WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

SECRETARIAT

MEDIA BRIEFER

Progress report on technical matters related to Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation of contents and disclosure of tobacco products, including waterpipe, smokeless tobacco and heated tobacco products)

Report by the World Health Organization

This media briefer summarizes the World Health Organization's (WHO) progress report on work related to Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC) on regulation of contents and disclosure of tobacco products. The report also outlines activities related to novel and emerging tobacco products, as well as electronic nicotine delivery systems and/or electronic non-nicotine delivery systems (ENDS/ENNDS), in response to decisions made by the Conference of the Parties (COP) to the WHO FCTC. The report also addresses emerging and ongoing issues in product regulation, particularly on flavours, nicotine pouches, and disposable ENDS.

Introduction

As part of the efforts to implement a comprehensive set of tobacco demand-reduction measures set out in the WHO FCTC, the WHO and its various networks work to identify scientific, policy and regulatory gaps and to build evidence and capacity to support the implementation of Articles 9 and 10 of the WHO FCTC.

Development of methods for testing and measuring of contents and emissions of ENDS/ENNDS

At COP7, the COP requested the Convention Secretariat to invite WHO to report on the development of methods by regional and international standards-development organizations for testing and measuring the contents and emissions of ENDS/ENNDS. In response, WHO commissioned a paper that identified existing standardised methods for determining the contents and emissions of ENDS/ENNDS. The paper reported that the components of interest in the contents and emissions of e-liquids include: nicotine, glycerol, propylene glycol, tobacco-specific nitrosamines (TSNAs), benzo[a]pyrene, carbonyls, phenolic compounds,

volatile organic compounds (VOCs), metals, and flavours. Efforts are underway in a few national, regional, and international standardization bodies to propose, develop, or validate methods for determining some of these components in e-liquids.

Broad regulatory objectives on ENDS/ENNDS

At COP7, a report submitted by WHO presented the following broad regulatory objectives, including options which Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider:

(i) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;
(ii) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;
(iii) prevent unproven health claims being made about ENDS/ENNDS; and
(iv) protect tobacco control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.

The current report notes that these options remain valid and that in line with the first and second regulatory objectives, Parties that have not banned the importation, sale and distribution of ENDS and ENNDS may consider (i) "banning or restricting the use of flavours that appeal to minors"; (ii) "testing heated and inhaled flavourants used in the e-liquids for safety, and banning or restricting the amount of those found to be of serious toxicological concern…"; and (iii) requiring the use of ingredients that are not a risk to health and are, when allowed, of the highest purity".

Technical and scientific assistance on ENDS/ENNDS and other products

At COP7, the COP requested the Convention Secretariat to invite "WHO to continue to provide technical and scientific assistance on ENDS/ENNDS upon request by the Parties or the Convention Secretariat". WHO continues to provide technical and scientific assistance to its Member States not only on ENDS/ENNDS, but also on other products, including novel and emerging nicotine and tobacco products, and conventional tobacco products.

WHO also published a Report on the scientific basis of tobacco product regulation (Eighth report of TobReg), which contains evidence-based recommendations on ENDS/ENNDS and heated tobacco products (HTPs). Two key recommendations are: (1) "to prohibit the sale of ENDS/ENNDS in which the user can control device features and liquid ingredients (i.e., open systems) and (2) to prohibit the addition of other pharmacologically active substances such as cannabis and tetrahydrocannabinol (in jurisdictions where they are legal) to ENDS and ENNDS".

Four systematic reviews on ENDS/ENNDS

The WHO also commissioned four systematic reviews on ENDS/ENNDS to update its 2016 systematic reviews on (i) prevalence of use among children and adolescents, (ii) association between ENDS/ENNDS with initiation of tobacco use, (iii) efficacy of ENDS/ENNDS as cessation aids, and (iv) health effects of ENDS/ENNDS.

(i) Prevalence of ENDS/ENNDS among children and younger adolescents

On prevalence of ENDS/ENNDS among children and young adolescents, a systematic review of global data found that:

- "Ever use" of ENDS/ENNDS ranged from 2% to 52%, with a combined pooled estimate of 17% in children and adolescents across all countries and territories.
- Current use of ENDS/ENNDS ranged from 1% to 33%, with a combined pooled estimate of 8% in children and adolescents across all countries and territories.
- Use of ENDS/ENNDS tended to be higher for males than females in children and adolescents.
- Use of ENDS/ENNDS by children and adolescents tended to be higher in high-income countries than for higher-middle- and lower-middle-income countries.

(ii) Association between ENDS/ENNDS with initiation of tobacco use

The review found that non-smoking children and adolescents below the age of 20 who use ENDS/ENNDS have over two times the increased risk of tobacco use at 6-24 months follow-up. Further, there are few studies assessing whether ENNDS or flavoured ENDS/ENNDS use increases risk of cigarette smoking, which warrants further investigation. Since publication of this systematic review, updated research on association between use of e-cigarettes among non-smoking young people has similarly reported more than three times increased risk, as compared with non-users of electronic cigarettes among youth and young people.

(iii) Efficacy of ENDS/ENNDS as cessation aids

The WHO report explains that the evidence on the efficacy of ENDS/ENNDS as cessation aids is rated as "low" or "insufficient". The incongruity in findings across published evidence and a number of unknown factors at this time mean that ENDS/ENNDS cannot be recommended as cessation aids at the population level. However, WHO recommends approved smoking cessation aids, such as nicotine replacement therapies (gums and patches) and pharmacotherapies, with established safety, quality, and efficacy, and which must be approved by each country's regulatory authority.

(iv) Health effects of ENDS/ENNDS

While the evidence of some health effects of ENDS has not yet been established, there is conclusive evidence that e-cigarettes cause poisoning, injuries and burns and immediate toxicity through inhalation, including seizures. Further, ENDS use leads to addiction, as well as increases airborne particulate matter in indoor environments. Among smokers, the use of e-cigarettes increases heart rate, systolic and diastolic blood pressure, and arterial stiffness acutely after use. There is sufficient evidence that ENDS are harmful, particularly to young

people. The long-term health effects of these products are unknown and the health impacts of dual use with cigarette smoking are not yet fully understood, but some studies suggest that dual use is at least as, or probably even more, harmful than exclusive smoking of conventional cigarettes.

Market developments and usage of novel and emerging tobacco products

WHO continues to monitor and examine market developments and usage of novel and emerging tobacco products as requested by the COP at COP7. At COP8, WHO provided an update on technical matters related to Articles 9 and 10 of the WHO FCTC, which also provided information on the global sales of these products, sales forecast until 2021 and referred readers to WHO's Heated Tobacco Products: Market Monitoring Information Sheet, which outlined the various strategies employed by the industry to market HTPs.

The current report also outlines newer tactics of the tobacco industry to expand its markets in new and emerging tobacco products such as HTPs, as well as on ENDS/ENNDS. WHO examined these tactics in the Eighth report of TobReg, which described a wide range of marketing strategies used to promote HTPs, often targeting adolescents and young adults, such as advertisements, pricing strategies, marketing to young people, and "corporate social responsibility" to boost the industry's image.

Further, the market for HTPs continues to grow. Their global sales generated US$ 32.4 billion in 2022 but are expected to reach a market value of US$ 77.2 billion by 2027. This projected rapid growth in sales, coupled with the increasing use of these products in some jurisdictions, is a concern for regulators.

Finalization of SOPs for testing of smokeless and water-pipe tobacco and HTPs

The WHO Tobacco Laboratory Network (TobLabNet) develops and validates methods to test the contents and emissions of nicotine and tobacco products and supports WHO in building testing capacity in WHO Member States. The report outlines the work undertaken by WHO in validating testing methods for tobacco products other than cigarettes, including smokeless tobacco and water-pipe smoke, in response to a request from the COP at COP6. Three standard operating procedures (SOPs) for smokeless tobacco have been published in April 2022, covering SOPs for determination of (i) nicotine content, (ii) moisture content, and (iii) pH of smokeless tobacco products, and which are now available for use by countries for regulatory purposes.

In response to a request at COP8, WHO is also working through TobLabNet to develop SOPs for the contents and emissions of HTPs. WHO has published the SOP for the determination of nicotine, glycerol, and propylene glycol content in the tobacco of HTPs in the third quarter of 2023. WHO has also published an '*Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health*,' which provides information on why it is important to measure and regulate HTP emissions.

Scientific evidence on impact of cigarette ventilation

At COP8, the COP requested the Convention Secretariat and the WHO to hold a face-to-face meeting with experts to discuss the latest scientific evidence on the impact of cigarette ventilation on cigarette use. WHO addressed the technical component of the request and commissioned experts to develop background papers. The meeting report, which informed the development of the report to COP9 on the scientific evidence on the impact of cigarette ventilation on cigarette use, is available for Parties' information.

Report on research and evidence on novel and emerging tobacco products

At COP8, the COP requested the Convention Secretariat to invite the WHO and TobLabNet to prepare a comprehensive report, with scientists and experts independent from the tobacco industry, on research and evidence on novel and emerging tobacco products, with a particular focus on heated tobacco products (HTPs).

WHO address this request in the Eighth Report of TobReg, the policy brief on research and evidence on novel and emerging tobacco products, in particular HTPs, and in document FCTC/COP9/8 – Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, now updated in document FCTC/COP10/10.

Emerging and ongoing issues in product regulation

Nicotine pouches

Nicotine pouches (also called "white pouches", "tobacco-free nicotine pouches," etc.) are among the products introduced by transnational tobacco companies to several markets circa 2018 to diversify product lines and sustain profitability. They are pre-proportioned pouches that contain nicotine, and are similar to snus, which are conventional smokeless tobacco products. This similarity to conventional products poses serious regulatory challenges to countries.

WHO has commissioned a paper in the Ninth TobReg report on the "characteristics, use, harmfulness and regulation of nicotine pouches." The paper noted that nicotine pouches have attractive properties, such as appealing flavours, can be used without the stigma of smoking, and also deliver sufficient nicotine to induce and sustain addiction.

WHO also commissioned a report on flavours in nicotine pouches, and touches on how these products are advertised and promoted in aggressive marketing campaigns, and are particularly appealing to youth. The report notes that in many countries, nicotine pouches are either unregulated or lightly regulated, leading to a rapid rise in sales over a short timeline. The paper is available on the WHO FCTC website as supplementary information.

Disposable ENDS

WHO notes that disposable ENDS (D-ENDS), which were introduced around 2018–2019 and began circulating on global markets, are fast becoming a global public health challenge. They are discarded after the e-liquid content is consumed, which means that all device components (plastic, metal casing, lithium battery, heating element, e-liquid, etc.) are intended to be used only once and thrown away. Given the popularity of these products among children and adolescents and the alarming trends among young people in a number of countries, WHO commissioned a background paper on the characteristics, marketing, challenges, and regulatory considerations of D-ENDS, which is available as supplementary information on the WHO FCTC website.

Flavours and flavouring agents

The Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC recognize that "*from the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive*". They further recommend that "*Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products*". To facilitate this, TobReg has made several recommendations on flavours, since its fifth report in 2015 and in every subsequent report, thereafter, including a recommendation to prohibit flavours in new products.

WHO has been engaging with countries, regions, international experts, and NGOs to address issues related to the use of flavours in nicotine and tobacco products. These engagements facilitated the sharing of country experiences and the exchange of knowledge and information and highlight the need for a comprehensive ban or otherwise comprehensive regulation of flavouring agents in all nicotine and tobacco products to protect the youth.

Policy options and WHO FCTC implementation approaches

The report provides the following non-exhaustive list of regulatory options that Parties might consider in accordance with their national laws, including options to continue building capacity for product testing and use of WHO TobLabNet SOPs to facilitate implementation of Articles 9 and 10 of the WHO FCTC:

- *ENDS/ENNDS:* Where the importation, sale and distribution of ENDS are not banned, governments should: (i) ban these products to children and adolescents, (ii) prevent the availability and marketing of the products to children and adolescents; and (iii) monitor the use of ENDS/ENNDS among children and adolescents and subsequent uptake of smoking by conducting the relevant national surveys.

- *Marketing of novel and emerging tobacco products:* Where countries have not banned the importation, sale and distribution of novel and emerging tobacco products, governments should consider banning all commercial marketing of novel and emerging tobacco products, including in social media and through organizations funded by and/or associated with the tobacco industry.

- *Research and evidence of novel and merging tobacco products:* Recognizing that HTPs are tobacco products, Parties that have not banned their importation, sale and distribution should fully apply the provisions of the WHO FCTC, as well as follow the implementation approaches enumerated in documents FCTC/COP9/8 and FCTC/COP9/10.

- *Nicotine pouches:* Parties should consider the recommendations of TobReg in its Ninth report, particularly to (a) establish or extend surveillance of products and their users, (b) regulate nicotine pouches to prevent all forms of marketing and take all other action necessary to minimize young people's access to them, (c) regulate non-therapeutic nicotine products in the same manner as products of similar appearance, content and use; and (d) ensure that nicotine pouches are not classified as pharmaceutical products unless they are proven to be nicotine replacement therapies by following stringent pharmaceutical pathways for licensing as prescribed by the national regulatory authority.

- *Disposable ENDS:* In addressing the challenges presented by these products, Parties should consider very strong regulations, which could include a ban, to protect children and adolescents. This should be done in the context of its regulatory environment, while maintaining focus on evidence-based tobacco control through full implementation of the WHO FCTC.

Action by the Conference of Parties

The report invites the COP to note the report and to provide further guidance.

For further information and media inquiries, please contact:

Samuel Compton
Media Officer
comptons@who.int
Tel: + 44 7714 856606
20, Avenue Appia | CH-1211 Geneva | Switzerland

Mitchel Lara
Web and Communication Officer
mediafctc@who.int
Tel: +41 79 126 2846
20, Avenue Appia | CH-1211 Geneva | Switzerland