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Control and prevention of smokeless tobacco products

Report by WHO

Introduction

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) to the Convention Secretariat to invite WHO to:

- identify, examine and collect existing best practices on prevention and control of smokeless tobacco (SLT) products;
- collate existing research, explore the research gap and identify the research areas that need to be focused upon; and,
- identify options for the prevention and control of SLT products.¹

2. Prior to the above request being made, the COP had reviewed, at its fourth session, a document² on this matter and subsequently requested that a comprehensive report based on the experience of the Parties on SLT be submitted to its fifth session.³ That report was duly submitted to the COP at its fifth session,⁴ and the present report should be seen as complementary to it.

3. In addition, this report incorporates the December 2013 deliberations and scientific recommendations on SLT by the WHO Study Group on Tobacco Product Regulation (TobReg),⁵ and analysis from the recent WHO survey on tobacco products. The survey was conducted between

¹ See decision FCTC/COP5(10).

² Document FCTC/COP4/12.

³ See decision FCTC/COP4(14).

⁴ Document FCTC/COP/5/12.

⁵ See http://www.who.int/tobacco/industry/product_regulation/tobreg/en/

November 2013 and April 2014 among all WHO Member States; 90 of them responded, representing 77% of the world's population. Four of them were States non-Parties to the Convention.¹

4. Documents FCTC/COP/4/12 and FCTC/COP/5/12 reviewed the definition, types, carcinogenic content, presentation and prevalence of SLT products. They also outlined the experiences of the Parties with respect to such products. This report provides expanded and up-to-date knowledge obtained from Parties' experiences and recommendations from the TobReg experts on research gaps and needs.

5. Understanding the use and impact of SLT products is complicated by the diversity of products and related behaviours that exist. Many different SLT products with different characteristics are in use around the world, including chewing tobacco, snuff, gutka, betel quid with tobacco, snus, toombak, iqmik and tobacco lozenges. 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 make generalizations about such products as a class.

6. SLT use has received less attention than cigarette use by the global public health community because it has been perceived to impose a smaller burden on human health and was previously mainly confined to a few South Asian countries, some Nordic countries, and the United States of America. However, the problem of SLT use is no longer a local or regional problem but a major global one affecting a large percentage of the world's population.

Results of the WHO survey

7. The results of the WHO survey are shown below; figures in parentheses that follow the numbers of countries represent the percentage of the world's population living in those countries:

- (a) SLT products are regulated under tobacco laws in 46 countries (26%), both tobacco and food safety laws in 8 countries (19%), and under other laws in 9 countries (23%); in the rest, it is not known under which the laws SLT products are regulated.
- (b) Production, distribution, and sale of SLT products are under some regulation in 54 countries (66%). The number of countries that regulate the production, distribution, and sale of commercially manufactured SLT products is 41 (60%), 43 (59%) and 51 (63%), respectively. The number of countries that regulate the production, distribution, and sale of cottage industry manufactured SLT products is 24 (31%), 30 (33%) and 36 (41%), respectively.
- (c) Contents and ingredients of SLT products on the market are regulated in 9 countries (22%).
- (d) Governmental sale licences are required in 26 countries (30%).

¹ The WHO tobacco products survey on smokeless tobacco products, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 countries, including 86 Parties to the WHO FCTC, had responded to the survey as of 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Botswana, Bolivia (Plurinational State of), Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Lao People's Democratic Republic, Latvia, Lithuania, Kenya, Kuwait, Lebanon, Malaysia, Maldives, Mali, Mauritania, Myanmar, Mongolia, Morocco, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, Uruguay, United Arab Emirates, United States of America, Uzbekistan, Viet Nam, Zambia.

- (e) Policies regulating sale of SLT products to minors exist in 64 countries (72%). Where specified, minimum required age for buying SLT products ranges from 16 to 21 years.
- (f) Comprehensive bans on SLT product advertising, promotion and sponsorship are in place in 50 countries (38%).
- (g) SLT product taxes are implemented as follows:
 - (i) no excise tax in 24 countries (13%);
 - (ii) uniform ad valorem excise tax in 8 countries (21%);
 - (iii) uniform specific excise tax in 11 countries (8%);
 - (iv) mix of uniform ad valorem and uniform specific excise taxes in 4 countries (2%);
 - (v) uniform ad valorem with minimum specific floors in 3 countries (1%);
 - (vi) tiered system in 1 countries (1%);
 - (vii) value added tax in 34 countries (53%);
 - (viii) import duty in 31 countries (53%).

Current regulation at the regional/country level

8. WHO African Region: In the last decade or so, the introduction of SLT products into many eastern and southern sub-Saharan African countries has mostly gone unnoticed by health and revenue authorities. A number of countries in the Region are now adopting comprehensive tobacco control policies and legislation that cover all tobacco products, including SLT products. In the United Republic of Tanzania, the sale of SLT products was banned in 2006, although it has been suggested that more stringent monitoring and enforcement are needed. Seychelles has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

9. WHO Region of the Americas: In Brazil, SLT products are allowed for sale if they are registered with the national health regulatory agency, ANVISA. However, since none are registered, SLT products sold in Brazil are illegal. In Canada, SLT products generally fall under the broader tobacco products regulation, including prohibition of sale to minors, restrictions on promotion, and requirements for manufacturer reporting. Labelling regulations for SLT products exist but only apply to chewing tobacco, nasal snuff, and oral snuff. In the United States, laws have been enacted which include provisions for product registration, warning labels on all products, enforcement of a minimum age of sale, and limits on the amount of nicotine, toxicants, and additives. Many countries in the Region, such as Chile, Costa Rica, Ecuador, El Salvador, Honduras, Nicaragua, Panama, Peru and Uruguay, have legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

10. WHO Eastern Mediterranean Region: While Bahrain and the United Arab Emirates have adopted policies banning the sale and importation of SLT products, relevant regulatory controls are mostly absent in the Region. Heavy fine-based measures have been used to enforce the laws where present. Many countries in the Region, such as Egypt, Islamic Republic of Iran, Kuwait, Morocco, Oman, Qatar, and United Arab Emirates, have legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

11. WHO European Region: The European Union (EU) provided leadership on regulatory practices, including through the recently revised Tobacco Products Directive that governs the manufacture, presentation and sale of tobacco and related products. EU member countries regulate SLT products by prohibiting the sale of tobacco for oral use, which includes all products for oral consumption made of tobacco except those intended to be smoked or chewed. Sweden, however, is exempted from this regulation. In many eastern European Parties, SLT is regulated in accordance with advertising and health warning regulations similar to those applicable to smoked tobacco products. Turkey has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

12. WHO South-East Asia Region: Many Parties in the Region have initiated steps to regulate SLT. Bhutan introduced a policy to ban the manufacture and sale of tobacco products, including SLT products, in 2004 and in 2010 introduced comprehensive legislation to implement the 2004 policy. India invoked food safety laws in 2011 to ban gutka and pan masala containing tobacco, some of the most common forms of SLT used in the country. India also strengthened pictorial health warnings and used intensive mass media campaigns to inform people of the harms of SLT. The country also introduced SLT cessation into tobacco dependence treatment guidelines and into the National Tobacco Control Programme. In the area of illicit trade, India introduced presumptive taxes on SLT, based on production capacity, and revenue collection on SLT products has increased more than fourfold in the last five years. Nepal has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT packaging. In 2013, Bangladesh introduced comprehensive tobacco control legislation that includes SLT. However, the countries of the Region lack adequate laboratory testing capacity to test for constituents of SLT.

13. WHO Western Pacific Region: In 2010, concerned by the increasing use of areca (betel nut) and chewing tobacco,¹ the WHO Regional Office for the Western Pacific supported the countries in the Region in the development of a regional action plan, identifying specific tobacco control indicators and actions related to the reduction of betel nut and tobacco use. In 2012, the report by the Regional Office, prepared in consultation with countries and territories² experiencing high betel nut and chewing tobacco burdens, recognized the widespread use of betel nut in the region³ and identified the need to increase the sharing of evidence of the harms caused by this SLT sub-type with policy-makers, and also the need to develop community-based strategies to bring about changes in behaviour towards SLT use.⁴ Some Parties, such as Singapore, have banned SLT products, for example chewing tobacco, new forms of tobacco derivative products such as dissolvable tobacco, and nicotine-based products. Singapore has a laboratory for measuring nicotine content in SLT products such as chewable tobacco, betel quid, and khaini. Mongolia and Viet Nam have implemented pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

Priority research needs

14. Until now, there has been limited research on SLT products and more relevant and specific data are needed on SLT use⁵ and the adverse health and economic costs of such use. Parties to the WHO FCTC, WHO and academic institutions have important roles to play in developing a deeper evidence base on the individual and social risks of different types of SLT. Current data- and information-gathering tools at all levels need to be adapted to collect more information on SLT.

15. Surveillance and monitoring: Comprehensive surveillance is needed to assess the scope of SLT use and changes in patterns of use, and to evaluate the impact of policies, interventions and other steps that could be taken to address SLT use, even in those Parties where SLT is banned or prevalence is very low. Surveillance and monitoring of trends in SLT use should include information on populations and subpopulations that use SLT, types of products used, rate of initiation of SLT and trajectory of tobacco use, patterns and intensity of use, combined use of other tobacco products, and

¹ Betel nut and tobacco, chewed together, is the most popular form of SLT in the WHO Western Pacific Region.

² Cambodia, Guam, Kiribati, Marshall Islands, Micronesia (Federated States of), Mariana Islands, Palau, Solomon Islands, and Vanuatu.

³ The report states that the use of betel nut “is widespread in parts of Melanesia, principally Papua New Guinea, Solomon Islands, the Northern Province of Vanuatu and in the Federated States of Micronesia, particularly in Guam, Palau, the Commonwealth of the Northern Mariana Islands and the Marshall Islands.”

⁴ The report is available from <http://www.wpro.who.int/tobacco/documents/betelnut.pdf>

⁵ Even data from Euromonitor International, which obtains its information from industry reports, show that there are just 14 out of 201 countries and territories with available records on tonnes of SLT sold in their country/territory, regardless of whether the SLT was made available by a local manufacturer or importation.

attitudes to, beliefs about and perceptions of tobacco products. Additionally, surveillance should include monitoring of changes in use and cessation of other tobacco products, including cigarettes.

16. **Economics and marketing:** There are only limited economic data available, including on pricing, tax structures and sales, to devise SLT taxation and pricing policies and programmes for different Parties. Data on SLT product marketing strategies are also very limited and information on the cost of health care to treat SLT-related disease is non-existent.

17. **Product characterization:** Given the diversity of products, modes of preparation, and scale of production around the world, a more comprehensive characterization of the properties of different products, their constituents, and methods of manufacture is needed. Additionally, attention should be given to estimating the health impact of carcinogenic non-tobacco products that are frequently used in conjunction with tobacco, such as areca nut (betel nut). Testing of products must occur regularly in order to assess national and regional variations and any changes in products over time.

18. **Health effects:** Despite the differences in the relative risks of the various SLT products, no SLT product is safe. However, the diversity of products, practices, and patterns of use precludes broad generalizations about the health effects of SLT use. Most studies of health effects have been conducted in Scandinavian countries, the United States, and India. There is a need to carry out product-specific and country-specific assessments of the health burden of SLTs products to determine the global disease burden.

19. **Interventions:** Population-based prevention and individual cessation interventions need to be tailored to SLT users, taking into account the heterogeneity of SLT products and their addictiveness. The use of mobile technology (mCessation) to reach the target population groups, along with the adoption of other cessation support services in primary health care settings, needs to be looked into. Furthermore, as most of the current evidence base for the effectiveness of cessation interventions comes from smoking cessation experiences in high-income Parties, there is a need for further research on development and evaluation of interventions for SLT cessation in low- and middle-income Parties.

Regulatory options for prevention and control of SLT products

20. **Develop Party-specific and product-specific interventions:** Comprehensive implementation of the WHO FCTC for regulating all tobacco products, including SLT products, is vital to the regulation of SLT products. However, given the heterogeneity of SLT products, there may be a need for product-specific policy interventions and strategies that fit the context of local community, prevalence rates, etc. For example, for some Parties, banning sales of and trade in all, or the most prevalent forms of, SLT products may be appropriate.

21. **Apply WHO FCTC requirements to SLT products:** Tobacco control policy interventions for cigarettes and other smoking forms of tobacco should also apply to SLT products. These interventions include: (1) health warnings on product packaging that cover the major proportion of packages, include text and pictorial warnings, are rotated, and are located on the top principal display areas; (2) restrictions or bans on advertising, promotion, and sponsorships; (3) bans on sales to minors; (4) taxation and pricing policies, with effective compliance, to discourage SLT use and lower demand – tax-induced price increases should be high enough to reduce consumption; (5) promotion and provision of evidence-based SLT cessation interventions; (6) education of the public about the harms of SLT use through information, education, and communication efforts to boost awareness of the harmful health effects of SLT use and to dispel myths – education should be targeted at health professionals, policy-makers, community leaders and the public, through mass media and other channels.

22. In addition, Parties that are considering or in the process of ratifying the Protocol to Eliminate the Illicit Trade in Tobacco Products should also take into consideration the domestic and cross-border trade of SLT.

23. WHO TobReg has noted that the following manufacturing practices are known to lessen somewhat toxicant levels in SLT:

- (a) air curing which produces lower levels of tobacco-specific nitrosamines as compared to other methods;
- (b) pasteurization as compared to fermentation; and
- (c) avoiding storage for prolonged periods in warm weather.

These manufacturing practices do not imply necessarily reductions in human exposure, risk or disease. Regulatory options in this domain should be considered only in light of the content of the section on regulation of tobacco product toxicants of document FCTC/COP/6/14.

24. Disclose constituents of SLT products: Manufacturers should be required to disclose to governments all ingredients and harmful and potentially harmful constituents of their SLT products.

25. Reduce the appeal of SLT products by banning or regulating sweeteners and flavouring substances (including herbs, spices, and flowers) as recommended in the partial guidelines for implementation of Articles 9 and 10, Section 3.1.2.2(i).¹

26. No health claims or claims of reduced exposure or harm should be allowed until scientific evidence in support of such claims has been reviewed and approved by an independent, scientific government regulatory agency.

27. Address information gaps by sharing current progress and challenges and expand the existing evidence base including the quantification of risks (burden on health, economy, environment, and social costs) by utilizing existing WHO Global Tobacco Surveillance System and WHO STEPS surveys. These surveys could be used to provide greater coverage of SLT use at the country level. Smaller, targeted surveys are also needed in order to understand patterns among specific subgroups.

28. Lack of laboratory capacity for the testing of tobacco products is a major challenge in regulating SLT products. Some countries lack the capacity to evaluate contents and toxicant levels. Despite the budget and resource limitations, improvements are needed in methods, specific product standards, and testing regimens. Testing methods should be standardized and, ideally, coordinated by region, perhaps through the WHO Tobacco Laboratory Network.²

29. Conduct impact assessments and evaluations of SLT-related policy and regulatory practices. Gathering relevant data and sharing of Parties' experiences of SLT importation and use is crucial to helping Parties adopt comprehensive, WHO FCTC compliant policies and programmes that encompass the regulation of SLT products.

ACTION BY THE CONFERENCE OF THE PARTIES

30. The COP is invited to note this report and provide further guidance.

¹ The Guidelines are available at: http://www.who.int/fctc/guidelines/adopted/article_9and10/en/

² See http://www.who.int/tobacco/industry/product_regulation/toblabnet/en/