

## Appendix

1. The report of the Royal College of Physicians on harm reduction concluded that:

The epidemiology of tobacco use in Sweden suggests that if the public is offered substantially less harmful smokeless tobacco product along with access to accurate information on relative risks, a substantial proportion can switch to the less harmful product. (The risk profile of smokeless tobaccos, page 161)

The report then went on to make the following additional conclusions:

- Smokeless tobacco is not a single product but rather a summary term for a range of different tobacco products which deliver nicotine without combustion.
- Smokeless tobacco products differ substantially in their risk profile on approximate relation to the content of toxins in tobacco.
- In some parts of the world (particularly Asia) smokeless tobacco is commonly mixed with other products that are themselves harmful.
- On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential to harm health.
- These Swedish smokeless products appear to increase the risk of pancreatic cancer and possibly cardiovascular disease, particularly myocardial infarction.
- Some smokeless tobacco also increase the risk of oral cancer, but if true of Swedish smokeless tobacco, the magnitude of this effect is small.
- All of the above hazards are of lower magnitude than those associated with cigarette smoking.
- Smokeless tobacco products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer.

- Therefore in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favorable.
- Smokeless tobacco use by pregnant woman is harmful to the unborn fetus, but the hazard of smokeless use relative to maternal smoking is not clearly established.
- In Sweden, the available low-harm smokeless products have been shown to be an acceptable substitute to many smokers, while 'gateway' progression from smokeless to smoking is relatively uncommon.
- Smokeless tobacco, there, has potential application as a lower hazard alternative to cigarette smoking.
- The applicability of smokeless tobacco as a substitute for cigarette smoking if made available to populations with no tradition of smokeless use is not known.

With respect to medicinal nicotine the Royal College of Physicians report concluded (page 126):

- Extensive experience with nicotine therapy in clinical trial and observational study settings demonstrates that medicinal nicotine is a very safe drug.
- Adverse effects are particularly local and specific to the mode of delivery used.
- NRT does not appear to provoke acute cardiovascular events, even in people with pre-existing cardiovascular disease.
- There is no direct evidence that NRT therapy is carcinogenic or influences the risk of other common smoking-related diseases in humans.
- Evidence on the safety of NRT during pregnancy is limited, but suggests that NRT does not increase the risk of major developmental anomalies or reduce birth weight. However, NRT may increase the risk of minor musculoskeletal anomalies. Further evidence on these effects is needed.

- Evidence on the safety of long-term use of NRT is lacking but there are no grounds to suspect appreciable long-term adverse effects on health.
- In any circumstance, the use of NRT is many orders of magnitude safer than smoking.

These findings both reflect and confirm why a new approach to dealing with these and other “smokefree” tobacco and nicotine products is urgently needed. There are significant opportunities from a public health standpoint, but where we go and how we get there must be done with greater dialogue and transparency involving a spectrum of interests and experts.

2. There clearly seems to be growing support for further discussions of the regulatory framework needed to ensure a more level playing field for tobacco and nicotine products (consistent with the recommendations of this paper). The Royal College of Physicians in their October report noted (pages 185-186):

- Nicotine product regulation has developed in a largely reactive and piecemeal fashion over the years.
- Smoked tobacco products remained free from regulation for many years, and are now subject to minimal controls on content, delivery and safety.
- Some smokeless products are regulated very strictly (that is, they are prohibited) whilst others are subject to even less regulation than cigarettes.
- Medicinal nicotine products are regulated very strictly, medicines.
- The lax regulation of most tobacco products affords considerable market freedom for tobacco companies to innovate and develop their products.
- The tight regulation of medicinal nicotine imposes very strict restrictions on new product development.
- Some newly launched tobacco products, including PREPS, seem to lie completely outside of the current regulation.

- This clear and unjustifiable regulatory imbalance works against public health.
- UK government resources dedicated to tobacco product regulation are very small.
- History demonstrates that regulatory change can achieve substantial changes in consumption of different tobacco products.
- The regulation of nicotine products needs to be radically overhauled to encourage the use of less harmful products and reduce the use of the more harmful sources of nicotine.
- Whilst some progress can be made in this regard through existing regulatory systems, the establishment of a nicotine and tobacco regulatory authority is the preferred way of bringing comprehensive and rational controls on the nicotine product market that will minimize the harm caused by nicotine use.