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Review Article

AN OVERVIEW OF CIGARETTES AND OTHER TOBACCO PRODUCTS REGULATION AND CONSUMPTION IN THE REPUBLIC OF NORTH MACEDONIA

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ABSTRACT

Cigarettes and other tobacco products are subject to a significant number of country-specific regulations regarding their content, conditions of sale, places where they can be consumed, who can smoke them, how they can be advertised or promoted and how they must be packaged. Such policies form the core of successful tobacco control.
The methodology in this research paper involves a multi-source desk research approach, drawing on academic literature, government reports and data from international organizations to provide a comprehensive overview of tobacco product regulation and consumption in the Republic of North Macedonia.
Key findings reveal that the legal framework for tobacco control in North Macedonia should be further upgraded to align with standards based on the World Health Organization's Framework Convention on Tobacco Control. The high rate of cigarette consumption has shown a slight decline over recent years.

Keywords: tobacco products, cigarettes, regulation, consumption, control

ПРЕГЛЕД НА РЕГУЛАТИВАТА И ПОТРОШУВАЧКАТА НА ЦИГАРИ И ДРУГИ ТУТУНСКИ ПРОИЗВОДИ ВО РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА

Цигарите и другите производи од тутун подлежат на значителен број специфични прописи за секоја земја во однос на нивниот состав, условите за продажба, местата каде што можат да се консумираат, кој може да ги пуши, како можат да се рекламираат или промовираат и како мора да се пакуваат. Ваквите политики го формираат јадрото на успешната контрола на тутунот.
Методологијата во овој истражувачки труд вклучува пристап на истражување на повеќе ресурси, потпирајќи се на академска литература, владини извештаи и податоци од меѓународни организации за да се обезбеди сеопфатен преглед на регулирањето и потрошувачката на тутунски производи во Република Северна Македонија.
Клучните наоди покажуваат дека законската рамка за контрола на тутунот во нашата земја треба да се надгради за да ги исполни стандардите засновани на Рамковната конвенција на Светската здравствена организација за контрола на тутунот. Високата стапка на потрошувачка на цигари покажува мало опаѓање во последните години.

Клучни зборови: тутунски производи, цигари, регулатива, потрошувачка, контрола

INTRODUCTION

Cigarette consumption has shown a long-term, steady decline in many countries due to increased awareness, regulation and control. However, global consumption remains high and is estimated to be between 4.5 and over 5 trillion cigarettes annually (Statista, 2025).

Various organizations, including the parties to the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC), the United Nations, the U.S. Food and Drug Administration (FDA) and the European Parliament, are working to strengthen the regulation of tobacco products (FDA, 2025; WHO, 2003).

To assist countries in the implementation of tobacco control policies, the World Health Organization (WHO) introduced the MPOWER package, an acronym representing six evidence-based tobacco control measures. To assess national-level legislation, WHO assigns a score to each MPOWER measure, ranging from 1 to 4 for the monitoring component (M) and 1 to 5 for the other components. According to Vardavas (2022), FCTC has served as a powerful tool to initiate, support and advance national, regional and global tobacco control efforts.

According to Wright (2015), the key requirement for implementing regulatory control of cigarettes is that the measurement of levels of substances of regulatory interest be conducted in a reproducible manner. Recommended test methods have been developed by TobLabNet for the determination of substances in cigarette smoke, which the FCTC Parties and the FDA have proposed to be reported. The Republic of North Macedonia has introduced various tobacco control policies over the past decade, including increased taxation of tobacco products, smoke-free areas, bans on advertising and graphic health warnings on packaging. However, monitoring the implementation of these strategies and programs, as well as the laws adopted on their basis, and assessing their effectiveness remains a major challenge of the North Macedonian legal system, which became particularly evident after the start of negotiations for the country's membership in the European Union.

Data from the Institute of Public Health of North Macedonia show that 45.4% of the population were active smokers in 2024, which is significantly above the European Union average and places the country among those with the highest smoking prevalence in the world (Mijovic Hristovska and Mijovic Spasova, 2024). Since cigarettes are the most widely used tobacco product in the country, our objective is to collect and analyze data on the regulation and consumption of this product. On the other hand, there are still significant gaps in research on the impact of FCTC measures in tobacco control and cigarette consumption in North Macedonia. Specifically, this research paper focuses on the following two research questions:

RQ1: How aligned is the Macedonian regulatory framework with European and international tobacco control standards?

RQ2: What are the current trends in the consumption of cigarettes in North Macedonia?

MATERIAL AND METHODS

The methodology for writing this research paper includes the systematic collection and analysis of existing data, literature references, reports and other relevant information from secondary sources. A thorough search of academic journals, conference proceedings, industry reports and books related to tobacco products regulation and consumption was conducted. To access a diverse range of scientific literature on the subject, online databases such as Tobacconomics, studies from Analytica Think Tank, Tobacco Control journal, Google Scholar and Scopus were accessed.

Organizations such as the World Health Organization (WHO), Food and Drug Administration (FDA), European Commission (EC), and market research firms Statista were also used as sources for their reports and publications related to tobacco control efforts, policy frameworks and data on tobacco products consumption.

For two research questions, efforts were made to utilize information from reliable and up-to-date primary and secondary sources to maintain the credibility of the research findings.

RESULTS AND DISCUSSION

1. How aligned is the Macedonian regulatory framework with European and international tobacco control standards?

Numerous international, governmental, and non-governmental organizations are heavily engaged in tobacco use control, driven primarily by the implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC). These entities work to reduce tobacco demand, promote cessation, and counter tobacco industry interference in tobacco control. Tobacco control refers to a comprehensive set of supply, demand and harm-reduction strategies, including policies, laws and educational programs, designed to reduce the use of tobacco products (cigarettes, cigars, pipes, roll-your-own (RYO) and smokeless tobacco. Table 1 shows that many organizations and bodies have participated in the implementation, adoption of rules and regulations, and activities to control the use of tobacco products. Today, regulation, control and monitoring of cigarettes and other tobacco product use are primarily guided by the WHO FCTC, a legally binding agreement adopted by 183 parties to restrict tobacco product use. WHO has engaged in a series of Tobacco Control Capacity Assessments, which are joint between national governments and WHO to identify country capacity (including strengths, opportunities, barriers and obstacles) for the implementation of effective tobacco control measures according to national circumstances and priorities and in the context of their obligations under the WHO FCTC.

Table 1. Capacity building, initiatives and activities in tobacco control

Organization/body	**Directive/Act/policy**	**Year**	**Activity**	**Reference**
World Health Organization (WHO)	Framework Convention on Tobacco Control (FCTC)	2003	Development of the first global treaty aimed at strengthening efforts to reduce tobacco	WHO, 2003
World Health Organization (WHO)	Tobacco control policies -MPOWER	2008	Implementation of tobacco control measures	WHO, 2008
European Parliament	Directive 2001/37/EC	2001	The European tobacco control framework (manufacture, sale and presentation) of tobacco products	Directive, 2001
European Parliament	Directive 2014/40/EU	2014	Regulations and administrative provisions of the manufacture, presentation and sale of tobacco and related products	Directive, 2014
U.S. Food and Drug Administration (FDA) Center for Tobacco Products	Family Smoking Prevention Tobacco Control Act	2009	Regulates the manufacturing, marketing, and distribution of tobacco products	Tobacco control act, 2009
United Nations Agency for non-communicable diseases	Agenda for Sustainable Development 2030	2015	Encompasses comprehensive policies as smoke-free regulations, health warnings, advertising bans and tobacco taxation.	UN, 2015; Gravely et al. 2017
Global Alliance for Tobacco Control Network of civil society organizations	Strategies that address barriers to WHO FCTC implementation	2022	Global network of civil society actors working towards tobacco control.	https://gatc-int.org/about-us/

The result of this capacity assessment is a set of recommendations to government and other stakeholders in developing and implementing tobacco control programmes in each country. Currently, the WHO analyses global progress in government action on tobacco products control and publishes an annual report. The 2025 report marks the tenth global report

tracking the six MPOWER measures, which include: monitoring tobacco use, protecting people from tobacco smoke, offering cessation support, warning about the dangers of tobacco, enforcing bans on advertising and raising taxes (WHO, 2025).

Monitoring the implementation of WHO FCTC strategies and programs, as well as the laws adopted based on them and assessing the effects of their implementation in North Macedonia, are discussed in the following section.

The Republic of North Macedonia ratified the WHO FCTC in 2006. Tobacco control legislation in the country is aligned with the WHO FCTC and the European Tobacco Products Directive (2014/40/EU) and includes several laws: the Law on Tobacco, Tobacco Products and Related Products (Law 98/19); the Law on Smoking Prevention (Law 36/9), the Law on Excise Duties (Law 16/04), the Law on Audio and Audio-visual Media Services (Law 184/2013).

The main reasons for adopting the Law on Tobacco, tobacco and related products in 2019 were to establish improved conditions for operation in the market of tobacco and tobacco products, ensure more efficient regulation of manufacturing and trade in tobacco products, and provide a legal framework to enable regulated manufacturing and trade in new related products. The ministries of economy, of agriculture, forestry and water management, of health, and of finance and customs are the responsible bodies. Implementation is ensured by the SIA, SMI, SSHI, the national administrative inspection, the State Educational Inspectorate, and the Scientific Tobacco Institute-Prilep, which assesses the quality of tobacco products. Concerning FCTC measures, in 2020 Republic of North Macedonia achieved 78.3% implementation in the capacity domain (González-Marrón et al., 2023). The assessment of policy compliance was conducted only in the areas of legal prohibitions and the increase in cigarette taxes. Concerning legal prohibitions, it was concluded that there was no compliance with the bans on the promotion and sponsorship of tobacco products. According to the WHO, later implementation has been fragmented and tobacco control remains suboptimal relative to FCTC standards, with North Macedonia receiving poor (no or minimal policy) ratings in the following domains: Protecting people from tobacco smoke (P) and Enforcing bans on tobacco advertising, promotion and sponsorship (E) in 2021 and 2023.

In the coming period, it is necessary for the Republic of North Macedonia to commit to fully implementing the WHO Framework Convention on Tobacco Control and to take urgent measures to strengthen other key activities. This includes implementing comprehensive anti-smoking measures in all public and indoor workplaces, smoking cessation programs and treatment for tobacco addiction, as well as increasing tobacco taxation to reduce the availability of tobacco products. The European tobacco control framework is supported by the Directive 2014/40/EU Tobacco Products Directive (TPD), the Tobacco Advertising Directive, the Tobacco Taxation Directive (TTD) and the Audiovisual Media Services Directive.

As previously demonstrated (Feliu et al., 2019; Palali and van Ours, 2019) the European countries have introduced various

tobacco control policies (e.g. increased taxation of tobacco products, no-smoking areas, advertising bans, graphic pack warnings and smoking cessation programs) over recent decades.

In order to systematically quantify the implementation of measures to reduce tobacco consumption in accordance with the FCTC in European countries, the Tobacco Control Scale was developed, which is published every three years, most recently for the year 2021. Joosens et al. (2022) report results of a survey of tobacco control activity in 37 European countries in 2021, using the Tobacco Control Scale (TCS). Membership in the European Union remains a strategic goal of the Republic of North Macedonia.

Consequently, the priority in accession is the adjustment of legislation and institutions for effective control of the use of tobacco products. According to EC reports from 2022 and 2023 the legislation of North Macedonia is partly aligned to the EU acquis on tobacco control; it is designed to be fully aligned with the EU acquis on tobacco products. Tobacco control measures are not yet fully and consistently implemented. North Macedonia has not yet ratified the Protocol to Eliminate Illicit Trade in Tobacco Products (EC Report, 2023; EC Report, 2024). No significant progress was noted in the implementation of tobacco control activities in the last EC report in 2025. This indicates a discrepancy between the formal alignment of national legislation with international standards and the observed high smoking prevalence. In 2024, efforts to control cigarette smoking in North Macedonia are implemented through several regulatory measures. A comprehensive ban on tobacco advertising is in place. The sale and use of cigarettes are permitted, including online purchasing, while sales through vending machines are prohibited. But it turned out that these measures did not have much effect because there is a high smoking prevalence among adults, at 45.4% in 2024 (IPH, 2025).

In the coming period, North Macedonia should adopt the Consumer Protection Strategy 2025-2028, set up a web-based platform to inform the public on consumer issues, and strengthen its market surveillance capacity. Second, it must ensure effective tobacco control by implementing relevant EU legislation and ratify the Protocol to Eliminate Illicit Trade in Tobacco Products.

2. What are the current trends in the consumption of tobacco products in North Macedonia?

Cigarette consumption continues a longstanding, steady decline in many countries due to increased awareness, regulation and control. Flor et al. (2021) find that based on WHO reports and 2025 projections, global tobacco use decreased from 1.38 billion users in 2000 to approximately 1.2 billion in 2024. So, the target of a 30% relative reduction by 2025 (compared to 2010) is likely to be slightly missed.

On average, 24.4% of adults in Europe currently smoke tobacco products. Several European countries have already set their national tobacco control targets ahead of the EU as a whole (Teshima et al., 2022). Ollila

et al. (2025) analyze the European Region, encompassing 53 countries including 27 Member States, and concludes that 25% of adults use tobacco products, mainly cigarettes. According to Ruokolainen and Laatikainen (2024), the European Region is the only one not expected to reach target, and it is projected to maintain the highest tobacco prevalence, at over 23%, by 2030.

Mechili et al. (2021) analyse the Balkan countries are among the European countries with the highest smoking rates. The highest proportion of active smokers is recorded in Bulgaria and Serbia, where 39.5% of the population uses tobacco. This is followed by Croatia with 37%, Greece with 32.8%, Slovakia with 32.4%, Hungary with 32.2% and Romania with 30%.

According to a 2023 survey conducted by WHO, 93.4% of adult tobacco users in North Macedonia smoke cigarettes, including both manufactured and hand-rolled products. This represents a slight decrease compared to 97.5% in 2019, suggesting a gradual shift towards alternative tobacco products (WHO, 2023). Among those who use hand-rolled cigarettes, almost all (99%) cite lower price as the main reason. Cigarettes remain the primary mode of tobacco consumption in North Macedonia, although a diverse range of other products is also available, including non-combustible products such as heated tobacco products and waterpipe, non-tobacco products such as e-cigarettes and nicotine pouches, and oral or nasal products such as snus and snuff. A survey conducted by Analytica in 2024 aimed to improve understanding of the use of heated tobacco products (HTP) and e-cigarettes among tobacco users in North Macedonia, which showed that a large percentage of users simultaneously use manufactured cigarettes and e-cigarettes.

According to Memeti et al. (2022), North Macedonia has a high adult smoking prevalence of 48.4%, and nearly 81.4% of the smokers started smoking before being 25 years of age. Gender, age, education and knowledge about the harmful side effects of tobacco use are assessed as relevant factors.

Mijovic Hristovska et al. (2025) investigate the crowding-out effect of tobacco expenditures on other household spending categories in North Macedonia, a country with one of the highest smoking prevalence rates in Europe. Kjosevska et al. (2025) analyse the data from the Institute of Public Health published for World Tobacco Day in 2025, 45.4% of the population are active smokers, placing North Macedonia among the countries with the highest smoking prevalence in Europe. This rate is higher than in neighbouring countries such as Montenegro (41%), Bosnia and Herzegovina (41%) and Serbia (37%). In our country, cigarettes remain widely affordable, which is conducive to tobacco use. The majority of smokers did not change their smoking habits in reaction to a recent increase in price generated by tax increases. Regulatory bodies should strengthen the enforcement of existing tobacco control measures, such as (1) implementing a comprehensive smoking ban in bars and restaurants and restricting smoking in the workplace and in public places, (2) investing in measures that aim to motivate smoking cessation, and (3) strengthening the enforcement of current laws on tobacco advertising, promotion and sponsorship, which would reduce the number

of new smokers. In the coming period, it is expected that the increased implementation of the intra-institutional decision-making system will ensure much better performance in implementing control over the use of tobacco products and a significant reduction in their consumption.

CONCLUSIONS

The legal framework for tobacco control in North Macedonia should be further upgraded to align with standards based on the FCTC and WHO positions, as well as to establish a legal basis for innovative solutions that would contribute to a reduction in cigarette consumption. The negotiating framework of Macedonia's accession to the European Union prioritizes the development of effective and functional institutions, a legitimate legal framework and its efficient implementation, which should result in measurable outcomes based on indicators of alignment with European standards. The available data indicate that smoking prevalence in North Macedonia remains consistently higher compared to the European Union average, suggesting limited effectiveness of current tobacco control measures despite formal regulatory alignment. The available data indicate that smoking prevalence in North Macedonia remains consistently higher compared to the European Union average, suggesting limited effectiveness of current tobacco control measures despite formal regulatory alignment. The rising influence of healthy living trends, shifting consumer preferences and growing interest in alternatives such as heated tobacco products and smokeless tobacco have contributed to a moderate decline in cigarette consumption in Republic of North Macedonia.

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