

CASE STUDIES
FOR REGULATORY APPROACHES
TO TOBACCO PRODUCTS

Menthol in
tobacco products



World Health
Organization



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EXECUTIVE SUMMARY

In keeping with WHO recommendations for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (FCTC) (1), many governments have taken steps to regulate or ban specific ingredients in tobacco products that increase the attractiveness of these products, particularly to youths, young adults and women.

Menthol is one of the most widely used and recognizable flavours in tobacco products, with unique cooling properties that help to mask the harshness and irritation of tobacco (2, 3). Use of menthol tobacco products is concentrated among the youngest ages in several countries (4, 5, 6), and these products are associated with:

- increased experimentation and trial use (2, 7–12)
- perceptions of reduced harm (2, 7, 13)
- higher levels of dependence (2, 14–16)
- greater difficulty quitting (2, 7, 17, 18)

The popularity of menthol tobacco products differs across countries, reflecting product availability, marketing and historical patterns of use. Given strong global evidence that menthol increases tobacco product attractiveness (2, 7), efforts to restrict or ban menthol in tobacco products are appropriate even in markets where the use of menthol remains limited. Regulations to date suggest multiple approaches to restricting the use of menthol:

- a ban on all flavouring agents (including menthol) that increase tobacco product attractiveness;
- a ban on the use of menthol as a flavouring agent;
- a ban on all products with a perceived menthol flavour or visible menthol identifiers; or
- a ban on menthol within a specific category of products (such as small cigars) or specific municipality, based on population evidence (such as high prevalence among youth).

Preliminary evidence indicates that restrictions such as those identified above can successfully reduce menthol tobacco product use (19). Regulators should consider the resources necessary to support ongoing evaluation and compliance, and the potential need for public education. Challenges to implementation of such restrictions can include:

- the availability of adequate surveillance to identify regulatory needs and measure outcomes, including potential unintended consequences;
- significant industry opposition, particularly in regions where menthol products make up a sizeable portion of the tobacco market; and/or
- a changing marketplace, including new products or product categories featuring menthol, or introduction of synthetic or other compounds in place of menthol.

OVERVIEW

Menthol is a widely used flavouring agent found in oral hygiene products, health remedies, and candies. Natural menthol is isolated from flowering plants of the *Mentha* genus (mint). In addition to its characteristic flavour and aroma, menthol has physiological properties, most notable of which are topical cooling and anesthetic effects through the activation of TRPM8 sensory nerve receptors (7). In the case of tobacco use, menthol suppresses natural defense reactions to the chemical irritation caused by nicotine and tobacco smoke, reducing aversion to tobacco among inexperienced users and facilitating continuing product use (2, 10, 19). More recent evidence indicates that menthol also plays a role in supporting addiction, both by conditioning the desire for nicotine (20) and by directly enhancing the reinforcing actions of nicotine in the brain (14, 15).

Menthol is the most commonly marketed cigarette flavour, representing approximately 10% of the global cigarette market and with a market share greater than 25% in many countries including the Philippines, Chile, Singapore, and the United States (2). Menthol is also a flavour category found in smokeless tobacco products (here more commonly identified as “mint”) and is frequently used at reduced levels in products not advertised as menthol. Product innovations include the use of flavour capsules housed in the cigarette filter that release menthol alongside other chemicals, and the use of synthetic compounds without taste or odor that mimic menthol’s cooling effects (2, 21, 22). Menthol products are often marketed as less irritating alternatives to regular products, with explicit health claims, as well as sensory descriptors and imagery implying that menthol products are safer or easier to use than nonmenthol products (2, 7). Many smokers perceive menthol cigarettes as smoother and associate these sensations with reduced harm (3, 7, 13).

Menthol tobacco products are used disproportionately by the youngest tobacco users across multiple studies and countries (4–7). Menthol cigarettes are associated with increased initiation and progression to regular smoking (7–12), and both adolescent and adult menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit compared to non-menthol smokers, with higher rates of relapse (7, 12, 17, 18). The findings support the conclusion that the use of menthol in tobacco products creates a greater public health burden.

REGULATORY OPTIONS

Regulation of menthol can include restrictions on sale of tobacco products identified or branded as menthol, restrictions on the use of menthol at noticeable or perceived levels, or a ban on the addition of menthol at any level (23). A complete ban on menthol limits the ability of manufacturers to market products that contain menthol but which are not directly identified as containing menthol. Extending the ban to all forms of tobacco reduces the potential for menthol use to shift to new tobacco products or categories.

Countries with an established menthol market may experience significant political or industry opposition to a complete menthol ban in tobacco products. A step-by-step approach to regulation may be more feasible, potentially including the introduction of restrictions at the sub-regional rather than country level. An evidence base using data collected from the region of interest can provide more direct support for regulation. A ban on all flavour agents that increase tobacco product attractiveness, rather than focusing on menthol exclusively, can provide an alternate route to restricting menthol, and may prevent the unwanted introduction of menthol substitutes.

The three case studies below outline potential approaches and challenges to regulation of menthol as drawn from a low-income, middle-income and high-income country. These examples should be considered by regulators in the context of their own jurisdictions, including legal framework, available resources, consumer use and sources of opposition.

ETHIOPIA

A ban on all flavours, including menthol

APPROACH. The government health authority in Ethiopia issued a Directive banning the manufacturing, import, distribution, and sale of flavoured tobacco products effective September 2015 (23, 24). The ban applies to all forms of tobacco, and restricts the use of any ingredient that imparts a taste or aroma distinguishable from tobacco, including menthol, as well as fruit, chocolate, honey, vanilla, candy, alcohol, herbs or spices. The ban also includes any ingredient used to create an impression of a health benefit, such as vitamins or stimulants. The justification for the ban was to prevent tobacco products from becoming appealing to children and adolescents (24).

ADVANTAGES. The Directive does not distinguish menthol from other ingredients that may be used to alter perceptions or appeal of tobacco. This approach reduces the need for country-specific data related to perceptions of menthol or menthol use. Ethiopia has no significant history of menthol-flavoured tobacco products, and the Directive preempts a category of menthol products from developing. By identifying aroma as well as taste, the Directive prevents use of menthol as an ingredient in tobacco packaging. The generalized language of the Directive also prevents the introduction of synthetic cooling compounds or other ingredients that might otherwise be considered as potential substitutes. Compliance is linked to human perception rather than chemical testing, which reduces the potential cost and complexity of product monitoring.

CHALLENGES. Although the Directive applies to all forms of tobacco, health authorities have observed an inaccurate public perception that waterpipe tobacco is excluded from the flavour ban (24). As such, further public education may be necessary to support successful compliance. Another potential challenge has been the lack of adequate enforcement at the retail level. To address this challenge, the health authority has identified the need for increased collaboration with the revenue and customs authority, given that nearly all flavoured products are either imported or smuggled into the country (24).

CHILE

A ban on sale of menthol products

APPROACH. Chilean law grants the Ministry of Health the authority to restrict or ban substances added to tobacco when the substances are shown to increase levels of addiction, harm or risk to consumers (23). The Ministry of Health sought to ban menthol tobacco products under this authority in 2013. The tobacco industry expressed in an open letter its belief that the scientific evidence did not support that mentholated tobacco products were different in addictiveness or health risks from tobacco products without menthol (25). The Office of the Comptroller General (an autonomous governmental body) ruled that the Ministry had failed to demonstrate that menthol directly increases addiction, harm, or risk (23). A new bill was introduced in 2015, in response to new data indicating that 38% of smokers in Santiago, Chile used menthol tobacco products with rates of 66% among minors under 18 years of age (5). The new bill addressed the problems faced in 2013 by linking the ban of menthol and other distinctive cigarette flavours to their high levels of use among youth (26). The provision to ban menthol was passed in the Senate in July 2015, but still needs the consent of the other legislative house as well as the president's signature.

ADVANTAGES. The targeting of menthol products by the Ministry of Health in 2015 was directly responsive to the demonstrated high prevalence of smoking among young (under 18) Chileans and global concerns about the role of menthol in facilitating the initiation of smoking among young people raised by WHO and the FDA (7, 27). The language in the proposed ban was not limited to distinctive flavours, but also extended to all tobacco products and flavouring additives that directly or indirectly increase tobacco product addiction or risk, limiting the likelihood that menthol use will simply shift to other products categories or flavouring mechanisms. While Chile identified protection of youth as a major justification for regulation, the framework of the authority used in Chile to regulate flavours also highlights the importance of addiction, a factor which differentiates menthol from many other flavour compounds.

CHALLENGES. Initially, authority over menthol was restricted due to the fact that

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