nitrosamines) and prohibiting sales of cigarettes that exceed these levels; developing maximum limits for a large number of constituents, especially those that are believed to contribute to heart and lung disease and cancer; and prohibiting any marketing or product labelling that implies greater safety of such products or that they meet regulatory standards^{1,10}. There can be no reason for companies not to reduce known harmful constituents immediately to the lowest levels currently found in some products, but without any associated claims or PR. Also, as part of the FCTC process (see below) more accurate measurement systems are being developed.

5. Snus

Cancer Research UK, in line with the considered view of the public health community, does not at this time support removing the EU ban on snus. However, given its low level of risk relative to smoked tobacco, and its reported effectiveness in helping Swedish men to stop smoking, it should be investigated as a potential aid to quitting. Therefore, following further research, and under very tight regulatory control, e.g. on prescription, the potential role of snus for cessation should be explored. Under the auspices of a comprehensive and independent tobacco and

⁷ McNeil A, Bedi R, Islam S et al, Levels of toxins in oral tobacco in the UK. *Tobacco Control* 2006; 15: 64-67

⁸ Broadstock M, Systematic review of the health effects of modified smokeless tobacco products. *New Zealand Health Technology Assessment Report* 2007; 10(1)

⁹ Gray N, The consequences of the unregulated cigarette. *Tobacco Control* 2006; 15: 405-408

¹⁰ World Health Organisation TobReg Committee. Report on Threshold Levels for Toxic Constituents in Cigarette Smoke. Geneva WHO 2006

nicotine regulatory regime, whether snus might replace smoked and other smokeless forms of tobacco use could be explored. But the ideal scenario is one where tobacco use in all its forms is reduced.

6. Framework Convention on Tobacco Control (FCTC)

Cancer Research UK strongly supports the FCTC's Articles 9-11 that will set down: standards for regulation and for accurate measurement of tobacco constituents, product disclosures, and the packaging and labelling of tobacco products¹¹. In particular what is needed is:

- Full disclosure of product contents, including information about the intended purpose of additives and their known and suspected effects.
- Information about product emissions (i.e. what happens when the product is burnt).
- Prohibition of any misleading terms on packaging and labelling which create the false impression that a particular tobacco product is less harmful than other tobacco products, such as 'low tar', 'light', 'ultra-light', or 'mild'.
- More generally, information about manufacturers' product research. For example, Canadian regulations require manufacturers to report annually, for every brand they produce, all research activity relating to toxicity, health effects, ingredients, taste and flavour, modifications, marketing, and the way it is used by consumers.

To the extent possible, regulators should aim to make data as widely available as possible to researchers and to the general public. For example, smokers should have the right to know that they are inhaling formaldehyde, cyanide, carbon monoxide, etc. and information should be provided on the effects of such chemicals on the human body⁵.

Working groups are currently elaborating guidelines on Articles 9, 10 and 11, and proposals are expected to be discussed at the next Conference of the Parties (COP) in November 2008. Cancer Research UK is actively pushing for these Guidelines to be as strong and comprehensive as possible.

7. EU Product Regulation Directive 2001/37/EC

This Directive banned the use of the misleading terms 'light' and 'mild' in the EU and put in place large, rotating written health warnings, that have been shown to increase smokers' reported intention to quit. Cancer Research UK supports the regular review of evidence and updating of the Directive. In particular, the Directive allows for pictorial warnings on cigarette packs and provides a library of images. There is good evidence from Canada, Brazil, Thailand and Australia, that such warnings reinforce motivation to quit¹². To date only one EU country, Belgium, has used such picture warnings on cigarettes, and Finland will follow in 2009. The UK will start to introduce picture warnings on all tobacco products from 1st October 2008, and all products will carry warnings by October 2010.

Cancer Research UK calls for the following amendments to the Directive:

- picture warnings to be mandatory across the EU;
- an updated picture library;
- pictures to be on the front of the pack so that, as long as cigarettes continue to be displayed at point of sale, the pictures will be clearly visible;

¹¹ Framework Convention Alliance Factsheet No 4, www.fctc.org

¹² Hammond D et al. Text and graphic warnings on cigarette packages. *Am J Prev Med* 2007; 32: 202-209

- misleading information to be removed (tar and nicotine yields measured by machines that do not represent actual smokers' exposure) and replaced with accurate, relevant information.

The EU should also enforce standards for Reduced Ignition Propensity (RIP) cigarettes (fire-safe cigarettes) to be in place by 2009¹³, a measure already introduced in 22 states in the U.S.A.

8. Pure Nicotine Products

Smoking is the main cause of health inequalities in the UK, with smoking rates among the most deprived and disadvantaged in society above 70% compared to 25% for the general population. More attractive and efficient pure nicotine products which contain only nicotine and not any other tobacco constituents, (like the current medicinal products on the market such as NRT) are needed for heavily addicted smokers, in particular the most disadvantaged, to relieve their cravings without the harmful effects of smoking. Currently NRT is regulated as a medicine and its availability is restricted. These barriers to product development and must be removed, and products must be made available in a form and at a price that is attractive as an alternative to smoking. This must be accompanied by effective social marketing so that people understand that it is not the nicotine itself that is harmful but that the harmfulness of delivery (burning tobacco in the case of cigarettes) varies greatly¹⁴.

A switch of only 1% of smokers a year from smoking to less harmful nicotine sources, a conservative target, could save around 60,000 lives in only 10 years¹⁵. Cancer Research UK calls for pure nicotine products (and other cessation products) to be more affordable, attractive and available (e.g. sold over the counter) and for tobacco products to be less affordable, attractive and available.

9. Nicotine and Tobacco Regulation

The Royal College of Physicians (RCP) and other organisations have called for a Tobacco and Nicotine Regulation Authority for the UK^{16,17}. Others have recommended EU regulation¹⁸ and there are convincing single market arguments for this. Whether via one agency, or several existing authorities,¹⁹ remains to be clarified. Cancer Research UK calls for an urgent consideration of these matters in the context of the FCTC guidelines being developed, to which EU countries are legally bound. Regulation should cover all aspects of promotion, marketing, information provision, packaging and sale, and should be controlled by appropriate public health and regulatory bodies. In addition to pictorial warnings, urgent consideration should be given to plain packaging and the removal of point of sale display and advertising²⁰. Given the track record of tobacco companies in seeking to conceal the harm caused by their products²¹, regulation must be entirely independent of the manufacturers of tobacco and nicotine products.

¹³ The Leuven Consensus. www.smokefreepartnership.eu/IMG/pdf/The_Leuven_Consensus.pdf

¹⁴ Action on Smoking and Health. Submission to the Comprehensive Spending Review, 2007. www.ash.org.uk

¹⁵ Lewis S, Arnott D, Godfrey C et al, Public health measures to reduce smoking prevalence in the UK: how many lives could be saved? *Tobacco Control* 2005; 14: 251-254

¹⁶ Royal College of Physicians, Protecting smokers, saving lives: the case for a Tobacco and Nicotine Regulatory Authority, RCP London, 2002

¹⁷ Royal College of Physicians RCP, London, Harm Reduction in Nicotine Addiction, RCP London, 2007

¹⁸ ASPECT Consortium, Tobacco or Health in the European Union, European Commission, 2004

¹⁹ For more information on the regulatory options, please see forthcoming report by ASH/CR-UK/BHF, Smoking Kills Revisited

²⁰ Pollay RW, More than meets the eye: on the importance of retail cigarette merchandising. *Tobacco Control* 2007; 16: 270-274

²¹ King J, Accepting tobacco industry money for research; has anything changed now that harm reduction is on the agenda? *Addiction* 2006; 101: 1067-1068