

# Scientific Advisory Committee on Tobacco Products Regulation

## Recommendation on Smokeless Tobacco Products

### Background

Smokeless tobacco use is a significant part of the overall world tobacco problem. Smokeless tobacco products are tobacco products without combustion or pyrolysis at the time of use. The prevalence of use is relatively high in many countries especially in South Asia (1). There is a great diversity of smokeless tobacco products and smokeless tobacco use patterns across the globe (1, 2). Oral use is by far the most common behaviour. Nasal use is very rare.

Different smokeless tobacco products have a range of health hazards that differ in magnitude. Many of the products have not been studied for ingredients and health effects.

Many studies of health risks did not classify smokeless tobacco by specific product characteristics. Many of the tobacco products include multiple ingredients. Most human studies have been case-control studies, although there is some evidence about health risks from a few cohort studies (3, 4, 5).

Health effects that have been studied to date are: oral cancer, other cancers, oral diseases (dental caries, gingival recession, tooth attrition, oral mucosal lesions), cardiovascular risk factors and disease, diabetes, reproductive health effects, and overall mortality.

There is conclusive evidence that certain smokeless tobacco products increase risk of oral cancer, specifically betel quid with tobacco, tobacco with lime, and other tobacco mixtures in South Asia, and smokeless tobacco in the United States (4). The few available studies on certain other smokeless tobacco products, such as toombak in Sudan and other African countries (6), shamamah in Saudi Arabia (7, 8), nass and nasswar in Central Asia republics indicate their use increases oral cancer risk (9). Evidence for associations between smokeless tobacco use and other cancers is inconclusive (10).

There are several studies that do not demonstrate a significantly increased risk of oral cancer, possibly due to design problems or lack of power (11, 12, 13). Two studies from Sweden that were well-designed and controlled for smoking showed no association between smokeless tobacco use overall, specifically ever use of snus, and oral cancer (14, 15). However, an increased risk was observed in one study among those who used only smokeless tobacco (14). In both studies ex-users of smokeless tobacco had increased risks, but the increased risk estimates did not reach statistical significance.

There are a few cohort studies from India that demonstrate significant excess all cause mortality among smokeless tobacco users (16, 17) whereas one from the U.S. does not (18).

The few studies of cardiovascular disease provide conflicting findings (19, 20, 21, 22).

One study from Sweden reported that smokeless tobacco use was associated with presence of diabetes and increased insulin resistance (23).

Several studies of smokeless tobacco use by pregnant women in India demonstrate adverse reproductive outcomes, especially low birth weight (24, 25, 26, 27, 28).

There is strong evidence that smokeless tobacco use leads to oral mucosal lesions (29), including oral pre-cancerous lesions, and gingival recession (30).

Most smokeless tobacco products have constituents that are known to be hazardous, such as tobacco-specific nitrosamines, cadmium, and nicotine (31, 32, 33, 34). Products which have not been studied or products for which no hazard has yet been demonstrated cannot be claimed to be free of harm. Products with reductions in some hazardous components, such as nitrosamines, have not been studied adequately for the range of potential health hazards.

All smokeless tobacco products have nicotine as a major constituent and are potentially addictive (35). Persons who experiment with smokeless tobacco often develop a pattern of regular daily use (35). Over time, many users increase amounts they consume (36). Cessation is difficult, as it is for smoking tobacco. Users of both smokeless and smoking products find tobacco cessation even more difficult to achieve than those who use only smokeless tobacco or only smoke (36, 37). Tobacco manufacturers encourage use of smokeless tobacco products by smokers on occasions when they are not permitted to smoke (38) and thereby promote individuals to adopt smokeless tobacco use in conjunction with continued smoking.

Youth are especially vulnerable to initiating smokeless tobacco use. In many cultures, particularly in South East Asia and increasingly in Sweden, smokeless tobacco use is more socially acceptable than smoking (39), and it is usually easy to practice without detection. There is evidence that some advertising of smokeless tobacco products targets children (40, 41, 42, 43).

Tobacco manufacturers sell “starter” products that are milder or sweeter for initiating users (44, 45). Smokeless tobacco products are usually cheaper than cigarettes. At present smokeless tobacco use is common among youth globally (46).

There is an ongoing debate in the public health community about the potential for smokeless tobacco, especially snus manufactured in Sweden, to be used as a substitute for smoking as part of a harm reduction strategy. This is being advocated by some on the premise that the range of health conditions potentially caused by smokeless tobacco is smaller than that caused by smoked tobacco (47, 48).

There are several reasons that argue against endorsing the use of smokeless tobacco products for the purpose of harm reduction. They are as follows:

*Benefits have not been demonstrated*

- Smokeless tobacco products have not been shown to be more effective smoking cessation aids than other cessation strategies
- It has not been shown that people substitute smokeless tobacco for smoking or that they will not relapse to smoking
- Smoking prevalence has not been shown to be decreased by substitution of smokeless tobacco for smoking

*Potential for harm exists*

- Promoting smokeless tobacco products may encourage individuals to adopt smokeless tobacco use in addition to continuing smoking
- Use of smokeless tobacco products has been reported to increase the chances of subsequent initiation of smoking (49)
- People who may have quit tobacco use altogether will not do so (37)
- Children who might not have started smoking may start smokeless tobacco use
- Health effects from the use of smokeless tobacco products remain unclear, and the potential for long term harm cannot be ruled out
- All smokeless tobacco products are addictive (35)

The designation of smokeless tobacco products as harm reducing agents may promote a false perception of safety. A lower risk of adverse health outcomes is achieved by reducing smoking and not by substituting another form of tobacco use.

Smokeless tobacco products frequently include other ingredients such as areca nut (in South Asia) and flavouring agents. They often contain products that affect pH, such as lime (calcium hydroxide), which in turn alters nicotine absorption (50). The tobacco may be fermented, pyrolysed, or otherwise processed before use. Product composition may change with storage (51, 52, 53). Products are frequently designed to provide properties that may affect nicotine absorption, flavour and taste, convenience of use that may affect health, among other properties (45, 50).

In most countries there is no specific mechanism for regulating smokeless tobacco products. Often smokeless tobacco products are not required to carry any health warnings. One country (India) has regulated some manufactured smokeless tobacco products as a food item as they are consumed orally. Smokeless tobacco contains tobacco but may not be marketed specifically as a tobacco product and may be disguised

as a consumer product such as toothpaste. There is a potential for regulating smokeless tobacco products as consumer products under categories such as food supplements, drugs, and toiletries and cosmetics.

## **RECOMMENDATIONS**

1. Current evidence does not indicate that use of any smokeless tobacco is free of health risks. Therefore, any such health claim is presently untenable and should not be permitted.
2. There is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy. Marketing of smokeless tobacco products with harm reduction claims should not be permitted unless validated by an independent regulatory authority on review of evidence to be submitted by the manufacturer.
3. It is recognized that the currently marketed tobacco products have not been subjected to adequate regulatory review prior to introduction. New smokeless tobacco products should be subjected to review based on procedures applicable to other consumer products intended for human consumption.
4. In countries where there is no established use of smokeless tobacco products, the introduction of such products should only be permitted if the manufacturer satisfies the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).
5. In countries where some smokeless tobacco products are in established use, new smokeless tobacco product categories should only be permitted if the manufacturer satisfies the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).
6. The incorporation of non-tobacco ingredients into smokeless tobacco products may increase the a) appeal of the product by changing the taste, flavour, and ease of use, b) addictiveness, or c) potential for harm independently or by interaction with tobacco. Therefore, such ingredients also need to be regulated.
7. Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim. Each type of claim requires a substantive body of evidence and an independent regulatory body capable of examining the claims to determine whether the claims are valid.
8. Information on potential adverse health effects should be communicated to consumers. For example, health warnings and labelling should reflect the known adverse health effects of the smokeless tobacco product.

9. More research should be undertaken to evaluate nicotine and toxin exposures and health hazards and risks to individuals from use of smokeless tobacco products, as well as to identify population health effects of changing patterns of smokeless tobacco and other tobacco use.

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