Regional consultation on novel tobacco products: health effects, research needs and provisional recommended actions for regulators¹

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Introduction

Shifts in the tobacco market due to awareness of tobacco risks, implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC) provisions (1), and tightening of regulations, have resulted in declining sales of cigarettes in high-income economies. The tobacco industry has responded by promoting so-called 'cleaner' or 'reduced risk' alternative products, including electronic nicotine delivery systems (ENDS), of which e-cigarettes are the most common type; electronic non-nicotine delivery systems (ENNDS); and other newer tobacco products such as new generation heated tobacco products (HTPs). Currently, HTPs are available in at least 40 WHO Member States and continue to spread (2). Moreover, the evolution of these products and the interchangeability of the component parts have posed a unique challenge to their monitoring, surveillance, classification and regulation

The high prevalence of tobacco use, paired with increasing measures to combat the use of traditional tobacco products, could drive a market move to these newer tobacco products, which are severely under regulated in many Member States. In 2016, ENDS were banned in 30 WHO Member States globally, 11 of which were in the EMR (3).

Following an emerging trend in the EMR for the legalization of e-cigarettes, a regional consultation was called upon by Member States from the Region to give further guidance on how to deal with these new products, and was held 3–4 July 2019 at the WHO Regional Office for the Eastern Mediterranean Region, Cairo, Egypt.

The objectives of the consultation were to:

- review the global and regional status of regulation on e-cigarettes and newer tobacco products
- examine best practice regulation on regulating e-cigarettes and newer tobacco products
- review and develop recommendations for EMR Memiber States on how to regulate e-cigarettes and newer tobacco products.

This consultation was attended by nearly 30 participants including international and regional

experts in addition to Member States' representatives. The consultation served as a platform for sharing recommendations for regulation of ENDS, ENNDS, and HTPs. Two side-by-side texts (one for ENDS/ENNDS and one for HTPs) were finalized during the consultation and are to be included in its final report. The findings of the regional consultation and the side-by-side texts will be the basis of a WHO global consultation to be held in early 2020.

The consultation addressed the following topics: the overarching scientific evidence on ENDS, ENNDS and HTPs and their prevalence in the Region; global recommendations (WHO FCTC/WHO) on ENDS and HTPs and the relevant Articles of the WHO FCTC; ENDS taxation; policy considerations and approaches towards regulating ENDS and HTPs (with a focus on protecting users and non-users and preventing unproven health claims); European perspectives on policies to control ENDS and HTPs; preventing youth initiation; protecting tobacco control policies from vested interests; Illicit tobacco trade in ENDS/ENNDS and HTPs; flavour regulation in the EU; and Member States' experiences in establishing strong policies to control ENDS and HTPs.

Summary of discussions

The work of the consultants and the Member States sought agreement on the elements of the side-by-side text for implementation of the WHO FCTC on ENDS and ENNDS; and the elements of the side-by-side text for implementation of the WHO FCTC on HTPs. During the consultation experts, Member States, and representatives from WHO Regional Office for the eastern Mediterranean Region, WHO FCTC and WHO HQ were divided into working groups based on their expertise. These groups developed side-by-side texts based on WHO FCTC and Conference of the Parties (COP) decisions, and provided options to Member States for regulations based on international best practices.

Recommendations to Member States

• Banning either ENDS and ENNDs products until further evidence is available or regulate these products.

This report is based on the proceedings of the Regional consultation on novel tobacco products: ENDS, ENNDS and HTPs. Health effects, research needs and provisional recommended actions for regulators, 3-4 July 2019, Cairo, Egypt.

 Regulating ENDS and ENNDS, if a Member State chooses to do so, using COP and WHO recommendations.

For HTPs, given COP decisions and WHO recommendations, Member States are called upon to regulate them as a tobacco products.

The side-by-side texts included in the report for the consultation contain regulatory options based on COP decisions, WHO recommendations and international

best practices for ENDS, ENNDS and HTPs.

Recommendations to WHO

- continuing its support to Member States for implementing effective control policies for the use of ENDS, ENNDS and HTPs.
- continuing supporting Parties to the WHO FCTC to fulfil their obligations under the treaty with respect to ENDS, ENNDS and HTPs.

References

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Regional framework for action	on tobacco control	World Health Organization
Strategic intervention	Progress indicator	Relevant WHO Framework Convention on Tobacco Control (FCTC) article
sovernance and political commitment		
 Become a Party to the WHO FCTC Develop national tobacco control strategies, plans and programmes aligned with the WHO FCTC Assign a full-time focal point for tobacco control Adopt measures to protect public health policies from the influence of the tobacco industry Ensure the sustainability of tobacco control programmes 	 → A comprehensive national tobacco control law is in place, in line with WHO FCTC commitments → Comprehensive, multisectoral national tobacco control strategies, plans and programmes, consistent with the WHO FCTC, are enacted → A designated national multisectoral coordinating mechanism for tobacco control is in place → A tobacco control focal point is in place → Measures to address Article 5.3 of the WHO FCTC are included in national tobacco control plans → Funding is available in the ministry of health budget for tobacco control programmes 	Article 5
Demand reduction		
 Increase tobacco taxes to at least 75% of the retail price, and include all tobacco products in tax increases Expand current smoke-free policies to cover all public places and workplaces Establish a complete ban on tobacco advertising, promotion and sponsorship, including a ban on tobacco promotion in drama Enforce graphic health warnings at least 50% of the pack size on all tobacco products and packaging in line with WHO FCTC guidelines Incorporate delivery of brief cessation advice into essential services package for primary health care, including 	 → Tobacco tax is at least 75% of retail price for all tobacco products, through using excise tax → All public places and workplaces are totally smoke-free with no designated smoking areas → All forms of tobacco advertising, promotion or sponsorship are banned → All tobacco products have graphic health warnings at least 50% of pack size → Brief tobacco cessation advice is integrated into primary health care, health promotion, risk reduction and disease control programmes. Primary health care workers are trained in brief tobacco cessation advice. Quit line is established 	Articles 6–14

Regional framework for action on tobacco control	l (continued)	
Strategic intervention	Progress indicator	Relevant WHO Framework Convention on Tobacco Control (FCTC) article
Demand reduction		
establishment of quit line, and ensure availability of nicotine replacement therapy and mandate training of all health professionals in giving brief cessation advice		
Supply restriction		
 → For Member States that are Parties to the WHO FCTC, pursue ratification of the Protocol to Eliminate Illicit Trade in Tobacco Products → Adopt measures to minimize illicit trade in tobacco products → Ban tobacco sales to and by minors → Transition tobacco farmers towards other crops → Eliminate incentives for tobacco agriculture 	 → The number of WHO FCTC Parties that have ratified the Protocol to Eliminate Illicit Trade in Tobacco Products has increased to nine → Tracking and tracing system of tobacco products is in place → Legislation banning sales of tobacco products to and by minors is enacted in all Member States → Policies and programmes to reduce tobacco agriculture are being established 	Articles 15–17
Surveillance, monitoring and research		
 → Regularly implement standard global/regional surveys (e.g. Global Tobacco Surveillance System surveys) and evaluation on tobacco control activities and disseminate results widely → Institute research to monitor tobacco industry efforts to circumvent tobacco control in the Region 	 → National adult and youth surveys are regularly conducted, every 5 years → Tobacco industry monitoring and research is actively being implemented in the Region 	Article 20 and part of Article 5

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