Conference of the Parties to the WHO Framework Convention on Tobacco Control

Fourth session
Punta del Este, Uruguay, 15–20 November 2010
Provisional agenda item 5.8

FCTC/COP/4/12
15 September 2010

Control and prevention of smokeless tobacco products and electronic cigarettes

Report by the Convention Secretariat

1. This paper was prepared to support consideration by the Conference of the Parties of Provisional agenda item 5.8 concerning smokeless tobacco and electronic cigarettes. In relation to the latter, the working group on Articles 9 and 10 separately requested guidance, in its report to the Conference of the Parties,[1] as to whether Electronic Nicotine Delivery Systems are to be considered "tobacco products" and should be part of the future work of the working group.

SMOKELESS TOBACCO

2. The term "smokeless tobacco" is used to describe tobacco that is consumed in unburnt form, either orally or nasally. It is a growing socioeconomic and health concern in many countries, particularly low- and lower-middle-income countries in the WHO South-East Asia, Eastern Mediterranean and Western Pacific Regions. It is also consumed in several developed countries in different parts of the world.

3. Smokeless tobacco contains several carcinogenic compounds and is usually of the species Nicotiana rustica (most smoking tobacco is Nicotiana tabacum). Samples of N. rustica have been found to contain higher concentrations of tobacco-specific nitrosamines than N. tabacum.[2] Smokeless tobacco also contains 24 polycyclic aromatic hydrocarbons (PAH) that cause oral and pancreatic cancers. Until recently it was erroneously believed that smokeless tobacco was a less harmful alternative to smoking tobacco as it did not contain PAH. This assumption was proved to be wrong by recent research that has established that moist snuff becomes contaminated with PAH during the

[1] Document FCTC/COP/4/6.

[2] See International Agency for Research on Cancer monographs at: http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php.

curing of tobacco leaves required for its preparation.[1] The consumption of smokeless tobacco, however, remains a social habit and cultural practice in many countries.

4. The harsh taste of smokeless tobacco is masked by adding flavors that are familiar to and popular among children and youth, such as vanilla, chocolate and strawberry. After using smokeless tobacco a few times, nicotine addiction starts to intensify and the product is then used primarily for obtaining nicotine.

5. The oral form of smokeless tobacco is commonly chewed, sucked or applied to the teeth and gums. Examples of sucking tobacco include chimó, dry snuff, gutkha, khaini, loose-leaf, maras, mishri, moist snuff, naswar, plug, shammah, snus, tobacco tablets and toombak; examples of chewing tobacco include betel quid, gutkha, iq'mik, khaini, khiwam, loose-leaf, mawa, plug, tobacco chewing gum twist or roll, and zarda; other oral tobaccos include creamy snuff, gudhaku, gul, mishri, mawa, red tooth powder, and tuibur (tobacco water).[2] In the nasal form, a small quantity of very fine tobacco powder mixed with aromatic substances, called snuff, is inhaled. It includes dry snuff and liquid snuff.

6. The use of betel quid with tobacco is very common in some countries of the WHO South-East Asia Region. Several oral tobacco preparations such as mishri, gudhaku, red tooth powder – lal dantmanjan and creamy snuff are intended primarily for cleaning teeth. Many tobacco companies have taken advantage of the lack of awareness about their products or the misconception that these products are less harmful than smoking tobacco, and have packaged and positioned some of them as dental-care products. This is especially true in rural populations, where smokeless tobacco is marketed as having curative or palliative effects for common discomforts such as toothache.

7. Analysis of the implementation reports submitted by Parties[3] indicates that the consumption of smokeless tobacco is a widespread and growing problem. Of the 135 Parties that submitted reports, 20 provided data on the use of smokeless tobacco products among adults and 25 provided data for youth.[4] In the adult population, the weighted regional averages calculated from the information submitted by Parties for "current smokeless tobacco consumers" showed large variability across WHO regions: for males the average regional rates varied from 1% for the Region of the Americas to 33% for the South-East Asia Region, and for females the rates varied from as low as 2% for the European Region to a high of 10% for the South-East Asia and the Western Pacific Regions.

8. In some countries, such as India, the current use of smokeless tobacco among adult males is as high as 36.5% and 8.4% for females. In Myanmar, Nepal and Sudan, the use of smokeless tobacco among males is around 25%, but prevalence figures for females differ from as low as 1% in Sudan to 11.7% in Nepal. The highest smokeless tobacco prevalence rate of 53.1% among male consumers has been observed in Yemen, and in Bangladesh the prevalence of smokeless tobacco use among females (27.9%) exceeds that of males (26.4%). In many of these countries, women continue to consume smokeless tobacco such as gutkha, pan masala and tobacco toothpaste during pregnancy. As for nasal

[1] Mitra K, Peterson L. Abstracts, American Chemical Society Division of Chemical Toxicology, 238th National Meeting and Exposition, Washington, DC, August 16–20 2009. *Chemical Research in Toxicology*, 2010, 23:264–290 (available at: http://pubs.acs.org/doi/pdfplus/10.1021/tx900403c).

[2] See International Agency for Research on Cancer monographs at: http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php.

[3] Party reports are available on the WHO FCTC web site at: http://www.who.int/fctc/reporting/en/.

[4] A detailed analysis of smokeless tobacco use among adults and youth can be found in the 2010 global progress report on the implementation of the Convention at http://www.who.int/fctc/reporting/summary_analysis.

snuff, Parties such as the Maldives, Myanmar, Norway and Sudan reported the highest prevalence figures among smokeless tobacco consumers.[1]

9. In some countries and population groups the prevalence of use of smokeless tobacco exceeds that of smoking tobacco. For example, in Yemen, there are almost twice as many male smokeless tobacco users (53.1%) than smoking tobacco users (27.4%). Similarly, in Bangladesh, the prevalence of smokeless tobacco use among females (27.9%) far exceeds prevalence of female smoking (1.5%).

10. For youth, information reported from the Global Youth Tobacco Surveys (GYTS) in the age group 13–15 years indicates that there is an increasing use of smokeless tobacco in this vulnerable age group in all WHO regions. Within the Parties that provided information on youth smokeless tobacco use in their implementation reports, the highest figures were found in the Marshall Islands (43.3% among boys and 21.6% among girls), the Federated States of Micronesia (41.8% and 32.1%) and the Democratic Republic of Congo (29.3% and 27.6%), followed by Sweden for boys (28.9%) and Mauritania for girls (17.3%).

11. Scientific evidence shows that the age-adjusted relative risk of mortality for users of smokeless tobacco is elevated compared to that of non-tobacco users. In 2006 the International Agency for Research on Cancer (IARC) concluded that smokeless tobacco is carcinogenic in human beings, causing cancer of the oral cavity and pancreas. The IARC noted wide variability between geographic regions in the type and extent of disease caused by use of smokeless tobacco, and that the disease dissimilarities were accompanied by large differences in the concentrations of carcinogens in the tobacco used in different regions.[2]

12. Studies in some South-East Asian countries also indicate that consumption of smokeless tobacco during pregnancy leads to adverse reproductive outcomes such as shorter gestation period, lower birth weight and increased male fetus wastage among smokeless tobacco users.[3]

13. The consumption of smokeless tobacco also has adverse socioeconomic consequences. In many low- and lower-middle-income countries scarce family resources are spent on tobacco products instead of food or other essential needs.

14. There are also reports that indicate that smokeless tobacco is illicitly traded in many countries, leading to substantial losses of tax revenue to governments. This also results in the inability of the governments concerned to use the raising of tobacco taxes as an effective demand-reduction strategy, with a view to eliminating the consumption of smokeless tobacco.

15. Although the WHO FCTC covers all tobacco products, many of the strategies developed under the Convention have been built on a cigarette-based model, owing to the fact that early tobacco-control efforts took place in developed countries. The tobacco industry, however, is expanding its operations in developing countries and increasingly places an emphasis on smokeless tobacco products. The tobacco industry regards smokeless tobacco as a low-cost and highly profitable vehicle

[1] Information obtained from national health statistics, including through WHO STEPwise approach to Surveillance (STEPS), Global Adult Tobacco Surveys (GATS) and Global Youth Tobacco Surveys (GYTS).

[2] See International Agency for Research on Cancer monographs at: http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php.

[3] Gupta PC, Subramoney S. Smokeless tobacco use and risk of stillbirth: a cohort study in Mumbai, India. *Epidemiology*, 2006, 17(1):47–51.

for creating dual users (those who use smokeless products along with cigarettes), whose addiction to more than one product makes cessation very difficult. The tobacco industry is also promoting the use of smokeless tobacco as an alternative in countries that have made good progress in ensuring smoke-free environments.

16. The increased use of smokeless tobacco products therefore represents a threat to developing countries in particular and raises the likelihood that there will be an increasing prevalence of dual users. It is important to emphasize that all forms of smokeless tobacco have an adverse impact on health and that smokeless tobacco should not be promoted as a harm-reduction product.

17. The consumption of smokeless tobacco is a global concern and not limited to a few countries. During the negotiations leading to the WHO FCTC, Parties agreed to address concerns relating to all forms of tobacco, not only the smoking forms. Some Parties have already formulated comprehensive tobacco-control legislation that is fully compliant with the WHO FCTC and are therefore addressing the issues related to both smoking and smokeless forms of tobacco; this still remains to be addressed by others.

18. It is vital to work out specific strategies that can "target" issues related to smokeless tobacco. However, given resource constraints and capacity challenges, Parties need to work towards developing an integrated tobacco-control programme as part of their ongoing programmes and initiatives. This may include training and capacity building and well-planned information, education and communication strategies and campaigns to boost awareness of the negative effects of smokeless tobacco, especially in vulnerable groups such as youth and pregnant women.

19. Further research is required to develop cost-effective strategies for smokeless tobacco cessation and standardized testing methods for smokeless tobacco. Some progress has already been made by the WHO Study Group on Tobacco Product Regulation.[1] The Study Group has recommended that all tobacco products, including smokeless tobacco, should be subjected to comprehensive regulatory control by an independent, scientific government agency; that such control requires disclosure of ingredients by manufacturers; that any health claim made for a smokeless tobacco product must be supported by sufficient scientific data, as determined by an independent, scientific government regulatory agency; that the contents and emissions of smokeless tobacco products must be tested and measured continuously in order to detect national and regional variations and changes over time; that research on the health hazards and risks to individuals and populations of use of smokeless tobacco products is essential for governments and for implementation of the WHO FCTC; that research on smokeless tobacco products, their effects and how their design and manufacture are modified in order to alter their effects is essential for adequate testing and measurement, to provide information for governments and for implementation of the Convention.[1]

20. One of the major challenges in regulating smokeless tobacco products is their low cost. This is one reason such products are accessible to youth. Uniform taxation policy on all tobacco products, so as to discourage shifts to cheaper tobacco products (as may occur if the tax is raised in a non-uniform manner), remains an important policy consideration, as do issues relating to the illicit cross-border trade of smokeless tobacco in many regions. Smokeless tobacco also poses substantial challenges to regulatory and control efforts because of the wide variety of products and production methods in use,

[1] See the WHO Study Group on Tobacco Product Regulation (TobReg) web site at: http://www.who.int/tobacco/global_interaction/tobreg/en/.

including individual point-of-use production, home- and village-based production, as well as manufacture by international corporations.

21. Owing to the scale of the epidemic, comprehensive legislative, technical, administrative and other measures and greater international cooperation will be needed for effective prevention and control of smokeless tobacco products.

ELECTRONIC NICOTINE DELIVERY SYSTEMS

22. Electronic Nicotine Delivery Systems are designed to deliver nicotine to the respiratory system. The term encompasses products that contain tobacco-derived substances, but in which tobacco is not necessary for operation. They are battery powered devices that provide inhaled doses of nicotine by delivering a vaporized propylene glycol/nicotine mixture.

23. Electronic Nicotine Delivery Systems are marketed under a variety of brand names and descriptors, of which the terms "electronic cigarettes" or "e-cigs" are the most common. On the evidence of many countries, electronic cigarettes are witnessing a significant increase in global distribution and sales. This increase coincides with implementation of Article 8 of the WHO FCTC (*Protection from exposure to tobacco smoke*) that is leading to the introduction of smoke-free environments in many countries. As market penetration of these products continues to rise, policy-makers and regulators in many countries have sought guidance from WHO on the scientific evidence-base and optimal regulatory approaches to be taken with regard to these products.

24. The WHO Study Group on Tobacco Product Regulation discussed Electronic Nicotine Delivery Systems and prepared a report[1] on the matter. The report was submitted to the WHO Executive Board at its 126th session by the Director-General, in January 2010.[2]

25. The report noted that manufacturers claimed that these products delivered nicotine without tar and carbon monoxide. It concluded that the safety and extent of nicotine uptake had not been established; that the products were marketed as smoking cessation aids, but that not enough scientific evidence existed to validate this claim; and that delivery to the lung might be dangerous and, independent of the effects of nicotine, it was of global importance to address lung delivery in scientific studies. The Study Group also concluded that Electronic Nicotine Delivery Systems that are designed for the purpose of direct nicotine delivery to the respiratory system fall into a regulatory gap in most countries, escaping regulation as drugs and avoiding the controls applicable to tobacco products. There is also insufficient evidence currently to assess whether Electronic Nicotine Delivery Systems may be used to aid cessation, whether they create or sustain addiction, and whether they deliver constituents other than nicotine to smokers.

26. The Study Group recommended that clinical trials, behavioural and psychological studies, and post-marketing studies at individual and population levels are needed to answer these questions. Claims that these products have health benefits, reduce harm, or can be used to aid smoking cessation should be prohibited until they are scientifically proven. They should be regulated as nicotine delivery

[1] WHO Study Group on Tobacco Product Regulation. *Report on the scientific basis of tobacco product regulation: third report of a WHO study group.* Geneva, World Health Organization, 2010 (WHO Technical Report Series No. 955). The report provides scientific and regulatory recommendations on Electronic Nicotine Delivery Systems.

[2] See document EB126/37.

devices, and where this regulation is not possible under tobacco control laws, should be subject to regulation of contents and labelling, prohibitions against use in public places, and restrictions on advertising, promotion, and sponsorship.

27. Following publication of the report, WHO convened a Regulatory Consultation on the Safety of Electronic Nicotine Delivery Systems on 6–7 May 2010. The meeting was attended by delegates of WHO Member States,[1] invited experts in the field of tobacco product regulation, members of the WHO Study Group on Tobacco Product Regulation, members of the Convention Secretariat, and WHO staff.

28. The purpose of the meeting was to share national regulatory experiences, raise awareness of potential safety concerns related to Electronic Nicotine Delivery Systems, consider current and future approaches to the regulation of these products, including the potential for standardization, and map out means of promoting and protecting public health through research and the development of clear regulatory guidelines. Issues of particular concern included: lack of understanding of the organic compounds or vaporization products used in electronic cigarettes, in addition to the absence of any published studies demonstrating their efficacy and safety; and the lack of any data that establish the safety of the nicotine and other constituents used in these products to confer the claimed cigarette-mimicking sensory characteristics when heated and delivered to the lung. A further concern that remains is the precise nature and the quantity of constituents in the emissions.

29. The participants of the regulatory consultation agreed to make the recommendations listed below.

- Nicotine is a highly toxic and addictive substance that poses a serious risk to health. Nicotine and nicotine products for human use should be regulated.

- There is an emerging group of products called Electronic Nicotine Delivery Systems that may or may not deliver nicotine. These products, commonly including e-cigarettes,[2] may be used to deliver other potentially toxic chemicals and drug ingredients. These products are often accompanied by inaccurate information. Regulators are concerned that the quality and safety of these products has not been established.

- Regulators of medical and tobacco products should collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) Electronic Nicotine Delivery Systems to protect public health.

- Where health and/or therapeutic claims are being made or implied, quality, safety and efficacy data substantiating those claims should be presented to the regulator.

- National regulators are encouraged to inform the public and other interested parties about concerns related to these products, including their safety and misleading marketing, and to

[1] The meeting was attended by delegates from Australia, Brazil, Canada, the European Commission, New Zealand, Saudi Arabia, Serbia, Singapore, South Africa, Switzerland, Thailand, Turkey, Ukraine, and the United States of America.

[2] These have been marketed as AltSmoke, Blu, CigLib, Crown 7, DSE, EastMall, Econoclope, Edsylver, GreenSmoke, Hydro, Intellicig, Janty, Joye, Kanger, KR808, Liberty-Cig, Modern Vapor, NJoy, NPRO, PureSmoker, Ruyan, Sedansa, Tecc, Totally Wicked, Vapor4Life, VaporKing or Vapure.

share information among themselves about these products, including research findings and related policies.

- National regulators encourage WHO to facilitate information exchange between tobacco control and medical products regulators.

30. The meeting participants also decided to establish two informal working groups to develop information documents on Electronic Nicotine Delivery Systems, for national regulators and the general public.

31. Overall it is evident that there is growing concern internationally about the quality, safety, and "regulatory gap" of these emerging products broadly called Electronic Nicotine Delivery Systems as they continue to penetrate new markets.

ACTION BY THE CONFERENCE OF THE PARTIES

32. The Conference of the Parties is invited to note this report and provide further guidance.

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