

# **Chapter 1**

## **The Global Challenge of Smokeless Tobacco**



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### Introduction

Smokeless tobacco (ST) products present a complex and widespread challenge to public health that has so far received limited attention from researchers and policymakers. In many regions and countries of the world, such as South-East Asia, ST use is the predominant form of tobacco use. Indeed, data from the Global Youth Tobacco Survey show that students aged 13–15 surveyed in 132 countries were more likely to report using non-cigarette tobacco products including ST products (11.2%) than to report smoking cigarettes (8.9%).<sup>1</sup> Yet international tobacco control efforts have largely focused on cigarettes, devoting only limited attention to other types of products, including smokeless tobacco.

### The Global Challenge

The serious health effects of ST have been documented. A 2004 International Agency for Research on Cancer (IARC) review found that there is sufficient evidence, based on epidemiologic and laboratory studies, to conclude that ST causes oral cancer, esophageal cancer, and pancreatic cancer in humans.<sup>2,3</sup> More than 30 carcinogens have been identified in ST products, including tobacco-specific nitrosamines (TSNAs), which cause tumors affecting the nasal cavity, lung, trachea, pancreas, liver, and esophagus in animal models.<sup>4</sup> Smokeless tobacco use also causes adverse oral health outcomes including oral mucosal lesions, leukoplakia, and periodontal disease.<sup>5,6</sup> Additionally, ST products contain nicotine, and users of ST products demonstrate signs of dependence similar to those of cigarette smokers, including tolerance with repeated use and symptoms of withdrawal upon cessation of use.<sup>7</sup>

Although ST use, like tobacco smoking, causes serious health damage, ST use poses substantial challenges for science and public health that are distinct from those presented by tobacco smoking.

### Wide Range of Products in Use

Understanding the use and impact of ST products is complicated by the diversity of products and related user behaviors. A wide range of ST products with different characteristics are in use around the world, including chewing tobacco, snuff, gutka, betel quid with tobacco, snus, toombak, iqmik, tobacco lozenges, and others. Yet limited data are available on the properties of these products, how they are used, and their prevalence within different population groups. This diversity makes it difficult to generalize about these products as a class. Additionally, the ways in which ST products are produced, sold, used, and regulated (such as through taxes or marketing restrictions) differ widely across countries and regions. (This report's occasional use of the word "traditional" to describe ST products that are unique to specific groups or have been used historically by those groups should not be taken to imply that these products have played a significant cultural role.)

### Complex and Limited Data

In addition to the known biologic effects of ST, the overall public health impact of ST use depends on a range of health and environmental factors, including the prevalence and patterns of use of different products in the population, the impact of marketing messages, and the effectiveness of prevention and cessation efforts. While certain groups have been identified as being at increased risk for ST use, limited data are available on why particular populations begin to use ST and what factors are most important in preventing or promoting initiation of ST use.

### Novel Products and Marketing

Tobacco manufacturers have introduced a new generation of ST products that may have broad consumer appeal due to use of attractive flavorings, such as mint or fruit flavors, and new delivery methods, such as lozenges or small pouches that eliminate the need to spit. Major multinational cigarette companies Philip Morris and R.J. Reynolds have introduced snus products carrying the well-known Marlboro and Camel brand names, thereby adding new product lines to these existing brand names and putting their marketing expertise and brand recognition to work for this new class of products. Tobacco control experts warn that increased marketing of these products may have an adverse impact on population health by appealing to young, new users or by helping current smokers maintain their nicotine dependence.<sup>8</sup> Novel nicotine delivery devices, such as electronic cigarettes, which use heat (rather than combustion) to release nicotine, are also being marketed in many countries as an alternative to conventional cigarettes. These products are not addressed in this report, but they may also have an important impact on patterns of tobacco use behavior<sup>9</sup> and therefore should be examined.

Some tobacco companies have also responded to the tremendous growth in smoke-free indoor air laws by advertising ST products to smokers as a temporary alternative to cigarettes for situations where they cannot smoke. In addition to increasing ST use, this marketing strategy may impede smoking cessation efforts by making it easier for smokers to maintain their nicotine addiction between cigarettes and in situations where cigarette smoking is not permitted, thus reducing their motivation to quit. This is an example of how progress made in one area of tobacco control, such as through smoke-free indoor air laws, has been followed by tobacco manufacturers' efforts to adapt, this time by introducing new products and marketing strategies.

### Impact on Youth and Development of Ongoing Tobacco Use Behaviors

The potential for increased initiation of ST use among youth also poses a major ongoing public health challenge. This increased initiation may be caused by increased marketing and the introduction of new, flavored products. Indeed, ST use among teens and young adults rose substantially in the United States during the 1970s after the introduction of products that were more accessible to new users, in that these products had attractive flavorings and lower nicotine content.<sup>10</sup> Evidence suggests that users who begin with low-nicotine "starter" products are more likely to subsequently "graduate" to products with higher nicotine content.<sup>11</sup> Moreover, a number of studies suggest that ST use is associated with and reinforces use of other tobacco products, including cigarettes. Thus, adolescents who use ST products may also be more likely to move on to cigarette smoking.<sup>12,13</sup>

### Limited Treatment Options

Intervention strategies for ST use cessation have had mixed success. Clinical trials have shown that behavioral interventions in particular settings, such as dental offices, may increase abstinence rates among ST users, although the available evidence is insufficient to support recommendations about the specific intervention components that should be applied.<sup>14,15</sup> In contrast, trials of pharmacotherapies in ST users, including the nicotine patch, nicotine gum, and bupropion, have shown no impact on abstinence rates over the long term (>6 months).<sup>16</sup> Some individual study results suggest that pharmacotherapies may help reduce symptoms associated with cessation, such as craving and weight gain, but such symptom reduction has not been shown to have any impact on cessation

outcomes.<sup>17</sup> Moreover, evidence suggests that people who use both cigarettes and ST demonstrate higher nicotine exposure levels and find cessation more difficult to achieve than those who only use ST or those who only smoke.<sup>18–20</sup>

### **Tobacco “Harm Reduction”**

The response to the hazards of ST use is complicated by discussions about the possibility of using ST as a means of harm reduction for cigarette smokers. Some scientists have suggested that ST use may actually reduce harm to smokers by providing an alternative to cigarettes—that is, smokers who switch completely to ST, which does not carry the same risk of lung cancer and respiratory diseases as cigarette smoking, might reduce their overall risk. While smokeless tobacco also causes cancer and other diseases, the overall health risks for a lifetime ST user may be lower than those for a lifetime cigarette smoker.

This inference requires a number of assumptions, however. Given the tremendous diversity of ST products and patterns of use around the world, it is difficult to support broad generalizations about the level of harm associated with ST products as a category. Little is known about the constituents of some ST products or the amount of exposure users receive from them. Will smokers who begin using ST products completely replace their cigarettes, or will they instead become dual product users, which may not yield any health benefit and could potentially increase their risk? Additionally, it is essential to consider the overall population-level impact of increased ST use. For example, will increased promotion of ST products lead to an increase in tobacco use initiation or have an adverse impact on smoking cessation efforts? Although the body of evidence on this topic is expanding, definitive studies to answer key questions are lacking. In short, there remain more questions than answers.

Discussions regarding harm reduction have been limited primarily to high-income countries, such as in North America and Western Europe, where cigarette smoking is the predominant form of tobacco use and there is a long history of tobacco control measures. Because tobacco products, patterns of use, disease profiles, and policy structures vary so widely across regions, these discussions are of limited relevance for other regions and are not explored in this global report.

### **Report Framework and Process**

With this information in mind, the goals for the report are as follows:

1. Bring together experts and information on ST use from all regions of the globe. The aim of this report is not to provide a comprehensive review of all the science on the health effects of ST use, which has been covered elsewhere, but to provide a snapshot of current knowledge and data sources on ST use, characteristics of products, and related policy efforts.
2. Summarize current survey information about the prevalence and characteristics of ST use and its health effects in different regions, as well as laboratory data on the contents of different products from around the world.
3. Outline what is currently known about the changing ST product market, industry marketing efforts, and economic and policy factors.

4. Provide an overview of the current state of scientific knowledge, public health information, and policy initiatives focused on ST in each major region.
5. Identify gaps and needs related to monitoring and surveillance of ST products and other information collection, and make recommendations for strengthening international collaboration and building a scientific basis for ST product control and regulation.

Thirty-two authors with expertise in ST, representing all six World Health Organization (WHO) regions, were involved in planning, researching, and writing this report. Two in-person author meetings were held to ensure coordination and consistency across chapters. Each chapter was reviewed by external expert peer reviewers not otherwise involved in the report, and the authors were charged with revising their chapters in response to the reviews. In all, 35 peer reviewers from 12 countries participated in this process. Additionally, information was compiled from a wide range of data sources, including data from the Global Tobacco Surveillance System, some of which are being reported for the first time. Given the wide variety and complexity of the ST product landscape, the report is also accompanied by a series of factsheets describing the characteristics and use of specific products (see Appendix B). These factsheets were developed and reviewed by individuals with expertise about the products. Each factsheet contains a description of the product, common and brand names, and geographic locations where the product is used, as well as information about mode of absorption, use patterns, main ingredients, processing/manufacturing data, and when available, an illustration and chemical measurements. For additional explanation of key terms and definitions, please refer to the glossary.

The report is divided into two parts:

**Part 1**—An overview of information on the global impact of ST from a variety of perspectives. Individual chapters in Part 1 describe patterns of use, characteristics of different products, health consequences, economics, marketing trends, interventions, and policies related to smokeless tobacco. Additionally, these chapters describe available tools, such as existing surveillance infrastructure, as well as gaps and research needs.

**Part 2**—Separate regional chapters providing information on all six WHO regions: Africa, the Americas, South-East Asia, Europe, the Eastern Mediterranean, and the Western Pacific. Because of the diversity of ST products and regional differences in tobacco and non-tobacco risk factors, conditions of use, and cultural and policy environments, it is essential to examine these regions independently. Each chapter describes patterns of use, types of products, known toxicity information, specific health effects, industry marketing practices, policies and interventions, and future needs and directions for the region.

### Report Background

A series of meetings and reports dating back to 1991 have identified some crucial research and policy gaps related to smokeless tobacco.<sup>4</sup> The 3rd International Conference on Smokeless Tobacco, held in Stockholm in 2002, defined research needs in a range of areas, including the chemistry and constituents of ST products, ST addiction and cessation, patterns of tobacco use, policy interventions, and harm reduction. One of the major outcomes of this conference was a set of factsheets profiling the range of ST products, traditional and manufactured, that are in use around the world. However, limited data were

available about the characteristics and use of these products. The conference speakers discussed ST use as the predominant form of tobacco use in some countries (such as Bangladesh), and its association with serious adverse population effects. These experts also described the available data on the relationship of ST use to other tobacco use as unclear, and they urged placing a high priority on further research on this topic. The need for more research on innovative cessation treatments for ST users was also highlighted.

In June 2006, the National Institutes of Health (United States) held its first ever State-of-the-Science Conference on tobacco control, “Tobacco Use: Prevention, Cessation, and Control.”<sup>21</sup> One of the key questions posed to the panel was “What is the effect of smokeless tobacco product marketing and use on population harm from tobacco use?” The panel heard testimony from leading experts in tobacco research and identified some substantial research gaps. The panel concluded that ST products were of great concern for three reasons: (1) ST use is associated with health risks, (2) data about the effect of ST on public health are limited, and (3) new products and aggressive marketing may increase use of ST in the United States. The panel stressed that more research is needed to determine the overall effect of marketing and use of these products. In particular, they concluded that “the paucity of evidence about ST in the United States leaves many questions unanswered.”<sup>21,p.13</sup>

The WHO Study Group on Tobacco Product Regulation has addressed research and regulatory needs related to ST products in two recent reports. A 2008 publication in this series urged that all ST products be subjected to comprehensive regulatory control by an independent scientific government agency. Moreover, the study group noted that “research on the health hazards and risks to individuals and populations of use of ST products is essential for governments and for implementation of the Framework Convention [on Tobacco Control].”<sup>22,p.12</sup> This research should address how the design and manufacture of tobacco products could be modified to alter their health effects. A subsequent report in the series, published in 2009, proposed establishing upper limits for two tobacco-specific nitrosamines (TSNAs) [*N*'-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)] and one polycyclic aromatic hydrocarbon [benzo(*a*)pyrene (BaP)] in ST products. This report also recommended that regulation of the distribution and sale of ST products should include measures to limit increases in TSNAs, including storage requirements and expiration dates. Although the authors acknowledged that existing evidence is not sufficient to establish whether reducing the levels of individual constituents in tobacco products will have a measurable impact on cancer risks, they asserted that “it is difficult to justify allowing high levels of known carcinogenic constituents in a product that is known to cause cancer, when lower levels are readily achievable with existing technology.”<sup>9,p.41</sup>

A second international conference focused on ST, the International Smokeless Tobacco Symposium, was held March 8, 2009, in Mumbai, India, in conjunction with the World Conference on Tobacco or Health. More than 150 participants representing dozens of countries from around the world attended the 1-day meeting. Presentations highlighted a number of challenges related to ST products, including relatively low prices for these products (which makes them appealing), the targeting of products toward youth, and the lack of organized public health and policy efforts focused on smokeless tobacco. At the end of the conference, participants agreed on several key conclusions:

- Smokeless tobacco use adversely affects all countries and regions.
- Increasing use and industry promotion of ST represents an increasing threat to public health worldwide.
- All forms of ST have an adverse impact on health.
- Smokeless tobacco should not be promoted as a harm-reduction product.
- Smokeless tobacco poses substantial challenges to regulatory and control efforts because of the wide variety of products and production methods in use, including individual point-of-use production, home- and village-based production, as well as manufacture by international corporations.
- Smokeless tobacco has not received adequate attention from researchers and policymakers, including the WHO Framework Convention on Tobacco Control (FCTC).
- Smokeless tobacco should receive increased attention (such as increased surveillance and monitoring) in all parts of the world.

Another important conference was the 2010 International Smokeless Tobacco Meeting hosted by the Tobacco Harm Reduction Network (THRN), funded by the National Cancer Institute (United States), in collaboration with the Centers for Disease Control and Prevention and the American Cancer Society. This meeting brought together leading global ST researchers to develop a coordinated and collaborative process to better understand and address the public health burden of ST worldwide. The meeting agenda included presentations highlighting findings and recommendations from previous meetings and reports; regional ST trends among populations in Asia, Africa, Europe, North America, South America, and the Eastern Mediterranean; existing research surveillance tools, databases, and networks; and opportunities and implications for ST product regulation through the FCTC and the U.S. Food and Drug Administration's new authority under the 2009 Family Smoking Prevention and Tobacco Control Act.

Among other recommendations and conclusions, the meeting identified three critical action steps to expand efforts against the ST epidemic.

- First, coordinate action to elevate the profile of ST within the broader tobacco control community. Specifically, it is urgent that reducing ST use be included as a priority in ongoing tobacco control efforts. These efforts should also focus on capacity building by attracting and supporting new researchers, especially those in low- and middle-income countries.
- Second, develop and expand global ST product monitoring and surveillance systems. These systems must address the significant heterogeneity of ST products, both commercial and local or homegrown, and their toxic constituents and additives; systems should also monitor and assess product trends and prevalence across population groups.
- Third, build the infrastructure needed to expand the evidence base critical for effective regulatory action. Strategies for developing this infrastructure should focus on building collaborations between scientists, tobacco control advocates, and policymakers. Research is urgently needed to address the diversity of ST products, changing patterns of ST use, and varied types of ST production. Timely and high-quality research is essential to the development and implementation of effective regulatory action.

Presentations at the International Smokeless Tobacco Meeting provided the basis for organizing and structuring the current report, which is an effort to address these critical action steps by raising the profile of the global challenge posed by ST use, identifying sources of information and gaps, and identifying research and policy needs related to smokeless tobacco.

### Major Conclusions

- Smokeless tobacco use is a global problem that is present in at least 70 low-, middle-, and high-income countries and affects more than 300 million people. The greatest burden from ST use is in the South-East Asia Region, which experiences the highest prevalence of ST use (including the majority [89%] of the world's users), carries the highest attributable disease burden, and has the greatest diversity in product types and forms of use.<sup>23-29</sup> Smokeless tobacco use is highly prevalent in India, where it exceeds cigarette smoking among both men and women.
- The magnitude of disease risks directly associated with ST use appears to differ across countries and regions, likely due in part to differences between ST products and patterns of use. Laboratory analyses have shown widely varying levels of known carcinogens and nicotine in ST products from different regions, and epidemiologic studies of ST users in different regions have reached varying risk estimates for cancer and cardiovascular disease from country to country. Yet data to precisely quantify these differences in disease risk and to identify the factors that drive them are lacking.
- Smokeless tobacco use and marketing present distinct public health challenges in different countries and regions. In particular, there is a divide between some high-income countries (such as in Scandinavia) with high prevalence of low-nitrosamine ST use, reductions in smoking prevalence, and strong tobacco control and regulatory frameworks, and low- or middle-income countries (such as India) where ST products are associated with very high levels of harmful constituents, where marketing of cigarettes is increasing, and a large unorganized business sector makes product control and regulation extremely challenging. Changes in product marketing, patterns of use, and tobacco control programs and interventions may have very different results in these different environments.
- Changing tobacco industry marketing strategies may influence the future public health impact of ST use. In some high-income countries where restrictions on public smoking have increased and smoking prevalence has decreased, tobacco companies have marketed oral tobacco products to smokers. However, the impact of this trend on smoking behavior, and possible dual or poly-tobacco use, remains uncertain. At the same time, multinational tobacco companies have an increasing presence among low- and middle-income countries with both smoked and smokeless products.
- In many regions, even those where ST use is highly prevalent, policies and programs aimed at ST use prevention and cessation are generally weaker than those that address smoked tobacco products. Prices are lower, warning labels are weaker, surveillance is less developed, fewer proven interventions are available, and fewer resources are devoted to prevention and control programs.

- Significant challenges exist in monitoring the use and health effects of smokeless tobacco. These challenges include the diversity of ST products and their use; the lack of information to characterize products and manner of use; the informal, unorganized nature of the ST market in some regions; and the limited attention given to tailored educational and intervention programs.
- A wide range of research gaps remain for ST products, including lack of surveillance data and data on: characteristics of diverse ST products; health consequences from use of different products, including fetal exposure and reproductive outcomes; economic policies concerning ST products and their use; and effective region-specific ST education, prevention, and treatment interventions.
- A range of different policies have been proposed or implemented for ST products in some countries, but data are often lacking on their impact or effectiveness. Greater attention is needed to strengthen the use of evidence-based policies for control of ST use, which could include: having tobacco industries disclose the contents of ST products; establishing performance standards for toxicants and maximum pH levels; banning flavorants; establishing effective and relevant health warning labels; increasing taxes on ST products; banning or restricting ST promotions, sponsorship, or marketing; and raising public awareness of the toxicity and health effects of ST products. In sum, prevention and cessation of ST use should form an integral part of any comprehensive tobacco control effort.
- Capacity for research and public health action around ST is limited in many countries, especially those where the public health burden is greatest. Development of international infrastructure for research and information sharing could enhance the ability of many countries to reduce the consequences of ST use. International collaboration and shared capacity building could include the following: (a) creating regional but globally accessible information clearinghouses for ST; (b) strengthening infrastructure for networking, communication, and collaboration; (c) building collaborations across disciplines and professions (e.g., scientists with policymakers and tobacco control advocates); and (d) developing ways to build research capacity by leveraging existing resources.

## Chapter Summaries and Key Findings

### Part 1—Overview

#### ***Chapter 1. The Global Challenge of Smokeless Tobacco***

Chapter 1 introduces and provides a framework for this report, summarizes its chapters, and sets out its major conclusions.

#### ***Chapter 2. Global Prevalence of Smokeless Tobacco Use Among Youth and Adults***

Chapter 2 describes available data on the prevalence of ST use by youth and adults in 114 countries of the 194 WHO member states. Data on ST use in many of these countries were available for the first time. Major data sources for ST prevalence included the 2007–2010 school-based Global Youth Tobacco Surveys (GYTS), the 2008–2010 Global Adult Tobacco Survey (GATS), and the 2005–2010 Demographic and Health Surveys (DHS) on adults, along with other national and subnational surveys.

### Key findings:

- More than 300 million adults in 70 countries across all WHO regions use smokeless tobacco. The largest share, 89%, are in South-East Asia. More than 250 million adult ST users are in low- and middle-income countries.<sup>23–29</sup> In a few countries, notably India and Bangladesh, ST use is very high and surpasses smoking.
- Smokeless tobacco use prevalence varies significantly across individual countries and regions, between youth and adults, and between males and females.
- Among youth and adults, males generally show higher prevalence of use than females. However, among adults, use by women is similar to or greater than use by men in some countries, including Bangladesh, Thailand, Cambodia, Malaysia, Vietnam, and some African countries, such as South Africa, Mauritania, and Sierra Leone.
- Current ST use prevalence is especially high (>15%) among adults in Myanmar, Bangladesh, India, Bhutan, Nepal, Sweden, and Sri Lanka, and among youth in Congo and Namibia. All six WHO regions reported prevalence of greater than 10% among boys, men, or overall in at least one country.
- Although data were available to measure overall prevalence for many countries, longitudinal data and data on patterns of use are lacking in most regions.

### Chapter 3. A Global View of Smokeless Tobacco Products

Chapter 3 provides information on the contents of the various types of ST products that are used around the world, including their levels of toxicants, carcinogens, and nicotine. This chapter presents a method of classifying the variety of ST products based on the inclusion or exclusion of alkaline modifiers, areca nut, or other chemical and plant ingredients with biologic activity. This chapter also describes the factors and processes that lead to the presence or formation of toxic and carcinogenic agents in ST products, and discusses the use of species of tobacco that can contribute to extremely high nicotine levels (*Nicotiana rustica*) and toxicity (*Nicotiana glauca*).

### Key findings:

- Globally, ST products vary greatly in chemical composition, with some products containing extremely high levels of nicotine, free nicotine, and carcinogens. Hence, the wide spectrum of ST products appears to represent differing levels of addictiveness, toxicity, carcinogenicity, and harmful health effects. For example, levels of certain carcinogenic TSNAs, such as NNN and NNK, can vary by several orders of magnitude among ST products distributed globally.<sup>30</sup>
- Smokeless tobacco products may be premade (sold ready to use) or custom-made (assembled by the user or a vendor according to user preferences). Premade products range from manufactured products made in factories or large production facilities to cottage industry products made in market stalls or shops.

- Levels of toxicity, carcinogens, and free nicotine in ST products are influenced by the tobacco species/type used, growing conditions (e.g., soil nitrate and metals concentrations), curing methods (air curing vs. fire curing), tobacco processing (fermentation vs. pasteurization), production methods, including the addition of certain ingredients (areca nut, tonka bean, alkaline agents), and product storage conditions.
- The presence of microorganisms (e.g., bacteria, fungi) in tobacco or their formation during production can potentially increase the levels of some carcinogens or toxicants in tobacco products.
- Reduction or elimination of fire-cured tobacco, microbial contamination, fermentation, and certain ingredients (areca nut, tonka bean) and improvements in storage conditions are potential means of reducing carcinogens or toxicants in ST products.
- Elimination of nicotine-enriched tobacco species and greatly reduced use of alkaline agents are means of reducing users' exposure to high nicotine levels and the addictive potential of some ST products.

Future research requires more thorough characterization of contents and harmful chemicals, including those not previously studied, in the wide variety of ST products that are used worldwide.

### **Chapter 4. Health Consequences of Smokeless Tobacco Use**

Chapter 4 summarizes the evidence on the adverse health consequences associated with ST products and their use, including addiction, oral conditions and precancerous lesions, cancer, cardiovascular disease, diabetes and insulin resistance, conditions of the nasal cavity, and reproductive outcomes. The chapter builds on previous reports and systematic reviews that have provided thorough assessments of the evidence. The chapter also provides estimates of the public health impact of ST product use in three countries where sufficient data are available—India, Sweden, and the United States.

Key findings:

- Compared with the vast amount of information linking adverse health effects to cigarette smoking, studies on ST use are not comprehensive. Epidemiologic studies of ST use have less information about what levels of use are associated with particular outcomes and, in some countries, fewer numbers of ST users on which to base conclusions. Also, because ST products contain varying levels of many known carcinogens as well as other plant materials, such as areca nut or tonka bean, comprehensive risk assessments must address complex mixtures of ingredients.
- There is sufficient evidence that ST products cause addiction; precancerous oral lesions; cancer of the oral cavity, esophagus, and pancreas; and adverse reproductive and developmental effects including stillbirth, preterm birth, and low birth weight. Some, but not all, ST products are associated with increased risk of fatal ischemic heart disease, type 2 diabetes, and fatal stroke.
- The extent of ST-related risks appears to vary by region, most likely due in part to differing levels of harmful constituents and ways in which these products are used.

- The proportion of cases of cancers of the oral cavity, esophagus, and pancreas that can be attributed to ST use (i.e., the attributable fraction) is greater in countries where ST use is highly prevalent. A high burden of ST-related cancers is estimated to occur in India because of the large population, high prevalence of ST use, and high incidence of cancers known to be associated with ST use.
- The public health impact of ST use can be estimated from the disease risk associated with the particular product, the prevalence and manner of use, and the population burden of disease known to be associated with ST use. The impact of ST use may be difficult to quantify where data specific to a product or region are lacking.

### **Chapter 5. The Economics of Smokeless Tobacco**

Chapter 5 summarizes the literature and available data on the economics of smokeless tobacco. It provides the first systematic overview of ST excise tax rates and points out the vast gaps in both economic data and economic research related to ST use.

Key findings:

- Very limited data exist on ST prices, tax rates, and tax structures, which makes research into the impact of ST taxes and prices on ST use very difficult, if not impossible. Very little is known about the extent to which higher ST taxes translate into higher ST prices and how these prices affect the affordability of ST products. Little is known about the comparability of tax levels between smoked and smokeless products.
- The best available estimates indicate that, by volume, 91% of ST products sold worldwide are sold through “traditional” markets (cottage industry and custom-made).<sup>31</sup>
- The tax system that best suits public health goals is likely to be country-specific. The excise tax system that should be favored is that which most effectively raises the prices of ST products and makes ST products less affordable over time, because this will discourage ST consumption. The current best practice for cigarette taxation favors the use of a specific excise tax that is regularly adjusted for inflation.
- The effectiveness of tax collection systems and the impact of higher taxes on ST use will also depend on the standardization of ST products. A standard unit may be based on dosage (average amount of a product used in a single session), the weight of the dry tobacco leaf used in a product, or the weight of a product (weight of the tobacco, water content, and all other additives). Lack of standardization complicates not only tax collection but also scientific research, as it hinders the use of econometric methods.
- Data on ST prices, taxes, ST tax revenue, and ST trade (both licit and illicit) are needed. Currently WHO FCTC reporting standards do not require collection of data on all types of tobacco products. Attention should be dedicated to monitoring and regulating the ST supply chain (manufacturing, trade, distribution) in order to develop an effective ST tax regime.

## **Chapter 6. Changing Smokeless Tobacco Products and Marketing Practices by Industry**

Chapter 6 describes novel ST products introduced over the past decade, how these products differ from more traditional ST products, and how they are being marketed.

Key findings:

- In some high-income countries, tobacco manufacturers have introduced novel ST products, using product innovations such as portion pouches, dissolvable tobacco, unique flavorings, and varying nicotine levels which may make novel products more attractive to consumers, including those who have not previously used ST products. Tobacco manufacturers, including cigarette manufacturers, have marketed new ST products to smokers for use in situations where they cannot smoke or do not want to smoke, such as at work, in airplanes, in smoke-free bars, or around family members. These marketing strategies may have an adverse public health impact if they encourage dual use or use of multiple tobacco products, discourage cessation, or encourage new tobacco use initiation.
- In low- and middle-income countries, product innovations may also make sale and use of products more convenient. For example, in India the gutka industry has promoted a packaged ready-to-use product based on a traditional custom-made mixture.
- Marketing encompasses more than advertising. Marketing practices of the ST industry should be thought of in terms of the “4 P’s”: product, price, placement, and promotion. Products are designed to appeal to targeted consumers, they are offered at a desirable price, and they are promoted effectively using multiple communication and placement channels.
- Understanding consumer perceptions of and responses to novel products is essential to assessing the public health impact of changing product and marketing strategies. Research is needed into the perceptions of consumers and their attitudes toward marketing messages, product packaging, and product characterization in order to support evidence-based control and regulation of ST products.
- Greater monitoring and research is needed regarding marketing practices in low- and middle-income countries.

## **Chapter 7. Prevention and Cessation Interventions**

Chapter 7 describes evidence-based prevention and treatment programs that have been tested in a range of countries. The interventions vary from community, to organizational, to individual levels of treatment. This chapter also explores treatments that have been targeted to specific populations of ST users.

Key findings:

- School-based and community-based prevention programs lead to short-term reductions in prevalence. Involvement of youth in the planning and implementation of programs is an important contributor to their success. School programs that are supplemented by effective family-based and mass media programs improve success over school programs alone.

- For adult ST users, dental office interventions and clinic interventions involving multiple sessions and counselor support have been shown to be effective treatments, although most studies have been conducted in high-income countries. Phone counseling and oral exam feedback appear to be key elements of an effective intervention. Training oral health professionals to intervene with ST users may also be an effective avenue for intervention.
- For resource-constrained countries, mailed self-help materials with follow-up contact by telephone or using mobile technology may be a cost-effective intervention method.
- Pharmacotherapies, with the possible exception of varenicline, have not been found effective in improving ST cessation rates. However, these medications may reduce withdrawal symptoms in individuals who stop using ST products.
- Public awareness and understanding of the detrimental health effects of ST use is incomplete and in some countries, extremely limited. Educational efforts on these harmful effects through media or health care systems are essential to support implementation of large-scale interventions.
- More research is necessary in order to develop country-specific ST intervention programs and to explore the best ways to make these interventions accessible to ST users, especially in countries where resources are limited.

### **Chapter 8. Smokeless Tobacco Regulation and Policy**

Chapter 8 describes the different types of regulations that have been implemented in different countries and regions and those countries' regulatory experiences. It also examines the challenges involved in regulating ST products and provides recommendations on how to address these challenges.

Key findings:

- Key provisions in the WHO Framework Convention on Tobacco Control as applied to ST have been implemented to varying degrees in some countries but not others. Almost all of the provisions in the FCTC have direct and distinct implications for ST products and, to be fully implemented, will require guidance specific to ST products. For example, demand-reduction measures—such as regulation of tobacco product contents, packaging and labeling, education and communication efforts, and dependence and cessation interventions—should be tailored to ST product users and to the context of their use. Additionally, WHO's TobReg committee has published recommended upper limits for key tobacco carcinogens in ST products.
- Countries and regions have had varied regulatory experiences, ranging from banning all or some ST products (Singapore, Brazil, Bahrain, United Arab Emirates, and the European Union except Sweden), following FCTC recommendations for ST products (Turkey), prohibiting ST sales to minors, restricting promotion, and requiring product reports by manufacturers (United States, Canada), requiring text-based warning labels on ST products (United States, Canada, India), to a total absence of regulation of ST (most countries in the Eastern Mediterranean Region).
- Key challenges for effective ST regulation and policy include: (a) low cost, high social acceptance, and easy availability of ST products; (b) tax evasion due to illicit sales and production in traditional markets, and illicit trade and low levels of taxation in other markets; (c) lack of standards for testing ST products; (d) industry marketing strategies for ST;

(e) heterogeneity of ST products in their composition and their manner of production, sale, and use; and (f) the introduction of newer tobacco products, which may impact efforts to quit tobacco use and may lead to dual use or use of multiple tobacco products.

- To support product regulation and control, research is needed on regular surveillance and monitoring of ST products, including laboratory testing, sales and pricing data, marketing and packaging, and consumer response. Additionally, research is needed on the characteristics of diverse products, their manner of use, and the effectiveness of policies and interventions in a variety of environments. Capacity building will also be needed to support laboratory testing and regular data collection on smokeless tobacco products.
- Overall, policies and regulation to control ST product use have been given less support by governments and public health leaders compared with efforts directed at cigarette smoking. Policies and interventions targeted to ST products should be an integral part of any comprehensive tobacco control policy and regulatory regime.

### Part 2—Regional Chapters

Chapters 9 through 14 describe the types of ST products, their production and patterns of use, as well as the regulatory environment in countries of the World Health Organization Regions: the American, European, Eastern Mediterranean, African, South-East Asian, and Western Pacific Regions.

#### Chapter 9. Smokeless Tobacco Use in the Region of the Americas

Key findings:

- Among youth, reported current ST use ranged from 1.8% in Canada to 9.8% in Barbados.<sup>32,33</sup> Smokeless tobacco use was more prevalent among boys than girls in nearly all countries and localities, with the greatest sex difference in the United States. The prevalence of ST use among boys ranged from 2.6% in Canada to 11.5% in Barbados, and among girls, from 0.8% in Canada to 8.5% in Jamaica.<sup>32,33</sup>
- For adult men, the highest reported prevalence of use was in the United States (7.1%), while use by adult women was highest in Haiti (2.5%).<sup>24,29</sup> However, detailed information on ST use for youth and adults is sparse or nonexistent for most countries in the region.
- Two types of snuff are manufactured and used in the United States: moist snuff and dry snuff. Moist snuff is by far the most widely consumed type in the United States and Canada. Loose leaf, plug, and twist are the three types of chewing tobacco sold in North America.
- In the United States, ST products have been marketed using flavorings and in pouches or lozenges, which may appeal to new ST users. Dissolvable forms of ST have been introduced in the U.S. market and a few other countries. Some of these products are compressed tobacco lozenges that resemble breath mints: Camel Orbs (R.J. Reynolds), Ariva (Star Scientific), and Stonewall (Star Scientific). (The latter two products were discontinued at the beginning of 2013.) Some of these products are produced by large cigarette companies and have been marketed to smokers to use in situations where they cannot smoke.

- Other types of products in the region include iqmik, traditionally used by Alaskan natives; chimó, the main smokeless product in Venezuela; and rapé, a type of dry snuff used in Brazil.
- Little is known about potential adverse health effects of many of the locally used products or the newer dissolvable products. More research is needed, including human and laboratory studies, to characterize the health effects of diverse products, including their use in combination with smoked tobacco products.
- Regulation of ST products in the Americas is generally weak or absent. Brazil prohibits sale of ST products by law, but they are still available in some areas of the country. Compared with cigarettes, ST products are taxed at a lower rate, have weaker warning labels, and fewer cessation supports throughout the region.

### **Chapter 10. Smokeless Tobacco Use in the European Region**

#### Key findings:

- European regional data on tobacco use are largely focused on smoking; limited information is available on smokeless tobacco. WHO datasets report adult ST prevalence for less than one-third of the European Region's countries. Additionally, limited data are available on youth ST use.
- From the available national evidence, prevalence of ST use among adults varies from 0.1% in Latvia and Switzerland to 17% in Sweden.<sup>25</sup> Men have higher rates of current use of these products than women, with 17% of Norwegian men, 22.5% of Uzbek men, and 26% of Swedish men reporting ST use.<sup>25</sup> Subnational surveys show higher ST prevalence among specific groups—for example, Bangladeshi women residents of the UK.
- Europeans use a variety of ST products. Moist snuff, or snus, originated in the Nordic countries of Sweden, Norway, Finland, and Iceland; a range of products are imported for use by communities of South Asian origin (India, Pakistan, Bangladesh, Sri Lanka) in the UK; and three national companies produce twisted tobacco for oral use primarily in Denmark. In Kyrgyzstan and Uzbekistan, nasway or nasvay is used, which is similar to the product known as nass or naswar in Iran, Pakistan, and surrounding countries. Snus and South-East Asian products have demonstrably different health risk profiles and negative health impacts.
- In Western Europe, the European Union (EU) has provided a regulatory framework for tobacco products. This framework is less rigorous for ST products compared to smoked tobacco products, particularly with respect to health warnings. Sale of moist snuff, or snus, is allowed in Sweden but prohibited in all other EU member countries, and snus is acquired illicitly in Finland, particularly by its Swedish-speaking minority. The prohibition of snus sales within the EU has repeatedly been challenged by the Swedish Match Company and by the Swedish Ministries of Trade and of Health and Social Affairs.
- The UK is home to the largest South Asian community within Europe. To varying degrees, members of these groups have brought their traditional ST use practices with them from their countries of origin, which have the highest global prevalence and negative health impacts.

- With the exception of Scandinavia, there is limited research available on the health effects of ST use in the region. Studies of long-term snus use in Sweden have yielded sometimes mixed results, but overall have shown elevated risk for cancer risk and cardiovascular mortality. Studies of communities of South-East Asian origin in the United Kingdom have shown high rates of oral cancers linked to tobacco use.
- The GothiaTek standard is a voluntary form of industry self-regulation of snus manufacturing and storage intended to reduce levels of carcinogens in the product. Because the GothiaTek standard was formally introduced by the Swedish tobacco industry in the late 1990s, the health effects of long-term exposure to modern snus manufactured under this standard are as yet largely unknown.

### **Chapter 11. Smokeless Tobacco Use in the Eastern Mediterranean Region**

#### Key findings:

- Data on ST use are not available for most countries in this region.
- Where there is documented use of ST, adult prevalence varies widely across this region and between specific subgroups. Smokeless tobacco is widely consumed in a few countries, including Yemen,<sup>34</sup> Pakistan,<sup>35-37</sup> and Sudan (unpublished results, Sudan Toombak and Smoking Research Center, 2012). While ST use has been documented among women, prevalence is substantially higher among men than among women in the region.
- The most frequently used products in the region include toombak (Sudan), shammah (Yemen), paan (Pakistan), and nass (Pakistan and Iran). Specific toxicity and nicotine profiles are only available for nass and toombak. Toombak has been reported to have the highest levels of nicotine and TSNAs ever measured in tobacco products.
- Studies in several countries in the region have documented associations between precancerous abnormalities, oral cancers, and head and neck cancers and the use of toombak, shammah, nass, and paan.
- In this region the production and marketing of ST products are primarily cottage industries, centered in tobacco farming areas and relying on locally available resources. Some ST products originating in South-East Asia are marketed to the large immigrant Asian labor force in the Gulf region.
- Well-structured interventions to prevent ST use or promote cessation of ST use are lacking in the region. The price of ST products remains low, and countries have generally not made use of taxation as a tobacco control policy. In 2009 the government of Bahrain banned the importation of chewable tobacco products.

## **Chapter 12. Smokeless Tobacco Use in the African Region**

### Key findings:

- Prevalence of ST use varies across countries and across geographic areas within countries. For example, the national prevalence was as high as 28.3% for women in Mauritania and 22.6% for men in Madagascar, and as low as 0.2% for men in Zambia and 0.5% for women in Nigeria and Zimbabwe.<sup>24,25</sup> Data collected from a state in the northeastern geopolitical zone of Nigeria in 2007 indicated high rates among people aged 15 years and older—10.8% for men and 4% for women.<sup>38</sup> For some countries, however, prevalence data are lacking.
- Smokeless tobacco products are sniffed, chewed, sucked, or applied to teeth and gums. Except in a few countries where imported premade manufactured products are marketed, most products are produced by small cottage industries or are handmade for personal use. These products are typically sold by street vendors, kiosks, convenience stores, or tobacconists.
- Customs associated with ST use vary widely across different parts of the African Region. Data suggest that there is a widespread perception that snuff possesses medicinal properties, such as relief of headache, toothache, or sinus problems.
- Based on limited existing data, the toxicity and nicotine levels of ST products appear to vary widely. Generally, commercially manufactured products tend to have lower levels of tobacco-specific nitrosamines than custom-made products, although there are exceptions.
- Very little data exist on the health effects of ST in this region, although existing data for some parts of Africa suggest oral ST use is associated with increased risk for oral pathologies and increased blood pressure. Nasal snuff use is associated with increased risk for nasopharyngeal cancer and respiratory disease.
- In general, no organized public health education programs or cessation programs for ST exist in the African Region. Policies regarding ST use vary from a ban on the sale of ST in Tanzania (but with limited enforcement) to no regulations on the distribution and marketing of ST products in other countries. South Africa bans advertisement and promotion of ST and requires a warning label on manufactured products. Smokeless tobacco products tend to be cheaper than cigarettes throughout the region.

## **Chapter 13. Smokeless Tobacco Use in the South-East Asia Region**

### Key findings:

- Prevalence of ST use among men is high across most of the region, varying between 25% and 51% in five countries, but less than 2% in Thailand.<sup>25</sup> Among women, ST use is high in India (18.4%), Bangladesh (28%), and Myanmar (16%).<sup>23,25</sup> Prevalence is also high across the region, equivalent to cigarettes, among youth aged 13 to 15 years.<sup>23</sup>
- This region is home to over 250 million ST users aged 15 and older. Rural users in India and Bangladesh make up 80% of total ST users in the world.<sup>39,40</sup> Smoking remains more common than ST use in Indonesia, Thailand, Bangladesh, Sri Lanka, and Nepal, but ST use is predominant in India and Myanmar among men.

- In India, the most common forms of ST used are tobacco with lime (khaini), gutka, and betel quid. Betel quid is typically freshly prepared by the user or a vendor. Pan masala and gutka have become increasingly popular as alternatives to traditional betel quid; they are manufactured on an industrial scale and sold in dried form.
- High levels of TSNA have been recorded in some products, including khaini and zarda. Areca nut used as an ingredient in betel quid contains additional harmful constituents. The fact that some products are produced and sold in cottage industries complicates efforts to characterize typical products in the region.
- Incidence of oral and pharyngeal cancers is high in South-East Asia Region countries compared to most of the rest of the world, and this high rate has been attributed in large part to ST and areca nut use. Historically, only 10% to 15% of people with oral cancer in India are diagnosed when their cancers are in an early, localized stage, which results in poor survival rates.<sup>41</sup>
- Most of the epidemiologic studies of specific health effects of ST use in the region come from India. Studies have documented associations between ST use and oral precancerous lesions, oral cancers, adverse reproductive outcomes, and cardiovascular diseases.
- A number of intervention programs—including school-based interventions, community interventions, and mass media campaigns, primarily in India—have been evaluated and shown to have some impact in the region. However, resources and capacity for large-scale intervention programs are limited in some countries.
- All member states in the region except Indonesia have ratified the FCTC. However, implementation of ST control policies in the region has been limited. In contrast to cigarettes, taxes on ST products are low or nonexistent. Unprocessed tobacco sold in loose form, including betel quid with tobacco, is often not taxed and does not display any package warning labels. Some countries have prohibited advertising of ST, including Bhutan, India, Maldives, Myanmar, Sri Lanka, and Thailand. Bhutan has banned the sale of all forms of tobacco, and several states in India have used national food safety regulations to ban gutka.

### **Chapter 14. Smokeless Tobacco Use in the Western Pacific Region**

#### Key findings:

- Prevalence data on ST use in this region are scant. Of the few countries that have ST use data, the rates vary from 22.4% among men aged 25–64 years in Micronesia, to 0.3% among males older than 15 years in Vietnam.<sup>23,25</sup> In some countries (Cambodia, Malaysia, and Vietnam), the rates of ST use are higher in females than males.<sup>23,25</sup>
- Forms of ST use involve areca nut/betel quid with or without tobacco, although in some countries tobacco is not traditionally added to areca nut/betel quid.
- Areca nut contains an alkaloid, arecoline, which is carcinogenic. The lack of data on health effects and toxicity of using areca nut with tobacco represents a significant data gap for this region. Potential health consequences include oral pathologies (leukoplakia and oral submucous fibrosis), head and neck cancer, and low birth weight in infants of mothers who used ST products during pregnancy.

- Current policies and interventions vary across countries in this region. Some countries have instituted bans on ST (Australia, New Zealand), bans on ST manufacturing (Taiwan), or bans on ST importation (Japan, Hong Kong, Singapore, Taiwan). However, these bans may not affect the use of areca nut/betel quit with tobacco, which sometimes is obtained from cigarettes. In addition, some of these bans remain weak because they do not prohibit importation of ST products for personal consumption.
- Some of the challenges associated with policy implementation include the notion that chewing areca nut/betel quid is symbolic of cultural identity, the belief that it has medicinal properties, and the lack of awareness of its harmful effects. Educational efforts on ST will require also addressing areca nut/betel quid, because use of these two substances is closely linked with ST use.

### **Chapter 15. Global Smokeless Tobacco Use: Future Research Needs and Policy Recommendations**

Chapter 15 summarizes the major conclusions of this report, discusses gaps in ST research, and describes needed policy changes.

Key findings:

- A wide range of research gaps remain in relation to understanding and addressing the global public health impact of ST products. Research needs include ongoing surveillance of patterns of use across product types, further characterization of diverse ST products and their constituents, assessment of the health consequences of using different products in different regions, evaluation of the economic impact of ST use and the impact of taxation policies across regions, as well as assessment of cost-effective, region-specific ST education, prevention, and treatment interventions.
- Implementation of effective strategies for control of ST use and related health effects will require increased scientific and public health capacity, particularly in low- and middle-income countries affected by high burdens of ST use. International collaboration and shared capacity building could be applied to: (a) create regional but globally accessible information clearinghouses for ST; (b) strengthen infrastructure for networking, communication, and collaboration; and (c) develop ways to build research capacity by leveraging existing resources. Collaborations are needed across disciplines and professions, such as between scientists, policymakers, and tobacco control advocates.
- Prevention and cessation of ST use should be fundamental to every comprehensive tobacco control effort. In all regions, greater awareness is needed about ST use and its health effects, including education of health professionals, consumers, policymakers, and community leaders. Effective interventions tailored specifically to ST users should be developed, evaluated, and implemented where appropriate.

- Specific guidelines are needed to ensure that the WHO FCTC requirements can be and are appropriately applied to ST products as well as cigarettes. Such guidance must also take into account the diversity of product types, patterns of use, and local contexts that are found around the world.
- A range of policies have been proposed or implemented for ST products in some countries, but data are often lacking on their impact or effectiveness. Greater attention should be directed toward strengthening the use of evidence-based policies for controlling ST use. These policies could include: requiring tobacco industries to disclose the contents of ST products; establishing performance standards for toxicants and maximum pH levels; banning flavorants; establishing effective and relevant health warning labels; increasing taxes on ST products; banning or restricting ST promotions, sponsorship, or marketing; and raising public awareness of the toxicity and health effects of ST products.

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