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< Review >

**Limited progress in tobacco control in Japan:
An assessment 20 years after the WHO FCTC**

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Abstract

Marking the 20th anniversary of the entry into force of the WHO Framework Convention on Tobacco Control (FCTC) in 2005, this study systematically evaluates the progress and stagnation factors of domestic tobacco control in Japan. The assessment was conducted with reference to the WHO MPOWER package and FCTC Articles 9 and 10. The analysis revealed significant disparities between different areas of Japan's tobacco control policy. Certain institutional advancements were recognized in "demand reduction measures," such as the strengthening of indoor passive smoking regulations through the amendment of the Health Promotion Act enforced in 2020 and the development of smoking cessation treatment systems, including insurance coverage and online medical consultations. However, Japan still falls considerably short of international best practices in adopting pictorial health warnings recommended by the WHO, implementing comprehensive legal bans on advertising and promotion, and significantly increasing taxes with public health as the primary objective. Particularly notable stagnation was observed in the areas governed by Articles 9 (regulation of the content of tobacco products) and 10 (regulation of tobacco product disclosure) of the FCTC. Japan lacks comprehensive tobacco product regulations, such as those in advanced cases in the EU. Its principal law, the Tobacco Business Act, falls under the jurisdiction of the Ministry of Finance and focuses primarily on fiscal contributions and the sound development of the industry. As a result, legal regulations on the contents of tobacco products and independent verification systems for those products independent of the tobacco industry remain undeveloped. The underlying causes of this stagnation are rooted in structural factors unique to Japan's tobacco control governance: misalignment of policy objectives due to the separation between the Ministry of Health, Labour and Welfare and the Ministry of Finance; institutional and economic ties, including capital relationships between the government and Japan Tobacco (JT); and the concentration of tobacco products information with the industry (asymmetry of information), all of which hinder the prompt incorporation of scientific public health findings into the legal regulations. The current situation regarding heated tobacco products (HTPs), where information dissemination led by manufacturers precedes the establishment of scientific evaluations in what has become one of the world's largest markets, further exemplifies these vulnerabilities. In conclusion, to advance Japan's tobacco control efforts, it is essential to strengthen individual measures and structurally separate industrial policy from public health policy and legally establish a decision-making process grounded in independent regulatory science.

keywords: WHO FCTC, Tobacco Control Governance, FCTC Articles 9 and 10, Heated Tobacco Products, Institutional Factors

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I. Introduction

Tobacco use remains one of the leading preventable causes of death worldwide, contributing to more than eight million deaths annually [1]. To address this global challenge, the World Health Organization (WHO) adopted the Framework Convention on Tobacco Control (FCTC) in 2003, which came into effect in 2005 [1]. The FCTC is the first internationally agreed treaty in the field of public health and currently has 183 signatory countries. This international framework highlights that tobacco control is both a unique issue for individual nations and a public health challenge that requires coordinated action across national borders. To organize the FCTC's demand-reduction measures into a practical policy framework, the WHO introduced the MPOWER package in 2008 [2]. MPOWER consists of six evidence-based interventions corresponding to the main provisions of the FCTC: 1. Monitoring tobacco use and prevention policies, 2. Protecting people from tobacco smoke, 3. Offering help to quit tobacco use, 4. Warning about the dangers of tobacco, 5. Enforcing bans on tobacco advertising, promotion, and sponsorship, and 6. Raising taxes on tobacco. It provides a standardized framework for assessing the implementation status in each country. According to the WHO Report on the Global Tobacco Epidemic 2025, steady progress has been observed globally, with approximately 6.1 billion people benefiting from at least one MPOWER measure at the best practice level [3]. Japan ratified the FCTC in 2004 and became a signatory nation [1]. Now, about 20 years since ratification, reviewing Japan's tobacco control measures in comparison with the international framework is an important milestone for policy evaluation. While there has been some progress, such as the amendment of the Health Promotion Act (enforced in 2020) and a long-term decline in smoking prevalence, Japan's tobacco control still has room for improvement compared to international best practices [4,5].

This review aims to organize the current state of tobacco control in Japan within the context of the international framework and provide an overview of policy developments since the FCTC's ratification. Specifically, it examines Japan's implementation status in line with each component of MPOWER, with particular attention to Articles 9 and 10 of the FCTC, concerning product regulation and disclosure [1,6,7]. Progress in institutionalizing these articles has been limited compared to other policy areas, making them important subjects when considering the overall implementation of tobacco control policies. Notably, as Japan is a market where heated tobacco products (HTPs) have spread on a large scale ahead of the rest of the world [8-10], the approach to product regulation provides valuable insights for

both domestic and international policy discussions. By clarifying the features of implementation in Japan, this review hopes to contribute to the evaluation of domestic policies and shed light on common challenges that may arise when translating international agreements into practical policies within each country's institutional context [11].

II. Review strategy and data sources and analytical framework

This review aims to organize and evaluate the implementation status of tobacco control in Japan in comparison with that of international frameworks. This narrative review integrated multiple international and domestic data sources. For international sources, the primary reference was the "WHO report on the global tobacco epidemic" (2008–2025), with particular emphasis on the latest 2025 report and the MPOWER indicators [2,12,13]. Additionally, OECD Health Statistics (2024 edition) were consulted to position Japan's situation in the context of international comparisons [13]. For domestic information sources, related laws such as the Health Promotion Act (including the 2019 revision), smoking prevalence surveys published by the Ministry of Health, Labour, and Welfare, and tobacco tax revenue statistics were used [14]. Furthermore, peer-reviewed academic articles and comparative policy analyses focusing on tobacco regulation in Japan were reviewed [7,8,16-22], and a comprehensive examination of the institutional positioning and actual implementation status was conducted.

For the analysis, MPOWER was adopted as the central framework, and its relationship with the corresponding FCTC provisions was clarified [1,2]. Through a multilayered examination of policy, systems, implementation, and outcomes, the characteristics of tobacco regulations in Japan were systematically identified.

III. Results: Japan's progress and challenges based on MPOWER

According to assessments based on the WHO MPOWER framework, tobacco control in Japan has shown varying degrees of progress in each component [3]. While some areas have seen certain improvements, implementation levels remain limited in other areas compared to the best international practices.

1. Monitor tobacco use and prevention

In Japan, adult smoking prevalence has been regularly tracked for years through national health and nutrition surveys, and in 2024, the smoking prevalence was 24.5% for men and 6.5% for women, with a consistent downward trend observed since the 1990s [4]. In this respect, Japan

can be said to have a certain institutional foundation for the “Monitor” element of the MPOWER. However, regarding continuous surveillance that distinguishes use by product type and new products (such as HTPs), as recommended by the WHO, Japan’s system is not yet sufficiently structured according to international standards [3]. This is partly due to the rapid technological evolution and constant updates to the HTP lineup, making it institutionally challenging to promptly update the survey designs accordingly.

2. Protect people from secondhand smoke

In terms of secondhand smoke measures, the 2018 amendment to the Health Promotion Act and its full enforcement in 2020 introduced a basic indoor smoking ban in schools, medical institutions, and administrative facilities, marking a significant institutional advancement in Japan’s tobacco control [5]. This amendment legally clarified the framework for secondhand smoke prevention, especially in venues where health concerns are paramount. However, certain exceptions and designated smoking areas are still permitted in restaurants and similar establishments; consequently, Japan’s implementation scope differs from the comprehensive indoor smoking bans recommended internationally [1,3]. According to the National Health and Nutrition Survey, which serves as an implementation indicator, exposure to secondhand smoke continues to be reported to some extent, particularly in dining-related environments, where 29.2% of men and 24.2% of women have experienced exposure⁵. Furthermore, among people in their 20s, the exposure rate is high (46.0% for men and 47.5% for women), suggesting that reducing exposure in socially active groups remains an issue [4]. These situations contrast with reports from other countries that have adopted comprehensive indoor smoking bans, where exposure to secondhand smoke in public spaces has dramatically decreased [3,12], indicating that further evaluation and improvements are needed from the perspective of policy implementation and effectiveness..

3. Offering help to quit tobacco use

Regarding support for smoking cessation, a health insurance-covered smoking cessation treatment system has been established, offering assistance that combines behavioral therapy and pharmacotherapy [23,24]. In recent years, smoking cessation treatment utilizing online medical consultations has also been institutionalized, helping to ease geographical and time constraints. These initiatives are consistent with the access-improvement direction outlined in Article 14 of the FCTC. However, the rate of use of smoking cessation treatment has been declining in recent years, with various factors pointed out as background causes, such as the supply situation of smoking cessation aids and changes in user behavior [18].

4. Warning about the dangers of tobacco

In Japan, health warning labels are required on all tobacco products. However, the content of these labels mainly consists of text, and the large graphic warnings recommended by the WHO have not been adopted [3]. Although hosting the Tokyo 2020 Olympic and Paralympic Games prompted a partial review of tobacco control measures, including the format of health warning labels, these changes did not extend to the introduction of graphic warnings. Compared internationally, there is room for improvement in the visual impact and amount of information provided by warning labels [25].

5. Enforce bans on tobacco advertising, promotion and sponsorship

Japan has long maintained a framework centered on voluntary self-regulation by the tobacco industry. In recent years, while certain restrictions on promotional activities have been introduced, it has been evaluated that, from the perspective of a comprehensive legal ban, Japan has not achieved full implementation of the advertising, promotion, and sponsorship requirements set out in Article 13 of the FCTC [3,26,27]. Japan does not have comprehensive legislation that broadly prohibits tobacco advertising, promotion, and sponsorship and has instead relied on self-regulation as a substitute. However, previous studies have highlighted the limitations of this approach [28,29]. According to the “WHO report on the global tobacco epidemic report,” while 68 countries have implemented the best practice level of comprehensive bans, tobacco advertising continues to be observed across multiple media and channels in Japan [3]. Specifically, advertisements appear in magazines for adults, product displays (POS displays) continue in retail stores, and tobacco-related expressions and marketing activities have been reported in online media, including streaming services [24,29,30]. In particular, it has been suggested that direct marketing of HTPs may not be sufficiently captured or managed under the current regulatory framework. Thus, a system based on self-regulation lacks a clear enforcement mechanism, resulting in a structure in which the scope of permissible marketing easily becomes subject to the industry’s interpretation [30, 31]. As a result, consumers can be continuously exposed to promotional messages about tobacco products, which is an issue that needs to be addressed in relation to the intent of Article 13 of the FCTC.

6. Raise taxes on tobacco

Tobacco taxes have been raised multiple times in Japan, but the price level remains relatively low compared to other high-income countries [32,33]. Evidence shows that price policies are effective in curbing smoking, but in Japan, the tax system has historically been operated with a dual role as a fiscal policy, and it has been pointed out that its position

as a public health policy is not necessarily clear [32,33].

7. Product regulation (Articles 9 and 10)

Within the MPOWER framework, Japan is particularly limited in terms of institutionalization regarding tobacco product ingredients, emission regulation, and information disclosure [6,7,34]. In Japan, there is no comprehensive regulatory authority or independent testing and evaluation system for the chemical components and emissions of tobacco products. This point is particularly distinctive compared to many other FCTC signatory countries and holds an important place when considering the implementation of tobacco regulations in Japan.

IV. Institutional factors related to implementation: Characteristics of tobacco control governance in Japan

To understand the implementation of tobacco regulation in Japan, it is necessary to consider not only the presence or absence of individual policies but also the systems under which these policies have been formed and administered. Previous studies have highlighted several characteristics of Japan's tobacco control governance, including the division of responsibilities among ministries, mechanisms for policy coordination, and institutional arrangements surrounding policymaking processes [21,35].

1. Inter-ministerial division and policy coordination framework

Tobacco control measures in Japan have traditionally involved multiple ministries, each participating according to its respective mandate. While the Ministry of Health, Labour and Welfare is responsible for smoking countermeasures and the prevention of secondhand smoke from a public health perspective, the Ministry of Finance oversees tobacco taxation from the standpoint of tax and fiscal policies. This division allows for the utilization of each field's expertise, but it has also been recognized as an area where the reconciliation of policy objectives and priorities is inevitable [35]. After ratifying the FCTC, the "Inter-Ministerial Liaison Council on Tobacco Control" was established to share information and collaborate among relevant ministries and, for a certain period, it served as a forum for exchanging opinions [36]. However, there have been no subsequent public records of the council's meetings since 2014, and it is unclear how the institutional coordination framework is currently being implemented. These points have been identified as issues to be considered when examining cross-ministerial policy integration [37].

2. Institutional relations between the government and the tobacco industry

In Japan, based on the Tobacco Business Act and related

laws and regulations, the government has historically maintained a certain institutional relationship with Japan Tobacco Inc. (JT) [38]. This institutional arrangement is understood as a uniquely Japanese governance structure, where the national government responsible for tobacco control has also constituted a part of the institutional framework surrounding the tobacco business. In governance studies, it has been pointed out that when regulatory authorities have institutional and economic relationships with the industries they regulate, the decision-making environment for policy formulation can become multifaceted [39]. In the case of tobacco regulation in Japan, policy decisions have been made amid the coexistence of multiple policy objectives, such as public health, fiscal, and industrial policies [37,39].

3. Institutional conditions surrounding information and expertise

The regulation of tobacco products, particularly regarding their ingredients and emissions, requires a high level of scientific and technical knowledge. In Japan, much of the detailed information about the manufacturing processes and chemical properties of tobacco products is concentrated within the industry, while the institutional framework for regulatory authorities to independently conduct testing and evaluation is limited [6,7]. Under such an information environment, it has been pointed out that the scope and nature of scientific knowledge available for policy formulation tend to be defined by institutional conditions [35]. This topic has been debated in regulatory science, not only in Japan but also as a common issue in many other countries.

4. Social and institutional backgrounds as policy formation environments

Regarding tobacco policy, it has been reported that administrative agencies, experts, related organizations, and various other actors have been involved in the policy formation process, engaging in exchanges of opinions [36,40]. Such processes are common in democratic policymaking, and their forms differ depending on each country's institutional design and policy culture. The WHO's "Global Tobacco Epidemic Report (2025)" points out that the possibility of the tobacco industry influencing the policy environment through various official and unofficial channels is a challenge shared by many countries [2]. Japan is also positioned as one of the subjects of analysis in this international context.

V. Unaddressed FCTC Articles: Articles 9 and 10 (Product regulation and disclosure of information)

Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (FCTC) stipulate the regulation of tobacco product contents and emissions, as well as the disclosure of

related information, serving as core areas that complement demand reduction measures [6,7]. The Third and Fourth Conferences of the Parties (COP) adopted implementation guidelines based on the premise that tobacco products are “intrinsically harmful consumer goods,” demanding strict regulations on product characteristics and transparency. Although Japan has made progress in areas such as measures against secondhand smoke since the WHO FCTC came into force in 2005, comprehensive legislation based on Articles 9 and 10 has yet to be achieved. [1,6,7]. In this area, the delay in institutionalization remains particularly pronounced in international comparisons, as highlighted in the WHO’s MPOWER indicators [2].

1. International trends and the status of product regulation

Internationally, the implementation of FCTC Articles 9 and 10 is steadily advancing as a framework that guarantees a “scientific foundation” for tobacco control. For example, through the Tobacco Products Directive (TPD), the European Union (EU) has established a comprehensive legal framework that includes obligations to report detailed ingredients and emissions, bans on certain components, independent verification of data, and ensuring consumer transparency [41]. In particular, it has been reported that regulations on flavors such as menthol have led to changes in quitting behaviors among smokers following enforcement [42], while at the same time, it has also become clear that the tobacco industry is responding strategically by exploiting regulatory “loopholes” to introduce alternative products [43]. The essence of these trends lies in redefining tobacco products—from being ordinary consumer goods subject to market forces to being subject to strict “public health regulation” by governments. Similar regulatory approaches have been introduced in Brazil, which leads to additive regulations; Canada, which requires detailed market reporting; and South Korea, which publishes government-led ingredient analyses. These cases demonstrate that the quantitative assessment of product characteristics and the move toward information transparency have become essential standard elements in contemporary tobacco regulation [43-46]. Furthermore, scientific guidance provided by the WHO Study Group on Tobacco Product Regulation (TobReg) and WHO Tobacco Laboratory Network (TobLabNet) support the premise that technically complex product regulation need not depend solely on individual countries’ capabilities but can be implemented through frameworks for international cooperation.

2. Institutional positioning in Japan

In contrast, Japan does not have a comprehensive product regulation law equivalent to the EU Directive. The main relevant law, the “Tobacco Business Act,” is primarily aimed

at distribution management and fiscal contributions, and provisions for scientific management of product characteristics or disclosure of information to consumers are extremely limited [40]. Consequently, regulatory measures such as the establishment of legal standards, standardized testing, independent verification, and prohibition of specific ingredients remain undeveloped. On the other hand, domestically, the National Institute of Public Health has participated in the WHO TobLabNet and has continuously conducted research on chemical analysis of products and exposure markers [47-51]. While these studies have accumulated valuable industry-independent insights, a “legal bridge” to directly reflect their findings in institutional regulations and disclosure requirements has not been established. This disconnect between research and regulation poses a significant governance challenge for Japan [40].

3. The spread of HTPs and institutional challenges

A symbol of stagnation in Japan is the rapid spread of HTPs. Japan is the world’s largest HTP market, with usage rates of 41.4% among male smokers and 44.2% among female smokers [4]. This trend is especially concentrated among younger and middle-aged people in their 20s to 40s [4], raising concerns that nicotine dependence may persist and be prolonged not by quitting but by switching products [39]. While research on the long-term health effects and risks of passive exposure to HTPs is ongoing and accumulating [17,52-55], Japan’s current regulatory framework is still in the process of addressing product classification, ingredient disclosure, and warning labeling issues. As a result, information dissemination about product characteristics led by manufacturers is allowed to get ahead before scientific evaluations are finalized [56-58]. Cases in which the EU and South Korea have applied existing strict advertising regulations and ingredient reporting requirements to HTPs suggest that regulation based on the “precautionary principle” is possible even for new products [41,46].

4. Positioning of product regulation and its relationship with other policies

Product regulation and information disclosure are fundamental elements that determine the effectiveness of other measures, such as taxation, advertising restrictions, and smoking cessation support. A lack of systematic organization can hinder the effectiveness of warning labels and appropriate risk communication in smoking cessation support. The delay in implementing these provisions in Japan can be understood not merely as a technical lag but as a reflection of the structural characteristics of governance regarding the prioritization of industrial and public health policies [35,40].

VI. Discussion and policy implications

This study examined the progress and challenges of tobacco control measures in Japan using the WHO Framework Convention on Tobacco Control (FCTC) and MPOWER package as reference frameworks. The results confirmed that in Japan, steady institution building has taken place in certain areas, such as measures to prevent secondhand smoke and the development of support systems for smoking cessation. In particular, measures against indoor secondhand smoke through revisions to the Health Promotion Act and the establishment of smoking cessation treatment systems, including insurance coverage and online medical consultations, are of significant importance from the perspective of protecting public health and improving access to healthcare.

However, from the perspective of comprehensive tobacco regulation, as indicated by the FCTC and MPOWER, it also became clear that the degree of institutional development varies across different fields. In particular, regarding measures corresponding to Articles 9 and 10, which pertain to product regulation and the disclosure of information, there remains scope for further deliberation compared to the standard frameworks that are increasingly shared internationally. This can be interpreted as the result of a phased approach based on Japan's unique institutional and historical background. It is important to recognize these differences as part of the policy formation process rather than as simple advantages or disadvantages.

Furthermore, when considering institutional factors at the implementation stage, tobacco control measures in Japan are closely linked to multiple policy areas, including the medical insurance system, local government authority, and industrial structures. Therefore, when evaluating individual measures, it is necessary to go beyond simply matching specific articles and assess the coherence and effectiveness of the entire system from a medium- to long-term perspective. In policy areas directly related to public health, such as smoking cessation support and secondhand smoke prevention, it is particularly important to continually examine not only the existence of the systems themselves but also their actual use and impact on behavioral changes.

As a policy implication, it is effective to develop measures in a phased and flexible manner, building upon existing systems while referencing international scientific evidence and successful examples from other countries. Since the FCTC presupposes implementation adapted to each country's context, Japan can leverage its accumulated experience and data to further develop more effective tobacco control measures. In summary, Japan's tobacco control policies are a developing policy area that has achieved certain results, and

the FCTC and MPOWER serve as useful frameworks for evaluating progress and considering future directions of tobacco control policies. This study provides a foundation for reaffirming the significance of current measures and constructive discussions on future institutional improvements.

Conflicts of Interest

The author declares that there are no conflicts of interest regarding the publication of this article.

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<総説>

日本のたばこ対策はなぜ進展しないのか
—FCTC 発効 20 年後の停滞要因の分析—

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抄録

本論文は、日本が2004年にWHOたばこ規制枠組条約（FCTC）を批准してから20年の節目を迎え、WHOのMPOWERパッケージおよびFCTC第9条・第10条を参照枠組みとして、国内のたばこ対策の進捗と停滞要因を体系的に評価することを目的とした。

分析の結果、日本の対策は分野間で顕著な差異があることが明らかとなった。2020年の改正健康増進法施行による屋内受動喫煙対策の強化や、保険適用およびオンライン診療を含む禁煙治療体制の整備といった「需要削減策」においては、一定の制度的進展が認められた。しかし、WHOが推奨する警告画像表示の採用や包括的な広告・宣伝の法的禁止、公衆衛生を主目的とした大幅な増税については、国際的なベストプラクティスと比較して依然として大きな乖離が存在する。特に深刻な停滞が確認されたのは、FCTC第9条（製品成分の規制）および第10条（情報開示）に関わる領域である。日本にはEU等の先進事例に見られるような包括的な製品規制法制が存在せず、主要法規である「たばこ事業法」が財務省の所管下で財政寄与や産業の健全な発展を主目的としているため、成分の法的基準値や独立した検証制度が未整備のままとなっている。この停滞の背景には、日本のたばこ制度的枠組み特有の構造的要因がある。厚生労働省と財務省の分立による政策目的の不一致、政府と日本たばこ産業（JT）との間の資本関係を含む一体的な構造、および製品情報の産業側への偏在（情報の非対称性）が、公衆衛生上の科学的知見を迅速に法規制へと反映させる際の障壁となっている。世界最大級の市場となった加熱式たばこ（HTP）への対応においても、科学的評価が確立する前にメーカー主導の情報発信が先行する現状は、こうした制度的脆弱性を象徴している。

結論として、日本のたばこ対策を今後さらに進展させるためには、個別施策の強化に加え、産業政策と公衆衛生政策の構造的な分離を図るとともに、独立した規制科学に基づく意思決定プロセスを法的に確立することが不可欠である。

キーワード：たばこの規制に関する世界保健機関枠組条約、たばこ製品規制と情報開示、たばこ規制ガバナンス、加熱式たばこ、制度的要因