Compilation of information briefs on forward-looking tobacco control measures developed by the experts

Expert Group on Forward-looking Tobacco Control Measures (in relation to Article 2.1 of the WHO FCTC)

Supplementary document

Purpose of the document

This document incorporates information briefs prepared by the experts of the Expert Group on Forward-looking Tobacco Control Measures (in relation to Article 2.1 of the WHO FCTC) established by the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) in decision FCTC/COP10(12), as part of its work conducted between the tenth and eleventh sessions of the COP.

Information briefs are provided for the 16 forward-looking tobacco control measures (FLMs) selected by the Expert Group, as outlined in document FCTC/COP/11/5. Short summaries (abstracts) for each FLM are provided in Annex 2 of document FCTC/COP/11/5.

This document informs and serves as a supplement to document FCTC/COP/11/5.

Details about the composition of the Expert Group and the three meetings held by the Expert Group are available as additional supplementary documents on the WHO FCTC website.¹

Please note that the Convention Secretariat is placing this report on its website for information purposes. The responsibility for the interpretation and use of the material lies with the reader. This publication contains the views of the experts comprising the Expert Group on Forward-looking Tobacco Control Measures (in relation to Article 2.1 of the WHO FCTC). Neither the Convention Secretariat nor the Expert Group guarantees the accuracy or completeness of information found in this document. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the Convention Secretariat or the Expert Group.

¹ COP11 Documentation: Supplementary information (accessed 29 August 2025).

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(i) Introduction

- 1. At its tenth session, the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) decided to establish an expert group on tobacco control measures that are forward-looking and could be contemplated within the scope of Article 2.1 of the WHO FCTC. In accordance with decision FCTC/COP10(12), the Expert Group was mandated to:
 - (a) identify and describe forward-looking tobacco control measures (FLMs) and measures that expand or intensify approaches to tobacco control as they apply to tobacco products, and that may be contemplated by the expert group within the scope of Article 2.1, taking into account the Guidelines for implementation of the WHO FCTC;
 - (b) consider, in conducting its research and elaborating its findings, Party experience and published literature, as well as any other source of information that it may find appropriate, and properly reference all sources; and
 - (c) prepare a report to be submitted to the Eleventh session of the COP (COP11) on the above matters.

(ii) Long list of forward-looking tobacco control measures considered

2. The Expert Group found that there was a very large number of FLMs that it could potentially identify and describe. The Expert Group had a wide-ranging discussion to identify possible FLMs for description and, as mandated by decision FCTC/COP10(12), a non-exhaustive long list of 40 FLMs was ultimately created (see Table 1). Based on subsequent discussions, a shorter list of 23 FLMs was defined, which was further reduced to 16 FLMs, based on agreed criteria (see Table 2).

Table 1. Long list of FLMs²

	Table 1. Long list of Flivis				
I.	Tobacco supply				
	1.	Retail reduction			
	2.	Model for the supply of tobacco			
	3.	Ban on incentives to retailers			
	4.	Change of retailer incentives from earnings per sale to incentives to promote quitting			
	5.	Ban on online sales of tobacco products			
	6.	Price controls for tobacco products and devices ("minimum price policies")			
	7.	Tobacco-free generation (Birthdate-based sales restrictions)			
	8.	Increase in minimum legal age for sales of tobacco products			
	9.	Ban sales of tobacco products			
	10.	Phase out combustible tobacco products or other product classes			
	11.	Quota on tobacco manufacture and imports and then reduce regularly ("sinking lid")			
II.	Institutional structure/market				

² The titles of the FLMs initially considered by the Expert Group were further refined and amended.

	12.	Supplemental national transfer from national excise taxes to subnational jurisdictions (incentives to subnational jurisdictions to reduce smoking rates)		
	13.	Financial divestment (pension/wealth funds) from tobacco		
	14.	Environmental controls ("producer pays")		
	15.	Ban government support for tobacco farming and production		
	16.	Phase out tobacco growing		
	17.	Tobacco supplier profit surtax/health levy/user fee		
	18.	Prohibit profit from sale of tobacco		
	19.	Performance-based regulation: companies reduce smoking prevalence on a schedule		
	20.	Large fines based on youth prevalence		
	21.	Quantifiable metrics warranting industry-wide corporate death penalties		
III.	Proc	Product		
	22.	Low/very low nicotine levels in cigarettes/combustible tobacco products		
	23.	Ban nicotine analogues		
	24.	Ban flavours/additives		
	25.	Performance standard for combustible tobacco		
	26.	Ban/moratorium on new products		
	27.	Ban on new brands, variants and packaging; single-presentation requirement		
	28.	Filter ban		
	29.	Mandatory labelling that filters are plastic waste		
	30.	Stick/device standards		
	31.	Ban on slims		
	32.	Ban on combustible tobacco products		
	33.	Low nitrosamine smokeless tobacco regulations		
	34.	Incentives in relation to other forms of nicotine		
IV.	Consumer			
	35.	Increase smoke-free venues (private homes, vehicles, multi-unit housing)		
	36.	Reduce third-hand exposure		
	37.	Licensing of tobacco users		
	38.	Cessation options for those who use non-tobacco products		
	39.	Prescription to purchase tobacco		
	40.	Restrictions or bans for groups in situations of vulnerability (minors, pregnant women, people with mental health conditions and psychosocial disabilities)		

(iii) Shortlisting and information assessment process

- 3. The criteria for identification and selection of FLMs for development into information briefs were discussed at the First meeting of the Expert Group, but were refined over time. The Expert Group agreed that it was important to stress that non-selection, or a decision not to take forward any FLMs (from the original list of those identified) to be developed into information briefs, does not imply that those FLMs lack merit as tobacco control interventions. The criteria that ultimately informed the selection of FLMs for development into information briefs were as follows.
 - (a) FLMs must apply to tobacco products, as defined under the WHO FCTC, in accordance with the mandate of the Expert Group, as articulated in decision FCTC/COP10(12).
 - (b) They must include measures that substantially expand or intensify approaches to tobacco control in line with the WHO FCTC or its Guidelines for implementation.
 - (c) There is a sufficient level of readily available research, modelling, commentary and/or jurisdictional experience, and/or a solid conceptual foundation to draw on to enable the Expert Group to provide a useful description of the measure.
 - (d) There is evidence, or high potential (based on experience from other interventions) for the measure, if implemented, to achieve one or more of the following:
 - (i) a significant contribution to the prevention, reduction and/or cessation of tobacco use, nicotine addiction and the tobacco epidemic;
 - (ii) positive benefits for vulnerable groups, including hard to reach population group(s); and/or
 - (iii) changes to the policy and wider settings under which the tobacco industry operates, and/or tobacco is grown, manufactured, supplied and/or used, supporting or enabling wider tobacco control efforts to be more successful.
- 4. The Expert Group sought to ensure that it selected a range of FLMs that:
 - (a) provide options for Parties at various stages of implementation of the WHO FCTC aiming at combating the tobacco epidemic (i.e. some measures would be able to be adopted regardless of the state of tobacco control in the selected Party, while other measures may have an easier path to adoption if the Party is further advanced in implementing the WHO FCTC and wider tobacco control efforts);
 - (b) provide options for those Parties that are least developed countries, low-income countries and lower-middle-income countries, not just those Parties that are uppermiddle-income countries and high-income countries; and
 - (c) capture all forms of tobacco use, and are consistent with Article 5.2(b) of the WHO FCTC, which sets a general obligation for Parties to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke.

Table 2. The 16 FLMs identified and described

(a)	a) Tobacco supply		
	(i)	Retail reduction	
	(ii)	Ban on incentives to retailers	
	(iii)	Price controls for tobacco products and devices ("minimum price policies")	
	(iv)	Birthdate-based sales restrictions (BSRs) ("tobacco-free generation")	
	(v)	Increase in minimum legal age for sales of tobacco products	
	(vi)	Ban/phase out sales of tobacco products	
(b)	Institutional structure/market		
	(i)	Environmental controls ("producer pays")	
	(ii)	End of any government support for tobacco farming	
	(iii)	Measures to reduce tobacco supplier profits and pricing power	
	(iv)	End the commercial sale of tobacco industry products	
	(v)	Quota on tobacco manufacture and imports, followed by regular reduction ("sinking lid")	
(c)	Product		
	(i)	Low/very low nicotine content levels in combustible tobacco products	
	(ii)	Ban on all flavouring agents and other additives in tobacco products	
	(iii)	Tobacco supply freeze on brands and reduction of variants	
	(iv)	Ban on cigarette filters	
(d)	Consumer		
	(i)	Expansion of smoke-free venues in private/semi-private environments and reduction of exposure to second- and third-hand tobacco smoke	

- 5. The information briefs are descriptive in nature. They are not intended to provide systematic evidential reviews of the proposed interventions but rather to present a current narrative summary of each FLM. Each brief was prepared primarily using readily available, predominantly English-language published literature, supplemented by select grey literature and expert insights available at the time of preparation. Thus, each brief would benefit from updating and revising as new evidence becomes available.
- 6. The information briefs focus on tobacco products as defined by the WHO FCTC, in line with the mandate of the Expert Group. Parties may wish to adopt and apply the FLMs to both tobacco and nicotine products, depending on their domestic definitions and approach to regulation of those products.

(iv) Overarching implementation considerations

7. The Expert Group has identified some potential challenges and barriers to adoption, some risks and some potential unintended consequences of the FLMs, and has included some commentary on

how to mitigate these. Any Party considering the adoption of an FLM could, consistent with their regulatory and policy-making procedures, identify potential challenges to adoption and implementation by conducting a full policy/regulatory impact analysis, and consider approaches to mitigate these challenges.

- 8. The Expert Group sought views on potential legal challenges and how to mitigate them in relation to some of the FLMs.³ The information briefs do not discuss legal analyses in depth; such legal matters will need to be considered by each Party in accordance with their legal system, legislation and jurisprudence.
- 9. A typical objection by opponents to FLMs may be that there is insufficient evidence that they will be effective in reducing tobacco use. This may be the case where a measure has not been implemented in other jurisdictions. However, absence of past implementation need not be a barrier to the adoption of FLMs. For measures that have not yet been implemented, there exist other kinds of evidence that may support the likelihood that those measures would lead to benefits. These include clinical trials, modelling, behavioural research and inference from other similar interventions, or interventions applied to other products, markets or behaviours. The information briefs developed by the Expert Group include and cite such sources of evidence.
- 10. The Expert Group notes that an expected challenge to the development and adoption of an FLM is tobacco industry interference. Tobacco industry interference may relate to specific FLM-related challenges but, overall, while tobacco industry interference can be expected in response to any new or expanded tobacco control measures, with effective planning and management, it need not be a barrier to adoption. In that respect, Parties are reminded of their obligations under Article 5.3 of the WHO FCTC and its Guidelines for implementation.
- 11. The tobacco industry often seeks to impede the implementation of tobacco control measures and FLMs by raising the spectre of increased illicit trade in tobacco. As emphasized by many experts, effective solutions to illicit trade in tobacco products are well documented for example, by the World Bank⁴ and the World Health Organization (WHO)⁵ and addressing illicit trade does not require compromising on tobacco control or broader public health measures that can continually and substantially reduce tobacco use and the tobacco epidemic. The Expert Group notes that the Protocol to Eliminate Illicit Trade in Tobacco Products includes a range of evidence-based measures to prevent and combat illicit trade in tobacco products.⁶
- 12. The Expert Group notes that the adoption of any FLM will depend on the readiness of Parties to take action, which is influenced by a number of factors such as political and/or social readiness, cultural and economic factors, and public support (among others). The Expert Group selected for description FLMs that can be adopted by a Party regardless of how advanced their tobacco control programme may be, and other FLMs that may be easier to adopt if a Party has a comprehensive tobacco control programme in place. While Parties should not necessarily consider any of these FLMs out of their reach, the adoption of some FLMs may, however, require supporting measures to be implemented concurrently, or may require greater emphasis on efforts to manage challenges to implementation. This is consistent with Article 4 of the WHO FCTC, which highlights the need for comprehensive multisectoral tobacco control measures, and Article 5, which provides that each

³ COP11 Documentation: Supplementary information (accessed 29 August 2025).

⁴ Confronting illicit tobacco trade: a global review of country experiences (vol. 2 of 2): executive summary (English). Washington, DC: World Bank Group; 2019 (accessed 22 May 2025).

⁵ WHO technical manual on tobacco tax policy and administration. Geneva: World Health Organization; 2021 (accessed 22 May 2025).

⁶ Protocol to Eliminate the Illicit Trade in Tobacco Products. 2003. World Health Organization.

Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with the WHO FCTC.

(v) Report of the Expert Group

The report of the Expert Group was submitted to the Eleventh session of the COP and is available on the WHO FCTC website.⁷

Information briefs full text of the 16 FLMs identified and described

(a) Tobacco supply

(i) Retail reduction

Abstract

Policy description and background. Retail reduction means reducing the number, density and/or type of retail outlets where tobacco products can be sold. Several forward-looking policy approaches have already been used or proposed in this regard, including: 1) limits on types of retailers allowed to sell tobacco; 2) zoning measures to create retail buffer zones around schools or other places; 3) restricting sales to a capped number of privately operated stores; 4) requiring minimum distance between tobacco retailers; 5) limiting and winnowing the number of tobacco sales licences issued, based on geographical area or population; and 6) restricting tobacco sales to a limited number of state-operated retail outlets.

This FLM aligns with Article 4.2(b) of the Guiding principles of the WHO FCTC, guiding Parties to take measures to prevent initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form. This FLM also serves to advance Article 12 of the Convention, by strengthening public awareness that the sale of harmful products such as tobacco products is no longer normalized; Article 13, as retail reduction measures also reduce exposure to tobacco products and advertising and promotion at points of sale; and potentially Article 17, since such initiatives may be designed with resources to help tobacco retailers make the transition from selling tobacco products to economically viable alternative activities.

Evidence of impact. There is a substantial, rapidly growing body of evidence from cross-sectional studies, modelling studies, meta-analyses and some real-world post-policy impact research suggesting that proximity to a tobacco retailer and/or higher density of tobacco retailers in a community is associated with daily smoking, greater youth tobacco use initiation, reduced success for people trying to quit using tobacco, greater exposure to tobacco product marketing and negative health outcomes. A pre-post study found decreases in smoking among adolescents and in illegal sales to young people in Hungary, following an 85% reduction in tobacco retail density.

Benefits and strengths. Retail reduction would significantly reduce tobacco availability and, with fewer retailers selling, could streamline monitoring and enforcement of regulations. Retail reduction also reduces the number of local tobacco industry allies, thus reducing industry interference and opposition to other types of tobacco control policy initiatives.

Implementation considerations. Reductions in the number of tobacco retail outlets need to be substantive in order to have measurable impacts on tobacco use.

⁷ COP11 Documentation: Main documents (accessed 29 August 2025).

Conclusion. Retail reduction as an FLM is supported by a large body of evidence indicating that more tobacco retailing is associated with more tobacco use initiation, difficulty quitting, more exposure to tobacco marketing and negative health outcomes. A range of retail reduction approaches have been proposed and studied, several have been implemented, and some outcomes have been measured. Retail reduction holds promise for materially changing the social environment of tobacco use initiation and cessation, altering the conditions that sustain the tobacco epidemic.

Description of the intervention

Retail reduction means reducing the number, density and/or type of retail outlets allowed to sell tobacco products. Several FLMs could/should be considered: 1) limit types of retailers allowed to sell tobacco; 2) zoning measures to create retail buffer zones around schools or other places; 3) restrict sales to a capped number of privately operated stores; 4) require minimum distance between tobacco retailers; 5) limit and winnow number of tobacco sales licences issued, based on geographic area or population; and 6) restrict tobacco sales to a limited number of state operated retail outlets.

These FLMs align with WHO FCTC Article 4.2 (b) guiding principles to implement measures to prevent initiation, support cessation, and decrease consumption of tobacco. Such policies also serve to advance Article 12, by educating the public that widespread sale of lethal products is no longer normalized; Article 13, as retail reduction measures also reduce exposure to tobacco products and marketing at points of sale; and potentially Article 17, since such initiatives may be designed with resources to help tobacco retailers make the transition from tobacco sales.

Availability of information/research evidence on the potential impact of the FLM

There is a very large body of research and analytic work on this FLM.

A 2024 scan of commercial combustible tobacco product retailing regulations by WHO region concluded that "tobacco retail policy that actively addresses the retail availability of tobacco is underutilise" (1). Yet there is a substantial, rapidly growing body of evidence from cross-sectional studies, meta-analyses and some real-world post-policy impact research suggesting that proximity to a tobacco retailer and/or density of tobacco retailers in a community is associated with daily smoking, greater youth tobacco use initiation and reduced success for people trying to quit use of tobacco, greater exposure to tobacco product marketing and negative health outcomes, including higher hospital discharge rates for chronic obstructive pulmonary disease, as well as a number of adverse birth outcomes (2-6).

In addition to directly reducing access and availability of tobacco products, and depending upon current policy in the jurisdiction, retail reduction may also have secondary additive effects in reducing exposure to smoking cues and product marketing and promotion, and denormalizing sales of lethal products (2).

A 2019 meta-analysis of 11 studies from six countries (Australia, Canada, India, New Zealand, Scotland and the United States of America) found that greater tobacco retail density near homes was associated with higher odds of past-month adolescent cigarette smoking (OR=1.08, 95% CI 1.04 to 1.13) (3). A 2022 meta-analysis of 27 studies concluded that both tobacco retailer density and proximity were positively associated with tobacco use behaviours (4).

A 2024 meta-analysis of 62 studies found positive associations between tobacco outlet density and cigarette smoking among pregnant people, youth and adults, with mixed findings related to cessation and relapse (5).

An observational longitudinal study of geolocation and tobacco use data (2008–2010) from a cohort of 2377 adults in the United States who smoked reported that those in high poverty areas living further from a tobacco retailer were over two times more likely to be abstinent than those living less than 500m from a retailer (7). A 2021 neuroimaging study provided interesting preliminary evidence into the neural mechanisms that may help explain the epidemiological links between exposure to retail outlets and smoking. Using GPS tracking and MRI scans, the study concluded that exposure to familiar tobacco retail outlets elicited greater neural activation among people who smoke, reinforcing the idea that retail exposure has strong effects on smoking behaviour (8).

A 2021 review and synthesis of published studies and grey literature evaluating the impact of retailer reduction policies reported that all types of policies showed promise in impacting tobacco use, attitudes, beliefs and behaviours, but policies in combination were most effective (9). A 2023 scoping review that included several retail reduction FLMs concluded that "there is evidence that having fewer retail[ers] reduces the level of impulse purchasing" of tobacco (10). A 2021 systematic review of 35 studies measuring density or proximity of tobacco retailers and youth tobacco use outcomes, such as smoking prevalence and susceptibility to smoking, found that "the evidence supports a positive association between tobacco retail outlet density and smoking behaviours among youth" (11). Likewise, a 2016 meta-analysis of retail tobacco promotion and youth smoking concluded that compared with youth less frequently exposed to retail tobacco marketing, those who were more exposed had 1.6 times higher odds of trying smoking and 1.3 times the odds of being susceptible to smoking in the future (12).

A study of adults who smoke in Finland found that those who lived within 0.5 kilometres of a tobacco retailer had a 27% lower likelihood of smoking cessation, compared to those living further away (13).

A study using data from 3080 counties in the United States between 2000 and 2010 analysed relationships between retailer density and smoking and found that while the structure of the measure used affected the *strength* of the supply-side effect as compared to demand effects, the supply effect was measurable and significant, providing a rationale for reducing tobacco supply in communities in order to reduce smoking prevalence (14).

The issue of reverse causality in correlational studies cannot be ruled out, as it may be that tobacco retailers are more likely to locate in areas where more people smoke. However, several studies found a positive association between retailer density and smoking behaviour, even after controlling for various individual and community level covariates (3, 4). Further, as one review noted, this does not explain the positive association between exposure to tobacco retail marketing and susceptibility to smoking among people who have never smoked (15).

Because of the large number of potential FLMs falling under the broad category of retail reduction, additional evidence about several of these is briefly discussed below. Phasing out or ending retail sales of tobacco products is another approach to retail reduction (See separate FLM evidence brief).

1) Limit types of retailers allowed to sell tobacco

Several studies and analyses have examined policies that would reduce retailers by either banning tobacco sales in pharmacies or restricting tobacco sales to *only* pharmacies or other types of retailers (16). While many countries already do not permit tobacco sales in pharmacies, it is still widespread in the United States. San Francisco was the first city in the United States to adopt a tobacco-free pharmacies policy, in 2008. Following litigation, the policy was expanded in 2010 to include grocery stores and big-box retailers with pharmacies. Pharmacy tobacco sales bans have been enacted in

numerous local jurisdictions across the United States, and statewide in Massachusetts and New York state (17,18). More recently, the Netherlands is banning tobacco sales from vending machines and grocery stores, which is projected to result in an 83% reduction in retail outlets (1).

Another potential retail reduction measure would allow tobacco sales only in pharmacies (19, 20). Such a proposal could reduce the number and density of retail outlets, but it may be unacceptable to pharmacists (19). However, a New Zealand modelling study examining the effect of such restrictions combined with brief cessation advice in pharmacy settings found that it could provide substantial health benefits and cost savings (20). This study modelled pharmacy-only tobacco supply combined with annual cessation advice, following a 10-year gradual reduction in the number of retailers based on licensing. The authors largely attributed this positive outcome to the provision of cessation advice by pharmacists (20). In 2011, policy-makers in Iceland proposed a multi-staged plan of restricting tobacco product sales to registered pharmacies with special tobacco licences (21). Policy-makers in Oregon in the United States proposed a similar measure in 2013 that would require users to obtain a prescription for tobacco to legally access from pharmacies (22). Neither of these two case examples were successfully adopted or implemented. A 2024 scoping review of 18 publications found four papers reporting on unsuccessful attempts to restrict tobacco supply to pharmacies (23). The review noted that simulation modelling from Scotland suggested that retailing tobacco only in pharmacies would reduce average tobacco retail outlet density by 75% and number of retailers by 87%.

Other options for retail reduction include restricting sales to adult-only and/or tobacco-only stores or banning online sales and home delivery of tobacco products. A modelling study in Minnesota found that among six types of policy measures, restricting cigarette sales to tobacco specialty shops would have the largest effect on total purchasing costs of cigarettes, accounting for travel time and other factors (24). However, as with some of the other approaches discussed, the estimated effects would be greater if combined with other density reduction policies, such as requiring minimum distances between tobacco retailers. Several communities in California and on the East Coast of the United States have enacted such policies for flavoured tobacco products. In Massachusetts, there was a significant reduction in tobacco product availability after the sale of flavoured tobacco products was restricted to adult-only establishments (25).

2) Licensing or zoning measures to create retail buffer zones around schools or other places

According to a 2024 global scan (1), many countries have enacted these types of measures, including Chad, Republic of Congo, Côte d'Ivoire, Ethiopia, Gambia, Mauritius, Senegal and Uganda in the African region; Chile, Paraguay and many subnational jurisdictions in the United States, in the Region of the Americas; India in the South-East Asian Region; Spain, Italy and France in the European Union; the Russian Federation, the Netherlands, Jordan, Pakistan, Qatar, the United Arab Emirates, New Zealand (proposed and then repealed), Balanga City in the Philippines, and China. However, enforcement of regulations is often inadequate (26).

3) Restrict sales to a capped number of privately operated stores

In 2014, San Francisco (California, United States) capped the numbers of tobacco licences per supervisorial district, seeking to reduce inequity by equalizing number of tobacco retailers across supervisory districts (minimum= 37, maximum=180, goal=45). Between 2014 and 2019, there was a 24% reduction in tobacco licences, with the greatest reduction in the lowest-income neighbourhood (32% reduction) (27). While no studies controlling for other factors have measured the impact of the retailer capping policy, the percentage of high school students who smoked cigarettes in the past 30

days dropped from 7.71% in 2013 to 4.74% in 2017, and packs of cigarettes sold decreased citywide(28). This may reflect the overall trend of reduced smoking among youth, but the policy clearly reduced youth exposure to products and marketing.

Several countries, including France, Spain and Italy allow sales only at state licensed tobacconists, and have voluntary regulations for permitted distances between stores. However, they do not appear to have permanent caps on the numbers of retailers, as the Government of Spain announced in 2022 plans to open 200 more tobacconists, including along the border with France (29). While most tobacco retailers in Spain were compliant with licensing rules, 75% of stores were situated within 300 metres from schools, suggesting that voluntary measures are ineffective (30). The authors argue that more restrictive regulations will be required for decreasing availability.

4) Require minimum distance between tobacco retailers

This policy has been adopted in a number of California communities in the United States (31) but globally, this approach appears less commonly adopted compared with restricting retailers through buffer zones near schools, churches, and other community locations, as discussed above (1). The San Francisco ordinance discussed above also limited retailers by proximity to schools or other retailers; a study of the policy found that the density/proximity ordinance (which applied only to new retailer licences) did not have a homogenous effect in reducing retailer numbers across the city but depended on whether a district had commercial areas or was predominantly residential. Because the process of retail reduction is through attrition, areas with the highest concentration of existing retailers, such as commercial districts, will over time see the greatest reductions (32).

A modelling study comparing several approaches to retail reduction in North Carolina, United States, found that a minimum distance policy had the single greatest impact and would reduce density by 22.1% at the state level (33). A study in Texas in the United States compared a simulated minimum distance between retailers with a simulated ban on retailers within 1000 feet of schools to evaluate the potential reductions in exposure to tobacco advertisements (34). Outlets closer to schools had significantly more tobacco advertisements than those further away, and the ban on retailers within 1000 feet of schools led to a slightly greater reduction in advertisements compared with the minimum-distance-between-retailers approach.

In another study comparing several retail reduction approaches for North Carolina in the United States on prenatal smoke exposure and perinatal health care utilization, limiting the number of retailers to the same density as the 2014 San Francisco policy was predicted to lead to moderate reductions in exposure to retailers for the majority of the sample as well as when stratified by race/ethnicity (35). A combination of policies was estimated to have slightly larger effects but regarded as potentially onerous to implement.

5) Limit and winnow number of tobacco sales licences issued, based on geographic area or population

This policy has been enacted in the large cities in the United States including San Francisco, Philadelphia and New York City and is discussed further below. Italy also limits the number of tobacconists based on population density (10). A similar approach was part of New Zealand's 2021 comprehensive tobacco-free plan, with a 95% reduction in retailers of smoked tobacco products planned through a license-limiting scheme. The retailer reduction policy alone was estimated to account for 19% of the health gains of the combined package of measures, on par with tobacco tax

increases and greater than mass media and quit programme interventions (36). Unfortunately, under a new government the entire plan was rescinded before implementation (37).

6) Restrict tobacco sales to limited number of state operated retail outlets

We identified no jurisdictions with solely state-owned or operated tobacco retail outlets. Such retailers would likely be similar to state-controlled alcohol outlets that operate in some countries and smaller jurisdictions. In some states in the United States, for example, the state has a monopoly on the sale of some forms of alcohol at both the wholesale and retail level (38). Although many of these state monopolies are less public-health oriented now than when they were initially established, they do typically control alcohol prices and limit the number of alcohol outlets, operating hours, and interior and exterior advertising (39). Studies show that states in the United States with these systems have higher alcohol prices on average, lower per capita spirits consumption, and fewer youth alcohol-impaired driving deaths than states without these systems (38, 40, 41). Similar state-owned or operated tobacco outlets could likewise control tobacco product prices, limit the number or density of tobacco outlets, and regulate their hours of operation and marketing environments (42). A jurisdiction with this approach to tobacco sales could also adopt an explicit public health focus, establishing goals to reduce tobacco consumption and phase out tobacco sales over time.

Some countries do have established monopolies on tobacco sales; however, most do not take advantage of many of the policy levers at their disposal, operating them more like jurisdictions that license tobacco retailers. For example, France, Italy and Spain are described as having monopolies on tobacco sales (43), with sales restricted to licensed sellers (referred to as tobacconists) who typically sell only tobacco, or tobacco and a limited number of other products. Italy and Spain require a certain distance between tobacconists and set the retailers' profit margin (30). However, neither country has adopted other retail measures that might reduce tobacco consumption. France requires tobacconists to "meet a number of personal and business criteria" and has a minimum population requirement for the establishment of a tobacconist in a community but appears to have otherwise adopted a hands-off approach to how tobacco is sold (10, 43). Similarly, China's Tobacco Monopoly Bureau licences retailers to sell tobacco, places some limits on retailer density and location, and requires posting of "no sales to minors" signs, but does not otherwise restrict tobacco sales, and compliance is variable (26, 44). The Lebanese state tobacco monopoly primarily controls tobacco wholesalers, although it does license retailers and set their profit margin; unlike the European tobacco monopolies, it also sets tobacco prices for retailers; however, because wholesalers are known to manipulate the price, in practice, the state's level of control over prices is limited and it has pursued expanding the tobacco market, rather than reducing it (45).

To date, Hungary is the only country that has implemented a major retail reduction policy at the national level. In 2013, in an effort to reduce youth access to tobacco products, the national government limited tobacco sales to government-licensed tobacco shops, called "National Tobacco Shops," and reduced the number of tobacco retailers by 85% (46, 47). Shops are required to have darkened windows so that tobacco products are not visible from the exterior of the store (46). Since the implementation of the policy, and several subsequent modifications, prevalence of lifetime and current cigarette smoking among adolescents declined by 13–24 percentage points and 4.8–15 percentage points respectively, based on data from 2012 to 2020. Illegal sales to minors decreased but compensatory access strategies (asking someone else to buy for a minor) increased (46). The simple pre-post design of this study cannot rule out other causes having contributed to the decline, and one critical analysis suggests there has been widespread dissatisfaction with what was perceived as political cronyism in distribution of licences (48). However, this real-world study provides some

evidence of the potential impact of a retail reduction policy on smoking prevalence. Studies comparing Hungary's outcomes with other European Union (EU) country data would be helpful in differentiating policy-specific results from overall EU trends.

Awareness and profile of the FLM as a potentially promising intervention

While several jurisdictions have enacted one or more measures designed to reduce tobacco retailing, some cities in the United States (San Francisco, Philadelphia and New York City) have enacted retail capping measures requiring gradual reductions through attrition. A study of the effect of New York City's ordinance found a reduction in total number of tobacco retailers, reduced density, and pro-equity effects for Black and lower income districts (49). Density caps in Philadelphia reduced density, reduced school zone retailers, and had overall pro-equity effects (50). Retail reduction measures have also been proposed or enacted in other countries, including New Zealand, the Netherlands (51), and others.

A 2024 analysis concluded that even in a country like Australia, long regarded as a tobacco control leader, "weaknesses in existing laws leave children exposed to tobacco product retailing in ways that normalise tobacco product sales and use" (52). Additional retail reduction measures, such as restricting their number or location, could enhance protections for children from exposure to tobacco products (53). A nationally representative survey of Australian adults conducted in 2019 found 76.3% support for restricting cigarette sales to places children are not permitted to enter (54).

Public opinion studies have found strong public support for retail reduction policies. In California in the United States 63.3% of adults supported reducing the number of stores that sell tobacco in 2022, 61.8% in 2021 supported specifically prohibiting the sale of tobacco in pharmacies, and more than 76% agreed that tobacco retailers should not be allowed near schools (55). Research from New Zealand found substantial public support for several retail reduction measures, including requiring shops selling tobacco to be adult-only premises, which was supported by 55% of participants. Almost half supported reducing the number of tobacco retailers by 95% (56).

A recent systematic review examining support for a number of FLMs found that among the general population, there was 61.8% support for policies to reduce retail density, and 38.5% support among people who smoke (57).

Reach of this measure depends upon jurisdiction and type of measure(s) employed. A combination of measures is likely to be most effective. A study of geocoded data from all 11,393 tobacco retailers in the Ohio in the United States found that the most impactful approach depended on the specific type of community. Specifically, school based reductions were more equitable than other approaches for reducing retail density in low-income, African American and urban neighbourhoods (58).

In New Zealand, a modelling study of different approaches to retail reduction — including the 95% reduction under a "sinking lid" gradual strategy, permitting sales only at half the liquor stores and eliminating sales in proximity to schools — found that none of the approaches alone would achieve the country's endgame goal of smoking prevalence below 5% by 2025 — even though each policy had an impact on reducing smoking prevalence and increasing the cost of cigarettes (59). Another New Zealand modelling study (36) examining the different proposed measures of the Smokefree 2025 plan found that while "denicotinization" had the largest predicted effect, retail reduction alone had a strong impact on cessation in the year of implementation, and over time would reduce differences in smoking prevalence and all-cause mortality between Māori and non-Māori.

An Australian study found that 88% of people who smoked reported daily availability of tobacco at retail within walking distance, with one outlet for every 77 users (60). Some studies have also found an association between socioeconomic status and retail availability. For example, a study from Western Australia found more than five times the number of tobacco outlets in the most disadvantaged areas as compared to the least disadvantaged (61). Another study in the same Australian state, controlling for smoking prevalence, confirmed the relationship between outlet density and social disadvantage (62), As noted by Greenhalgh et al. (53) greater tobacco outlet density increases price competition among retailers, contributes to normalization of tobacco use, and contributes to financial hardship and more difficulty quitting.

Implementation considerations specific to this FLM

Since in many countries there are more tobacco retailers in underprivileged communities (63, 64), tobacco retailer reduction can have pro-equity effects, depending on the measures used (9). However, different approaches may have the effect of widening disparities in retail density in disadvantaged communities (65), so modelling specific to the jurisdiction is important in deciding on the approach(es) taken. For example, in countries where pharmacies are primarily medicine dispensaries, restricting sales to these locations is likely to be effective. In countries where pharmacies are common locations for the purchase of household items, however, banning sales in pharmacies and restricting sales to other retail outlets through different measures may be more effective. Restricting sales to specific types of outlets should be implemented in conjunction with licensing and capping measures to prevent further proliferation of these types of outlets.

Given evidence that tobacco retailers tend to be clustered near schools (66, 67) and areas with many young people (53), and the inequitable distribution of tobacco retailers, with more availability in neighbourhoods in the United States with Black, Hispanic/Latino and Asian residents (68), planning should consider potential impacts on tobacco disparities by age, race/ethnicity, level of economic disadvantage, rurality and other factors. Advance assessment of potential impacts on low socioeconomic and underprivileged groups based on local data will be needed. All retail reduction measures make material changes in the environmental visibility and availability of tobacco products for the population as a whole. Population-level impact on smoking will depend upon local contextual factors and distribution patterns of retailers (69).

The tobacco industry and small retailers are likely to argue that without tobacco, their businesses will suffer. However, multiple studies from several countries suggest this is unlikely, as tobacco sales transactions constitute a small percentage of transactions in most stores, most sales did not include tobacco, tobacco is not a high profit margin item for most retailers, and most tobacco sales did not include other items (70–73). A study from the United Kingdom used point-of-sale systems data from convenience stores and found that tobacco's importance as a "footfall driver" was diminishing over time, contrary to tobacco industry claims (74). Further, some retailers now find tobacco sales inconsistent with their stores' image; some are voluntarily phasing out sales for a variety of reasons (75–78).

Tobacco retail licensing (TRL) is recommended under the WHO FCTC partial guidelines for the implementation of Articles 9 and 10. Jurisdictions lacking tobacco retailer licensing would have challenges with implementation/enforcement of retail reduction policies. A local licensing system enables jurisdictions to identify and collect data on retailers and enforce existing local policies; it also enables future retailer-based enforcement. Strong TRLs may lower rates of smoking among youth and adults (79). TRLs can include requirements such as requiring provision of quit smoking materials at point of sale, and may also form the basis for future, stronger policies, such as

prohibiting sales of flavoured products or tobacco-free pharmacies (80, 81). Raising license fees can also reduce the total number of retailers selling tobacco (82, 83). High annual tobacco license fees may serve to motivate retailers to stop selling tobacco (84). For example, in Santa Clara County, California (United States), the implementation of comprehensive tobacco retail licensing regulations led to significant reductions in tobacco retailer density, proximity to schools, and number of locations (85). An example of a comprehensive tobacco retail licensing system for local jurisdictions in the United States is available (86).

Depending upon the specific measure enacted, resistance from retailers should be anticipated. However, given that this measure is perhaps most likely to be undertaken in jurisdictions where tobacco use prevalence is declining, retailers may already be seeing tobacco sales drop and may be receptive to resources to assist them in transitioning to other products with higher profit margins and fewer negative impacts on their community.

Online sales remain an understudied and unresolved problem. While retail reduction decreases product and marketing visibility in brick-and-mortar stores, it may lead to more online sales unless policies include banning such sales and are accompanied by resources to monitor and enforce the provisions.

While much of the research on retail reduction has been conducted in Western countries, a simulation modelling study in Shanghai, China, found that several types of retail reduction policies would reduce availability of tobacco; however, some could increase social inequality (87).

This set of FLMs is likely to have some immediate effects, particularly for youth access and cessation. Overall and longer-term impact may be influenced by other factors, such as policies in contiguous jurisdictions or cross-border effects. Surprisingly, even some long-term approaches, such as reduction through attrition and capping numbers of retailers, may result in short-term reductions in the number of tobacco retailers in a community, if they are structured to include other measures (e.g., raising license fees).

Case studies

Giovenco (49) provides a case study evaluation of New York City's experience with capping numbers of retail outlets. The New York City policy, enacted in 2018, capped the number of tobacco retail licences in each of 59 community districts with targets set at 50% of the number of operational licences at the 2017 baseline. Until the number of licences decreased through attrition below that cap, no new retail licences would be issued. The retail capping policy was combined with other measures, including minimum price, banning sales in pharmacies, and raising the cigarette retail license fee substantially. After implementation, the number of retail licences decreased from 9304 in 2010 to 5107 in 2022, and the rate of decline accelerated after the policy was implemented. Further, the policy had positive effects in reducing inequity, with stronger effects in districts with lower income and greater proportions of African American people.

San Francisco's retail density policy caps the number of retail tobacco sales permits in each supervisorial district at 45. It includes a ban on new licences for locations within 500 feet of a school, another tobacco retailer or at new locations. In the first 10 months after the policy took effect, all districts saw a decline in tobacco retail licences, and a larger decline was found in those that had more retailers at baseline. The referenced case study (27) includes useful details on how the policy was developed and implemented.

Summary

Retail reduction makes visible, material changes in exposure to and availability of tobacco products, contributing to de-normalization. Retail reduction may also destabilize or eliminate industry relationships with retailers, thereby reducing numbers of local area industry allies. Thus, retail reduction can alter the industry's ability to mobilize opposition to other tobacco control measures at the level of the jurisdiction.

Retail reduction as a FLM is supported by a substantial body of evidence indicating that more tobacco retailing is associated with more tobacco use initiation, difficulty quitting, more exposure to tobacco marketing, and negative health outcomes on the community level. A range of retail reduction approaches have been proposed and studied, and several have been implemented and evaluated. Studies have shown substantial public support for retail reduction.

Like many FLMs, retail reduction is likely to be most effective when combined with other tobacco control measures. Retail licensing is essential for effective implementation and enforcement of any approach to retail reduction.

Widening of existing disparities in exposure to tobacco retailing is a potential unintended consequence of tobacco retail reduction policies. As such, local community and contextual factors should be considered in the design of regulatory actions. Notably, nearly all studies have been conducted in high-income countries, most in the United States, where resources for monitoring compliance are higher than in many countries.

While local retailer opposition should be anticipated, research shows that contrary to industry and retailer claims, tobacco is not a large part of sales for most retailers. Parties considering this measure may consider incentive programmes to assist retailers transitioning from selling tobacco, thus mitigating the effect of local retail opposition.

In sum, retail reduction holds considerable promise for materially changing the social environment to prevent tobacco use initiation and promote cessation, thus altering the conditions that sustain the tobacco epidemic.

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Appendix

https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-retailer-2010.pdf

(ii) Ban on incentives to retailers

Abstract

Policy description and background. This policy prohibits tobacco industry retailer incentive programmes that affect tobacco consumer behaviours through modifications to the retail environment and retailer behaviour. These include programmes with the aim of increasing tobacco product sales, obtaining favourable tobacco product placement, forcing tobacco product promotion and increasing specific tobacco product availability. These incentives contribute to increased tobacco consumption, exposure to marketing and impulse purchases. To date, only a few countries have banned retailer incentive programmes. This FLM aligns with Article 13 of the WHO FCTC, aiming to "restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public". Additionally, the Guidelines for implementation of Article 13 and Specific guidelines to address cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in entertainment media for implementation of Article 13 provide further details on the nature and extent of incentives to tobacco retailers that may be subject to banning, including in relation to the promotion of tobacco products on digital media communication platforms.

Evidence of impact. A review of evidence identified that the "4 Ps" (placement, price, promotion and product) included as main elements in the contracts of tobacco retail marketing eventually target increased purchasing by the consumer and use of discounted products by retailers. Research on the impact of tobacco retailer incentive programmes suggests that banning such programmes would decrease impulse tobacco purchases, exposure to tobacco retail marketing and use of discounted tobacco products. An evaluation of a ban on tobacco retailer incentives in Quebec, Canada, found that the ban had no significant effects on tobacco pricing. This suggests that these bans may not be effective on their own and might need additional supportive measures or complementary policies; it could also indicate that compliance and enforcement had been insufficient. There is a lack of research on the impact of similar bans that have been implemented by some jurisdictions in the United States of America and in low- and middle-income countries. As many countries have adopted only some form of ban on incentives to retailers, the impact of specific partial bans — and how outcomes of such partial bans might be measured — is unclear. Effective implementation and comprehensive enforcement could lead to observable short-term changes in disrupting the tobacco industry's marketing strategies.

Benefits and strengths. Comprehensive bans on incentives to tobacco retailers will minimize the tobacco industry's ability to promote new, low-cost brands, and to implement discounts and coupons at retail locations to circumvent tax/price increases, preventing young people from initiating tobacco use and supporting tobacco users to treat their tobacco dependence.

Implementation considerations. Partial bans on tobacco retailer incentives that have been implemented by some countries leave gaps that allow the tobacco industry to adapt its marketing strategies. It remains unclear how the outcomes of these partial restrictions will be measured. Tobacco companies have fostered alliances with convenience stores that undermine tobacco control policies: 97% of the tobacco industry's marketing budget in the United States is now focused on saturating convenience stores and other retailers with incentives for consumers to buy its products. This highlights the need for comprehensive bans on tobacco retailer incentive programmes and for regulatory clarity and comprehensiveness.

Conclusion. Comprehensive bans on incentives to retailers could effectively weaken relationships between retailers and the tobacco industry, if implemented comprehensively with a strong

monitoring and enforcement mechanism to prevent the tobacco industry shift in its retail incentive marketing schemes.

Description of the intervention

This FLM would ban tobacco companies from providing any type of incentive to retailers that affects tobacco consumer behaviours through modifications to the retail environment and retailer behaviour — with the aim to increase tobacco product sales, obtain favourable tobacco product placement, force tobacco product promotion, and increase specific tobacco product availability. The WHO FCTC has only brief guidance on this FLM as part of Article 13. There is guidance on banning incentives to tobacco retailers under WHO FCTC Article 13 on tobacco advertising, promotion, and sponsorship: "4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall: ...(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public." (1)

WHO FCTC Article 13 guidelines provide further details on the nature and extent of incentives to tobacco retailers: "It is important to note that both 'tobacco advertising and promotion' and 'tobacco sponsorship' cover promotion not only of particular tobacco products but also of tobacco use generally; not only acts with a promotional aim but also acts that have a promotional effect or are likely to have a promotional effect; and not only direct promotion but also indirect promotion. 'Tobacco advertising and promotion' is not restricted to 'communications', but also includes 'recommendations' and 'actions', which should cover at least the following categories: (a) various sales and/or distribution arrangements..." (2)

Article 13 guidelines provide some examples of tobacco retailer incentive schemes, such as "display at points of sale, lotteries, free gifts, free samples, discounts, competitions (whether the purchase of tobacco products is required or not), incentive promotions or loyalty schemes (e.g., redeemable coupons provided with purchase of tobacco products), and payments or other contributions to retailers to encourage or induce them to sell products, including retailer incentive programmes (e.g., rewards to retailers for achieving certain sales volumes)". (2)

WHO FCTC Article 13 guidelines also recommend banning incentives to and sponsorship of incentives to individuals for the promotion of tobacco products on digital media platforms: "Digital media-sharing platforms provide the tobacco industry an additional platform for promoting their products and undermining tobacco control strategies. TAPS on these sites include: ... (b) Influencer promotions. Tobacco industry entities, or those working to further their interests, incentivise or sponsor individuals to post content online featuring product brands. Social media influencers often are trained on what brands to promote, when to post for maximum exposure and how to avoid posting content that look like staged advertisements. Tobacco industry entities, or those working to further their interests, organize parties and contests with brand sponsorships and encourage participants to post on their social media accounts. Influencers and individuals are often instructed to include specific hashtags when promoting products on social media posts." (2, 3)

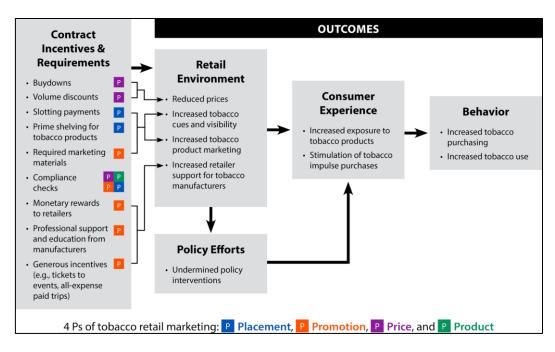
Availability of information/research evidence on the potential impact of the FLM

There is considerable evidence that tobacco companies use retailer incentive programmes to undermine tobacco control efforts. However, limited research evaluating the impact of retailer incentive bans is currently available. Thus, as with other FLMs, only preliminary evidence is available on the potential impact of banning incentives to tobacco retailers because the available research predominantly reflects evidence that conceptually draws on the impact of existing tobacco retailer incentive programmes, not on the effectiveness of banning them.

A 2023 scoping review by Reimold et al. compiled qualitative and quantitative evidence on the impact of industry incentives to retailers in high- and one middle-income countries (4), including Australia (5–7), Canada (8), Indonesia (9), the Republic of Korea (10, 11), New Zealand (12), the United Kingdom (13, 14), and the United States of America (15–31). Findings showed that tobacco suppliers incentivize retailers through contracts that are widely used and are often invisible to tobacco product consumers – 12 (75%) out of 16 studies found that more than half of the surveyed retailers participated in contracts with tobacco manufacturers (4). Such contracts enable tobacco companies to control tobacco product availability, placement, pricing and promotion at the retail level, and to promote retailer loyalty, which undermines tobacco control efforts (4). While some of the reported evidence is about price-reduction incentives to consumers, the 4 Ps (placement, price, promotion, and product) included in the contracts of tobacco retail marketing eventually target increased purchase by the consumer and the use of discounted products. Further details on the definitions and terminology-related tobacco company contracts with retailers are provided in Reimold et al. (2023)(4).

Fig. 1 from Reimold et al. (2023) (4) provides examples from tobacco industry documents illustrating the four 4 Ps denoting preferential tobacco product availability, placement, pricing, and promotional targeting in contracts between manufacturers and retailers.

Fig. 1. Conceptual model visualising the impact of contract incentive requirements and incentives on the retail environment, consumer experience and behaviour.



Source: Reimold et al., 2023) (4)

Tobacco companies have offered incentive programmes to retailers in countries, including Australia, Canada, Indonesia, among others, since the late 1990s. However, a comprehensive ban on tobacco retailer incentives has not been implemented in any country to date (4). To date, one study of the impact of a real-world restrictions on tobacco retailer incentive programmes in the Canadian province of Quebec found that no significant changes in tobacco pricing one year after the restrictions were implemented (8). This suggests that contract bans may not be effective on their own and might need additional supportive measures or complementary policies; or could indicate that compliance and enforcement had been insufficient. Further research may also be necessary to evaluate other aspects of this type of ban in the tobacco retail environment (4).

Some jurisdictions in the United States have implemented other partial forms of tobacco retailer incentive bans, such as "prohibiting buydowns, implementing counter-advertising alongside buydowns, using clear language that forbids 'advertising' rather than just 'promotion,' banning all business-to-business and business-to-consumer advertising to close loopholes that manufacturers exploit, and mandating that all payments from manufacturers to retailers be publicly disclosed, similar to sunshine laws in the USA that enhance transparency in government and corporate activities." (4, 32–34)

However, no studies of the impact of such bans are currently available. A 2023 scoping review (4) highlights the recent tobacco control policies that were associated with lower prevalence of tobacco retailer contracts, reflecting the enactment of more general TAPS bans that include some form of prohibiting retailer incentives. In Australia, such advertising efforts are prohibited under a general TAPS ban (35) In San Francisco, California (United States), such ban is under banning tobacco advertising on public billboards and retail signs that can be viewed from the outside of stores (36).

To date, no studies have evaluated the potential impact of total bans on tobacco retailer incentives or examined whether such bans exist in low-and middle-income settings with more informal economies, indicating a need to address these research gaps. However, the potential impact of this FLM could be conceptually inferred through the model outlined by Reimold et al. (2023) (4) in Fig. 1, even if its specific impact cannot be explicitly measured. Enacting this FLM would therefore disrupt these systems that perpetuate and entrench tobacco use. Nevertheless, there is global awareness about instituting some form of restrictions on price-based marketing (as a form of tobacco retailer incentives). As of 2023, 130 and 136 out of 197 countries, including many low- and middle-income countries (LMICs), respectively, have legislation in place that bans promotional discounts and free distribution of tobacco products (37). To our knowledge, no published studies have assessed the impact of and compliance with such bans to date.

A conceptual model of the impact of tobacco retailer incentive programmes on the retail environment, consumer experience and tobacco use behaviours suggests that prohibiting tobacco companies from offering incentives to retailers would disrupt the systems that perpetuate and entrench tobacco use (see Fig. 1) (4), To conceptually depict how banning incentives to tobacco retailers can disrupt this system, Fig. 1 by Reimold et al. (2023) (4), presented above, depicts how tobacco company contract components impact the retail environment in ways that may increase tobacco purchases and use. Specifically, Reimold et al. reported that buydowns and volume discounts facilitate tobacco price reduction (20, 30) while slotting fees, product placement, and promotion increase tobacco product visibility and marketing (19, 21, 29). Enacting this FLM would therefore have the potential to disrupt these systems that perpetuate and entrench tobacco use.

The limited evidence on the specific impact of banning incentives to retailers is not unexpected, given that this measure would seldom be implemented in isolation and its impact is hard to quantify.

Nonetheless, this should not inadvertently undermine the proven effectiveness of bans on tobacco advertising, promotion and sponsorship (as an overarching tobacco control measure for this FLM). Also, the evidence demonstrates that bans on tobacco advertising, promotion and sponsorship need to be comprehensive – any loopholes can significantly undermine the impact that such bans have – so even a small exception to allow retailer incentives can have out of proportion impacts (38).

While many countries have introduced some controls on price-related marketing, which can be a form of retailer incentive, there is lack of evidence on the strength of this FLM when it is comprehensively enacted. One study from the Canadian province of Quebec found that restrictions on tobacco industry incentive programmes for retailers did not eliminate cigarette price differentiation (8).

Evidence suggests that the industry reallocates marketing expenditures when faced with restrictions (39) In 2022, there were 66 countries with comprehensive TAPS bans, including 51 LMICs. Another 24 countries are only one provision away from a comprehensive TAPS ban. However, the rest of the world's countries have partial or complete absence of TAPS bans (40). This incomplete implementation exposes the population to the tobacco industry's manipulation of its retail incentive schemes. Hence, such bans would need to encompass all forms of price-related promotions, including price-reducing promotions (e.g., voucher schemes), price-based promotions (e.g., price-marked packaging) and retailer incentives (41).

There is evidence suggesting that this FLM would be more effective if implemented with other policies. For example, one study from the United Kingdom noted that despite prohibitions of all in-store promotions, including placing cigarettes below the counter and thereby reducing the visibility of price-based promotions to consumers (and likely diminishing the effectiveness of retailer incentives), unregulated packaging could still convey prices (42). Thus, to fully eliminate price-based marketing, bans on retail level marketing and the implementation of standardized packaging, in accordance with WHO FCTC Article 13 guidelines (2), would be necessary.

A single study found no significant changes tobacco pricing at one year after the implementation of a comprehensive ban on incentives to retailers in Quebec, Canada (8). This suggests that such a ban may not have an immediate impact and highlights the need for further research.

There is no evidence on the reach of this FLM to the population. However, conceptually, a comprehensive ban on incentives to all points of sales and digital marketing outlets would be felt among the majority of the population, reducing exposure to products and marketing cues.

It could be argued that adopting this FLM would significantly reduce the positive aspects of the relationship of retailers to the tobacco industry – less incentive and gains, the less the linkage. Tobacco company contract components impact the retail environment in ways that may increase tobacco purchases and use (4). Specifically, buydowns and volume discounts facilitate tobacco price reduction (20, 30) while slotting fees, product placement, and promotion increase tobacco product visibility and marketing (19, 21, 29). Implementation of this FLM could potentially reduce the political support that retailers have provided to the industry and disrupt systems that perpetuate and entrench tobacco use.

Banning tobacco industry incentives to retailers could result in decreased display/signage for tobacco products and potentially begin to weaken relationships between retailers and the tobacco industry. Beyond that, this measure does not appreciably disrupt governmental/societal systems that perpetuate and entrench tobacco use.

However, this FLM would have a higher potential for disrupting such systems if some complementary measures are strictly applied: 1) requirements for tobacco companies to publicly and transparently report any tobacco retailer incentive contracts; 2) implementation of WHO FCTC Article 5.3 measures to prevent tobacco industry interference; and 3) increasing capacity for effective monitoring and enforcement capacity, with high financial penalties for violations.

As an example of how a stricter application of these complementary measures can increase potential of banning tobacco retailer incentives for disrupting systems, the WHO FCTC Report on Tobacco Advertising, Promotion and Sponsorship (43) noted that for "disclosure of expenditures on TAPS by the tobacco industry", where Canadian legislation requires tobacco companies to report on their promotional expenditures "Canada requires highly detailed semi-annual reports describing tobacco industry promotional activities. Article 16 outlines reporting requirements for promotional activities, Article 17 information on advertisements, Article 18 on sponsorship, Article 19 on permanent facilities, Article 20 on packaging, Article 21 on services, Article 22 on display at retail, Article 23 on accessories and Article 24 on other products. For example, the tobacco manufacturer has to report on where the advertisement was published, the dates it was published, the cost and to provide a copy of the advertisement." (44) However, such mandated reporting is rare and the detailed information contained is rarely made publicly available, limiting its utility (41).

As many countries have adopted only some form of ban on incentives to retailers, it is unclear which/how outcomes of such partial bans would be measured. There are many marketing strategies that potentially fall under such a ban that governments may still not be fully aware of, creating loopholes that enable tobacco industry shifting of its retail incentive schemes in response to these partial restrictions (45). TAPS policies should not allow business-to-business loopholes that permit retailer incentives. Banning incentives to retailers, if effectively and comprehensively enforced, could begin the process of weakening ties between industry and individual retailers.

Awareness and profile of the FLM as a potentially promising intervention

Most people, including policy-makers, are unaware of these tobacco retailer incentives, which are privately negotiated contracts with retailers (4). There is little evidence that such contracts "are publicly acknowledged and use mobile technology to promote brand loyalty (46)."

There is little global awareness of this FLM – at least as a comprehensive ban on incentives to tobacco retailers and not in its various partial forms – and limited reports exist on whether banning all types of tobacco retailer incentives are included in agendas of governments and stakeholders (4, 8, 24, 33, 35, 36).

In the United States, some governments can form contracts with retailers in the form of "Assurances of Voluntary Compliance", which are agreements between corporate retailers and state attorney generals. These government agreements act as legal contracts and may include clauses aimed at reducing tobacco product marketing exposure. Unlike many tobacco marketing regulations in the United States, these agreements are not subject to the same First Amendment protections. Limited research shows that "Assurances of Voluntary Compliance" agreements/contracts can successfully decrease access to tobacco products and advertising, but they need to be rigorously enforced to be effective (47,48). Such government contracts may be a practical counter-tactic in countries with free market systems or those that have lengthy policymaking processes. Also, the United States Federal Trade Commission defines the tobacco industry price-related marketing activities for smokeless tobacco products in the United States and the reporting of related marketing expenditures is required by the United States federal legislation (41).

In the European Union, some Member States have adopted measures that prohibit "the use and communication of sales promotion, such as a discount, a free gift, a premium or an opportunity to participate in a promotional contest or game (41)." Similarly, available data suggest there is some awareness of the potential impact of this FLM, as reflected in the implementation of a ban on the use of voucher schemes in the United Kingdom (41), and bans on promotional discounts and free distribution in many LMICs (37).

Retailer incentives are highlighted in tobacco marketing literature, reports and FCTC reporting routinely, although it is not often called out as a specific measure by itself.

Implementation considerations specific to this FLM

In response to tobacco marketing restrictions, tobacco companies in the United States now allocate 97% of their marketing budget – approximately US\$ 8.6 billion annually – to saturate convenience stores, gas stations, and other retail locations with incentives and reminders to purchase their addictive products. These companies pay retailers to ensure that tobacco products are heavily advertised, prominently displayed, and priced attractively to appeal to both young people and current users. Consequently, convenience stores have become allies of the tobacco industry, actively opposing restrictions on flavoured tobacco sales, higher tobacco taxes and other public policies that have been shown to reduce tobacco use (49). Thus, the comprehensive implementation of this FLM could challenge the current alliance between tobacco manufacturers and retailers, as the two work together to undermine tobacco control policy efforts and undermine equity (4, 49).

McDaniel et al. recommend policies without exemptions as clearer, easier to justify, enforce, and defend legally (50). For example, despite the fact that the United Kingdom Tobacco Advertising and Promotions Act bans the use of voucher schemes and direct consumer communication, recent evidence indicates that tobacco companies still provide display cabinets and incentives for displaying their products (13). The use of price-based marketing has also increased following full implementation of the legislation in the United Kingdom (42).

On the basis of the above-mentioned barriers, there may be major potential challenges to adopting this FLM. However, it could be argued that barriers can be overcome, especially as Article 13 has good traction globally.

There may be some potential negative consequences of this FLM if implemented in a partial, non-comprehensive form. Therefore, any policy that includes exemptions or exceptions should be drafted carefully to prevent retailers from exploiting them as loopholes. The way tobacco advertising and promotion is defined in legislation is often one of the barriers to ending incentives, as "business-to-business" marketing is exempt or falls outside of narrow definitions.

Case studies

In the United States, some states have begun tightening regulations on discounting practices that were previously allowed under their cigarette and tobacco pricing laws. For example, in 2000, New York clarified its Cigarette Marketing Standards Act, stating that trade discount allowances for stamping agents, wholesalers, and retailers do not encompass buydowns or master-type programmes, as these incentive schemes do not deduct applicable rebates from the manufacturer's invoice; rather, they provide credits for these sales separately. Similarly, Massachusetts's pricing law prohibits any discounts that bring the retail price below the statutory minimum, including coupons and multi-pack discounts (51). In addition to state regulations, several municipalities have enacted laws to reduce the impact of price promotions on cigarette sales. In 2013, a city in Rhode Island

passed a law that prohibits the redemption of coupons and multi-pack deals that lower prices below cost. In 2014, New York City introduced a hybrid pricing formula for cigarettes and little cigars, which retains the state-level wholesaler mark-up while setting the retailer mark-up to a fixed dollar amount (US\$ 10.5 per pack). Both municipalities were successful in defending their laws against tobacco industry legal challenges (51).

As detailed earlier, one of the few examples of restriction on incentives from tobacco manufacturers to retailers was legislated in Quebec, Canada, in 2015. This restriction, as part of the Tobacco Control Act, prevents manufacturers from providing price-related incentives to retailers (8, 52).

Summary

Tobacco companies use retailer incentive programmes to gain preferential placement, pricing and promotional targeting, undermining tobacco control and minimum price laws. These incentives contribute to increased tobacco consumption, exposure to marketing and impulse purchases. Banning such incentives aligns with WHO FCTC Article 13 and its guidelines, but only a few countries have enacted such bans, and there is limited research on their effectiveness to date. Comprehensive bans could disrupt the tobacco industry's marketing strategies, but their success depends on strong enforcement and preventing industry adaptations.

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Appendix

Fig. A1. Examples of the 4 Ps in contracts between manufacturers and retailers. Excerpts are exact quotes from two tobacco contracts: RAI Trade Marketing Services (RAITMS) Retail Partners Marketing Plan Contract and Philip Morris USA Retail Leaders Program Agreement. The plan-o-gram in the Philip Morris 2015 Retail Leaders Program Agreement was blank and thus replaced with a completed RJ Reynolds plan-o-gram from 2002.

Tobacco industry contract excerpts demonstrating the 4Ps of tobacco retail marketing:

P Placement, P Promotion, P Price, and P Product

Placement

PHILIP MORRIS USA INC. 2015 RETAIL LEADERS PROGRAM AGREEMENT (Fixture Plan)

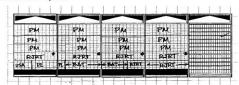
2015 Retail Leaders Program Form of Plan-O-Gram

Retailer agrees to merchandise PM USA products and PM USA Cigarette Signs in accordance with the requirements of this Agreement. With respect to a Store participating in the Fixture Plan, Retailer understands and agrees that certain requirements are illustrated in this Plan-O-Gram. Retailer is solely responsible for full compliance with the terms and conditions of this Agreement, including this Plan-O-Gram. In the event of a conflict between the Plan-O-Gram and the terms and conditions of the Agreement, the terms and conditions of the Agreement will control.

PM USA Share (expressed as a percentage) means the greater of:

- PM USA's share, for a period of time designated by PM USA, of the aggregate cigarette purchases (as reported in STARS) by the Store, or, for any Store that is part of a Chain, all Stores associated with such Store's AGDC management account number=__%; or
- PM USA's share, for a period of time designated by PM USA, of the aggregate cigarette purchases (as reported in STARS) by all AGDC Workload stores in the zip codes of the AGDC sales territory in which the Store is located, or if the Store is part of a Chain, by all AGDC Workload stores in the zip codes in which any Store associated with such Store's AGDC management account number is located =

PCMA Fixture Layout



PHILIP MORRIS USA INC. 2015 RETAIL LEADERS PROGRAM AGREEMENT (Fixture Plan)

Choice Level and Premium Level Requirements

By choosing to participate in the Program at a particular Participation Level with respect to one or more Stores, Retailer agrees that such Stores will comply with the merchandising, signage, and other requirements applicable to that Participation Level, as set forth below. Retailer may not participate in a Display Plan with respect to a Store that is eligible to participate in a Fixture Plan.

1. Merchandising Requirements

A. General Requirements.
 (1) All cigarette and PM USA product merchandising and sales in a Store must be NSS.

(2) All PM USA cigarettes in a Store must be merchandised such that they are clearly visible and proximate to adult tobacco

(3) All space designated to merchandise front-facing cigarette packs in a PM USA Display must be occupied by front-facing PM USA cigarette packs.

(4) Each PM USA Display must visibly merchandise at least six contiguous front facings of PM USA cigarette packs.

(5) In no event may there be more than three PM USA Displays or three PM USA Cigarette

B. Choice Level Requirements. Each Store must (a) display at least one PM USA Interior Cigarette Sign or (b) merchandise PM USA Cigarettes on at least one PM USA Display.

C. Premium Level Requirements. Each Store must (a) display at least one PM USA Interior Cigarette Sign and (b) merchandise PM USA Cigarettes on at least one PM USA Display or one Industry Display.

Price

RAI TRADE MARKETING SERVICES COMPANY ("RAITMS") RETAIL PARTNERS MARKETING PLAN CONTRACT 2017 MENTHOL OUTLET PLAN - AMENDED 04/02/2018

Consumer Pricing Fairness Program (Applicable to all Contracts)

- · Retailer must comply with all provisions of the Consumer Pricing Fairness Program ("CPF Program").
- · Retailer will maintain prominent and accurate pricing communication on and off the merchandising set as determined by RAITMS.

 Retailer will not engage in deceptive or misleading price communications.
- · Retailer will ensure that the price charged to consumers is not greater than communicated
- · Retailer will prominently and accurately communicate prices on all discounted (off-invoice and/or retail discounts) and/or otherwise promoted brand styles.
- · The ability to advertise price for the Products will be no less than
- parity with other tobacco companies.
 Retailer will perform price changeovers, and execute all pricing changes at the beginning date of all price promotion timeframes, as determined by RAITMS.
- · RAITMS may offer price reductions or promotions to meet reductions or promotions made by competitors. [...]
- Retailer shall price all RAITMS tobacco products competitively with other tobacco products.
- · Retailer must pass through to purchasers no less than the full amount of all RAITMS discounting (whether provided by RAITMS through monthly or pulse discounting). Retailer must pass through the discounting regardless of unit configurations (e.g. packs, multi-pack specials, cartons, tins, sleeves) or loyalty/frequent shopper programs. Retailer must apply the discounting on a product by product, brand style-by-brand style, outlet-by-outlet, value-by-value basis.

Product

RAI TRADE MARKETING SERVICES COMPANY ("RAITMS") RETAIL PARTNERS MARKETING PLAN CONTRACT 2017 MENTHOL OUTLET PLAN - AMENDED 04/02/2018

Base Requirements (Applicable to all Contracts)

- Outlet or account average Cartons Per Week (CPW) of the Products must be 5 CPW or greater. In the states of New Jersey and New York, the CPW of the Products must be 2 CPW or greater.
- Outlet must have a menthol share of market of 50% or greater.
- The Products, and displays and signage for the Products, will be maintained in a highly visible, primary line of sight position, and must occupy the #1 position as defined by RAITMS. If Philip Morris USA (PM USA) has a Retail Leaders Program in the outlet, RAITMS may occupy the #2 position as defined by RAITMS.
- · Retailer will carry and maintain ongoing availability of brands and styles of the Products in all price tiers as requested by RAITMS
- · Retailer will accept product force outs for new brand introductions and/or promotions.
- Retailer will merchandise and offer for sale single packs of cigarettes in each of its outlets. The by-the-pack offerings for RJRT and/or SFNTC cigarettes will include a variety and quantity of brand styles in all price tiers adequate to satisfy local market demand.

General Merchandising/Presence Requirements (Applicable to all Contracts)

- Retailer will provide the space required for RAITMS distribution needs both on and off the primary merchandising fixture. RAITMS total contracted space must be sufficient in size to maintain no less than 1.5 weeks inventory of designated brand styles of the Products.
- · Retailer will provide sufficient space to allow a minimum of one tagged merchandising slot for each brand style of the Products as designated by RAITMS.
- · Retailer will maintain an adequate inventory of required brand styles and will accept new items as requested by RAITMS.

Source: Reimold et al., 2023 (4)

(iii) Price controls for tobacco products and devices ("minimum price policies")

Abstract

Policy description and background. Setting a minimum price for tobacco products aims to reduce tobacco consumption by making products less affordable. These policies set minimum prices for all tobacco products, including, when feasible, heated tobacco product devices that support tobacco use. Products cannot be below the set minimum prices, which limits the ability of tobacco companies to offer low-priced options through price manipulation. While minimum price policies have been implemented in the majority of states across the United States, Brazil, and Pakistan, and are under consideration in Scotland (United Kingdom of Great Britain and Northern Ireland), there is limited adoption of these measures globally. Such policies serve as a complementary measure in combination with tax increases, and are an alternative that could be considered in contexts where raising taxes on tobacco products and devices may be legally or politically challenging.

Minimum price policies can increase the impact of implementing WHO FCTC measures related to both the demand and supply of tobacco products, such as those under Article 6 calling for price and tax measures to reduce the demand for tobacco; Article 11 providing for measures on packaging and labelling of tobacco products; Article 13 in respect of tobacco advertising, promotion and sponsorship; Article 14 in respect of demand reduction measures concerning tobacco dependence and cessation; and Article 16 on measures related to sales to and by minors.

Evidence of impact. Modelling studies suggest that higher minimum prices for cigarettes could decrease smoking rates, especially among people on low incomes who smoke.

Benefits and strengths. A minimum price policy would prevent tobacco companies from reducing prices on lower-cost brands to undermine tobacco excise tax increases. This would ensure that the lowest-price brands that are often purchased by people on low incomes and subpopulations experiencing vulnerability are not excluded, thereby helping to reduce tobacco use prevalence among these groups.

Implementation considerations. To be effective, strict penalties for non-compliance, careful consideration of the policies' potential impact on widening health inequities in underserved communities, regular adjustments for annual inflation and real income growth (to ensure that the impact of the policies is not reduced over time), and implementation of the policies along with other tobacco control measures – including raising excise taxes, minimum pack sizes, bans on promotions and free cessation services – should be considered, with tax increases being the most essential to pair with minimum price policies.

Conclusion. Minimum price policies can complement existing tobacco control efforts by making tobacco products less affordable, and thus less appealing to consumers, especially for price-sensitive populations. The effectiveness of minimum price policies depends on the design of schemes and the legal context within a jurisdiction. Regulators can avoid pitfalls through careful crafting and implementation of laws. A comprehensive strategy that prioritizes regular excise tax increases adjusted to inflation and real income growth, in combination with minimum price laws applied to tobacco products and devices with other tobacco control measures, would be most effective for curbing tobacco use.

Description of the intervention

Making tobacco products less affordable may deincentivize people, especially price-sensitive populations like adolescents and vulnerable groups, to start or to continue using tobacco products (1). A policy that sets a minimum sales price for tobacco products ensures that they cannot be sold below that price, and prevents tobacco companies from shifting prices to continue providing

consumers with low-priced products (1). Laws for this policy should set a floor price for tobacco products and devices that support tobacco use that is consistently higher than the existing free-market price(s). Ideally, this minimum price policy would be regularly adjusted for annual inflation and for increases in real income, to ensure that the impact of the policy would not be reduced over time (2). These price control measures are also an alternative approach for jurisdictions where increasing taxes on tobacco products and devices may not be legally or politically feasible (3). Minimum price policies can complement existing tobacco control efforts by making tobacco products more expensive, thus less desirable for purchase and consumption – interrupting the supply chain (4). Additionally, minimum price policies can increase the impact of implementing other measures of the WHO FCTC related to both the demand and supply of tobacco products, such as those of Articles 6, 11, 13, 14 and 16 (5, 6).

Availability of information/research evidence on the potential impact of the FLM

Requirements of an effective minimum price policy and its potential impact

Studies from the United States , where minimum price policies for tobacco products have been implemented in at least half of the states, suggest that minimum price policies can complement existing tobacco control efforts by making tobacco products more expensive (4). For instance, coupling the following four strategies with minimum price policies may enhance their impact: applying minimum price policies for all tobacco products and devices; pairing minimum price policies with minimum pack sizes; prohibiting promotions like the redemption of coupons and price discounts (3,7); and pairing minimum price policies with free cessation services (8). If the first three complementary strategies are applied in conjunction with raising excise taxes, this could restrict the ability of the tobacco industry ability to weaken the impact of higher excise taxes upon consumer prices (7).

Research shows that raising tobacco prices significantly reduces tobacco consumption and prevalence, smoking initiation among youth, socioeconomic disparities in smoking, tobacco-related diseases and deaths, and health-care costs and productivity losses, and it also promotes smoking cessation (3). Minimum price policies may be used to increase the price of tobacco products, which could offset tobacco industry price manipulation, provide an opportunity to set floor prices for different tobacco products to avoid product shifting, and reduce income-, racial- and geographicalbased disparities in smoking rates (3). To date, no studies have evaluated the actual impact of a minimum price policy in the United States. A modelling study estimated that a minimum price of US\$ 10 per cigarette pack would reduce cigarette sales by 5.7 billion packs annually, and result in 10 million people quitting smoking (9). The research literature suggests that price controls are generally very difficult to implement and criticized by economists because the tobacco industry can undermine these measures by reducing tax pass-through or providing coupons to consumers and discounts to retailers. However, when a minimum floor price is set high enough, it can effectively eliminate discount brands altogether. Hence, minimum price policies are likely to have the greatest impact on people who smoke who are particularly price sensitive or have limited incomes because such policies would raise the price for the lowest-price products, which are more likely to be used by the lowest resource consumers. This would lead to proportionately greater impact in reducing demand among those who are most greatly harmed by tobacco products and are also more responsive to price (i.e., the price elasticity of demand is greater for these consumers). In this way, minimum price policies would have a positive equity impact (7, 10). Appendix 1 shows the International Agency for Research on Cancer's evaluation of evidence to support tobacco tax policies, including some items on increasing prices (10). However, minimum price policies were not proposed/reviewed explicitly.

Differentials in available evidence by policy, region, and tobacco product type

There is strong global evidence that higher tobacco product prices are associated with lower affordability and reduced consumption (11, 12). However, most existing studies have examined the impact of increasing excise tax, which is only one component of the retail price of tobacco products. Research has also focused on tax increases for cigarettes, with limited studies of non-cigarette tobacco products (13–15). Affordability of tobacco products depends on their price relative to consumer income; thus, a policy that sets a minimum floor price for tobacco products has the potential to reduce the affordability of these products.

To date, the vast majority of studies on the actual and anticipated public health impacts of minimum price policies for tobacco products are from the United States (16). Similar studies from low-and middle-income countries are needed, as research suggests that affordability elasticity is more likely to be observed in countries with initial low- or middle-income rather than in high-income countries (16).

Consumer responses to price/tax increases and the potential role of minimum price policies

Price differentials between tobacco products likely reflect differences in tax policy and structure. For instance, non-cigarette products such as waterpipe tobacco and fine-cut tobacco are generally less expensive than cigarettes, which are more frequently used in the Middle East and Europe, respectively. Nevertheless, wide variations in prices (cigarette prices were lowest in countries in the African Region and highest in countries in the Western Pacific Region) and price differentials (medians for cigarettes were largest in the Eastern Mediterranean and African regions and smallest in the European Region) exist across WHO regions (17). A 2024 systematic review on the effect of tobacco tax increases on price-minimizing tobacco purchasing behaviours reported that lower income and higher nicotine dependence were associated with purchasing lower-priced brands and roll-your-own tobacco, whereas higher income and nicotine dependence were associated with purchasing cartons, large-sized packs and cross-border sales (18). As such, minimum price policies could have an added value in reducing the options for consumers to switch to cheaper tobacco products, thereby encouraging them to quit and increasing the effectiveness of tax policies.

Tobacco industry responses to price/tax increases and the potential role of minimum price policies

Research on how the tobacco industry responds to tax increases through price shifting to ensure lower-priced products is mainly from high-income countries. A 2023 systematic review concluded that the tobacco industry responds to tobacco excise tax policies using similar strategies in high- and low- and middle-income countries. This includes differentially shifting taxes between products; launching new brands/products as pathways for downtrading, product promotions and different prices for the same products for different consumers; price smoothing; and changing product attributes such as length/size of cigarettes or production processes (19). For instance, producers/importers of tobacco products in Sweden are required to set a retail price for tobacco products annually, and that set price is used to calculate the excise tax, even if the product is sold at a lower price. Moreover, retailers are obliged to pay additional excise taxes if they sell the product at a higher price (20).

Awareness and profile of the FLM as a potentially promising intervention

To date, minimum pricing regulations for tobacco have been implemented in several high-income countries. In the United States, at least half of the states have implemented some form of minimum price policies (3, 8, 21). These state-level policies were introduced between the 1940s and 1960s to

protect businesses rather than public health (10). For example, a majority of minimum pricing rules in the United States permit cigarette companies to include promotional incentives — such as buy-downs and Retail Leaders Programmes — when calculating the minimum price (10). A small number of European Union Member States (such as Austria, France, Italy, Belgium and Ireland) have also adopted minimum pricing regulations to safeguard retailers (10). One exception is New Zealand, where the public health sector advocated making smoked tobacco products less affordable through continued above-inflation tobacco excise increases and introducing a minimum price for tobacco products (22).

In other high-income countries, minimum price policies have been proposed as an agenda within public health groups, but those policies did not move to the next level of governmental endorsement. In Europe, the Joint Action on Tobacco Control 2 project outlined best practices to develop effective tobacco endgame strategies, including tobacco taxation and price policies. There was no specific focus on minimum price policies, but the document included a mention of uniform pricing strategies across the European Union: "Increase the intersectoral initiatives to raise the price of tobacco products, increase tobacco prices at the same level all EU around, and similar." (23) In Canada, Health Canada's Tobacco Control Directorate consulted tobacco control experts representing governmental organizations, academia, and civil society to determine what measures Parties to the WHO FCTC have implemented, or could implement, that go beyond the WHO FCTC and its guidelines (24). Measures that were deemed implicit in the WHO FCTC and its guidelines by the informal consultations were pricing measures that would require government approval to maintain high prices that are synchronized with taxes and updated annually, citing exemplary countries that have implemented this strategy (France, Brazil and Japan). These price policies did not include minimum pricing policies, but mentioned standardized pricing, ending promotional pricing and official price lists (24, 25). Participants in the 2016 Summit on Tobacco Endgame for Canada did not reach a consensus on imposing a minimum price policy. Some felt that this policy would create revenues to the industry, versus taxes that create revenues to the government. Others pointed out that minimum price policies drive up prices at the low end of the market producing the largest reduction in prevalence among people with low income who smoke. Therefore, combining an increase in minimum price with a tax increase results in a price increase that affects all smokers (26).

Similarly, tobacco control experts in the United Kingdom expressed strong support for increased prices (with no explicit reference to minimum price policies), and price capping schemes to ensure that tax increases begin to reduce industry profits (27). Minimum price policies for tobacco are being considered in Scotland as a part of its strategy to achieve tobacco-free generation by 2034 (28). A 2024 Public Health Scotland report estimated that a 60 pence minimum price per stick would raise the price of all hand-rolling tobacco and the price of the cheapest factory-made cigarettes, resulting in an estimated 16 327 fewer people who smoke. Implementation of minimum pricing for tobacco products in Scotland alongside excise tax increases introduced by the Government of the United Kingdom would ensure that the tobacco industry cannot keep tobacco products below the minimum price on the market, and reduce the likelihood that people continue smoking by switching to cheaper products (29).

Minimum pricing policies have also been implemented in several low- and middle-income countries. In Malaysia, a minimum price law on prices of licit and illicit cigarette brands was introduced in 2011 to reduce cigarette purchases among children and people on low-incomes who smoke, alongside a ban on terms that imply discounts or cheap sales (30). Following the enactment of the law, the percentage of legal brand cigarette purchases priced below the inflation-adjusted minimum price

set in 2011 significantly decreased, while the average real price of illegal cigarettes stayed the same. This underscores the complicating effect of the high availability of illicit products on accurately evaluating the minimum price law. These findings suggest that addressing the illicit cigarette trade is essential before a comprehensive assessment of the minimum price law impact on public health can be conducted (30). In Indonesia, excise regulations prohibit companies from launching brands at prices lower than the lowest market price for the current year, a minimum that has been consistently raised through regulation. This prevents a fall in the lowest prices in the market (31). This approach, however, may complicate efforts to raise excise taxes as it adds the burden of advocating for increases in both tax rates and minimum retail prices.

In Pakistan, the federal Government sets minimum and maximum price limits for the sale of domestic tobacco products (32). However, evidence suggests cigarette packs continue to be sold below the legal minimum retail price. For example, a 2023 study found that 18% and 27% of people who smoke reported purchasing cigarette packs below the minimum price in 2021–2022 and 2023–2024, respectively (33). This likely reflects tax evasion by legal manufacturers, and the Government of Pakistan is working to address this issue through a track and trace system.

In Brazil, minimum price policies for cigarettes were implemented in combination with specific excise tax increases in 2011, which led to reductions in smoking prevalence and increased tobacco tax revenue between 2011 and 2014. Since 2016, however, cigarette minimum prices and specific excise taxes have not been adjusted. This has resulted in reductions in the real minimum price reductions between 2016 and 2019 and created opportunities for cheaper brands that often are marketed to vulnerable populations (34). Cigarette minimum prices were recently increased in 2025, and further research is needed to monitor its impact.

Public support for implementing minimum price policies was not explicitly measured in any of these high-income settings. In New Zealand, one study reported public support for other measures to make smoked tobacco products less affordable within the context of the country's smokefree 2025 goal, but not specifically for minimum price policies. Only a quarter of participants reported support for proposals to increase tobacco excise taxes or uniform tobacco products taxation, but public support increased to 60% if the additional revenue was used to promote healthy lifestyles and cessation services (22). It is important to note that minimum price policies alone will not effectively increase revenue and decrease tobacco consumption – they must be paired with tax increases to achieve the intended impact. Indeed, if tax increases are not appropriately integrated into a minimum price policy, the policy will lead to increased profits for the tobacco industry. A properly configured increase in tax policy will reduce that consequence (refer to information brief on Measures to Reduce Tobacco Supplier Profits and Pricing Power for further details).

The reach of minimum price policies for tobacco products depends on how they are structured, the jurisdiction law environment, and whether local governments could be prohibited from enacting certain types of tobacco pricing policies. In the United States, 31 states regulate the price of cigarettes through pricing laws as of 2015. However, only seven states apply pricing laws to some form of non-cigarette tobacco products, with the majority applying the same pricing laws to both cigarettes and non-cigarette tobacco products. Two states (New York and Rhode Island) use a more stringent "minimum markup" scheme to set prices on cigarettes (requires distributors to apply a markup percentage to the base cost of the product, which is often applied at multiple levels of the distribution chain, leading to increased consumer prices), in contrast to a less effective "minimum pricing" scheme to establish prices on non-cigarette tobacco products (sets a floor price based on product cost without requiring distributors to apply a specific markup percentage to the base cost of the product, with limited guidance on definitions of product cost, application of taxes and

regulation of discounts). While most states in the United States apply their pricing laws to multiple tobacco products, Massachusetts and Pennsylvania only apply their non-cigarette tobacco products pricing laws to little cigars (35).

To date, no studies have evaluated the population-level reach of minimum price policies that have been implemented in the United States. However, analysis of existing policy strategies to regulate the tobacco product prices suggests that if enforcement of such policies is not equitably applied, underserved communities could be disproportionately targeted by tobacco industry tactics. Thus, if strong minimum price laws are implemented in conjunction with other complementary tobacco price raising policies, their impact could potentially reach all tobacco purchasers, as well as their families, with more favourable impacts on those from low-income populations and subpopulations experiencing vulnerability (2).

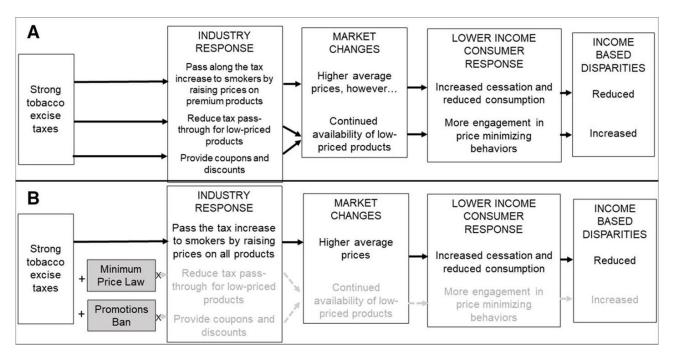
The strength of minimum price policies in terms of the effect size of their implementation on target outcomes among general and specific populations depends on the level of price and price sensitivity of these populations. Projections from modelling studies in the United States suggest that minimum price policies could reduce income-based cigarette smoking variations more effectively than excise taxes, producing larger reductions in consumption among people with low-income who smoke (21). For instance, models predict that the short-term (at 12 months after implementation) effects of minimum price policies as high as US\$ 9.50 per cigarette pack in California, a 25% increase in the average pack price of US\$ 7.63 at the time of the simulation, would result in a 4.6% and 4.0% reduction in smoking prevalence among those in low-income and higher-income households, respectively (36). However, a modelling study in the United States suggests that the impact of a minimum price requirement could vary significantly, ranging from a minimal effect at the US\$ 4.00 level to a reduction of 5.7 billion packs in annual sales and a reduction of 10 million smokers at the US\$ 10.00 level. Annual state-level data were used to model per capita cigarette sales in relation to price, allowing a comparison of current sales with hypothetical scenarios involving a federal minimum price, ranging from US\$ 0 to US\$ 12. Findings showed that a federal minimum price policy could substantially advance tobacco control and public health by uniformly raising cigarette prices and eliminating many of the current price-reducing tactics available to both sellers and consumers (9). Additionally, minimum price policies can prevent price manipulation and reduce tobacco industry targeting of people of colour, women and school-age residents (37–39).

Evidence on the population-level impact of minimum price policies remains restricted to cigarettes and hypothetical simulations, even in the United States, where more than half of the states have established minimum price laws for cigarettes and other smoked and smokeless tobacco products. The same evidence indicating that raising tobacco taxes effectively reduces tobacco use at the population level by discouraging initiation, encouraging cessation, and lowering overall consumption also suggests that minimum floor price laws could similarly decrease tobacco use (12).

Although applying minimum price policies could limit the tobacco industry's ability to shift prices, systems that perpetuate and entrench tobacco use would remain basically unchanged. Evidence from the United States shows that existing state-level tax increases have failed to increase the retail price, despite the adoption of minimum price policies based on price "mark-ups" defined by the state over the invoice price. A 2024 study analysed three new variations of minimum price policies that could more effectively raise tobacco prices and reduce consumption. These variations include "a flat rate minimum price law similar to a recent enactment in New York City, an enhanced markup law, and a law that incorporates both elements" (2). Findings showed that a well-crafted and thorough minimum price law that: a) significantly raises tobacco prices; b) prohibits discounting strategies; and c) is periodically revised to minimize loopholes could tackle some of the political and

practical issues associated with current price-related policies. A flat rate law offers notable benefits for implementation and enforcement and may drive price discount brands out of the market. For states with suitable enforcement mechanisms, a hybrid approach could be even more effective for preventing tobacco product experimentation among youth, and increasing quitting among people who smoke (2). Ribisl et al., 2022 propose that a more comprehensive pricing policy combining: a) regular, large increases in specific excise taxes; b) minimum pricing policies; and c) bans on coupons and promotions could eliminate the persistence of lower-priced products in the face of tax increases (7) (see Fig. 1).

Fig. 1. Proposed mechanisms of how tobacco excise taxes influence income-based disparities (A) and the potential impact of a comprehensive three-pronged pricing approach (B).



Source: Ribisl et al., 2022 (7)

To be effective at the population-level, minimum price policies should cover different types of tobacco products and devices in order to discourage people who use tobacco from substituting to cheaper alternatives.

A 2018 study reported that cigarette minimum price laws in states in the United States have not led to increases in cigarette retail prices. At the time of study, only New York City had implemented a minimum floor price policy, making it difficult to evaluate its benefits compared to excise taxes. To address this, the researchers developed several potential state minimum floor price options and compared them to state excise tax increases that would produce similar average price increases. Using self-reported price and cigarette consumption data from 23 521 participants, setting minimum price laws at the average reported pack price was projected to increase prices by US\$ 0.30 and reduce cigarette consumption by about 4.0%. In comparison, a tax with a similar price effect would reduce consumption by 2.3%. Minimum price policies and taxes that raise average prices by more than US\$ 2.00 would decrease consumption by 15.9% in low-income and 13.5% in high-income groups. These findings demonstrate that minimum price policies would have a greater impact on reducing income-related smoking disparities than comparable excise tax increases. It concluded that

setting minimum cigarette prices at or above current consumer prices could help lower overall tobacco use and reduce socioeconomic gaps in smoking (21).

Modelling studies from California in the United States suggest that minimum floor price laws may be effective for reducing socioeconomic disparities in cigarette smoking prevalence and increasing cigarette prices. For example, a 2020 study that modelled the effects of minimum floor price laws on smoking behaviours among adults, and cigarette prices showed that as the floor price increased from US\$ 7.00 to US\$ 9.50, the predicted changes in prices, prevalence and consumption increased exponentially. The simulation was done among 300 000 individuals based on race and ethnicity, sex, age and poverty status in California. The projected increases in average cigarette prices ranged from US\$ 0.2 to US\$ 1.60, assuming 15% policy avoidance. The reduction in smoking prevalence ranged from 0.1 to 0.4 percentage points, and reduction in average monthly cigarette consumption ranged from 1.4 to 12.3 cigarettes. Projected prices rose, and both prevalence and consumption declined more significantly among individuals in households earning less than 250% of the federal poverty level, indicating that minimum floor price laws have the potential to reduce socioeconomic disparities in cigarette smoking prevalence and consumption, especially for lower-income tobacco users (36). A 2021 study projected that setting minimum floor prices between US\$ 8.00 and US\$ 13.00 per pack in Oakland, California, in the United States, and assuming a 15% rate of policy evasion, would lead to a projected increase in the average price paid per pack by US\$ 1.10 to US\$ 4.70. This was expected to lead to a reduction in cigarette smoking prevalence by 0.3% to 0.8%, and a decrease in smoking intensity by 0.7% to 2.0% among people who smoke. The total number of cigarettes smoked per month was projected to fall by 246 000 to 734 000 cigarettes, representing a 3.0% to 9.0% reduction from the current level of 8.2 million cigarettes. The most significant reductions in cigarette smoking prevalence were projected for individuals aged 12 to 24, those of non-Hispanic Black or other racial/ethnic backgrounds, and those living below the federal poverty level (40).

The broader economic literature outlines two primary reasons for establishing minimum prices: 1) to enable collusion (price fixing) among firms by preventing price wars; and 2) to help sustain profit margins, which provides necessary funds for marketing. As a result, most tobacco minimum pricing regulations are designed to protect businesses rather than public health. However, these minimum prices can also be employed for public health goals – such as discouraging low-cost selling by existing firms and blocking new entrants with cheaper offers – and several countries have implemented such measures for this purpose (10).

It is important for minimum price policies to be formulated so that multiple packs are also subject to the same minimum price per stick. New York City's minimum price law on cigars originally applied only to single cigars, which led to a significant impact on price of just single cigars, but not on four-packs. Indeed, the price of four-packs, which had before the single-cigar law been close to four times the price of single cigarettes (see the Pre Aug 2014 section of Fig. 2), were now priced even lower than before shown in the Post Aug 2014 section of Fig. 2. Consequently, consumers could simply purchase four-packs at a significantly lower price per cigar, thereby completely avoiding the minimum price law on single cigars. After New York City strengthened its minimum price law to include four-packs of cigars, there was a significant increase in price of these packs, as reflected in the Post-Jun 2018 section of Fig. 2, when the four-pack price was more commensurate with the minimum price for singles, although still not entirely so (37).

Center for Tobacco Studies Rutgers School of Public Health NYC cigar prices before/after 4-pack law, and with minimum price law Single Cigar and Cigar 4-Packs Prices from 2013 to 2018 \$13.25* 10 \$8.25 \$8* \$7.5 \$5.25 \$2.25 Pre Aug 2014 Post Aug 2014 Post Jun 2018

Fig. 22. New York City cigar prices before/after four-pack law, and with minimum price law.

Source: Schroth, 2019 (41)

It should be noted, however, that this New York City study did not measure the impact of the minimum price law on consumption, prevalence, and cessation rates (41).

■ Single Cigar ■ 4-Pack

*Indicates minimum price; average retail price is not available.

Implementation considerations specific to this FLM

A main challenge to adoption of minimum price policies is the use of price promotions and discounting mechanisms by the tobacco industry to keep lower-priced products on the market, encouraging both retailers and consumers to continue purchasing tobacco products. People who smoke and do not quit following a price increase might switch to cheaper brands, buy in bulk, or choose less expensive tobacco products, particularly those who are price-sensitive, such as lower-income individuals. Evidence on such challenges is available from the United States. Although many states mandate that distributors sell tobacco products at a minimum price, these laws often permit various discounting practices that can effectively reduce the statutory minimum. These discount mechanisms (including coupons, combination or multi-pack deals, competitor price matching, trade discounts) can be utilized by both the distributors and the end consumers (35). Regulators could avoid this policy loophole in minimum price laws by prohibiting discounting mechanisms that allow the sale of tobacco products that are below the set price.

A 2020 study (42) analysed tobacco industry documents, state legislation, and court cases from 1987 to 2016 to investigate how tobacco manufacturers sought to alter minimum price laws in the United States. Results showed that tobacco companies have increasingly relied on trade discounts to circumvent other promotional methods with increasing restrictions. From 1940 to 1960 minimum

price laws that prohibited manufacturer promotions were common, but by the time of the study, in most states in the United States, these discounts were legally protected. Starting in 2000, these manufacturers began lobbying to revise minimum price regulations after state regulators ruled that their promotions were illegal under existing laws. Tobacco companies considered changing these laws essential to sustaining their sales, and following an industry lobbying campaign, at least 20 states adjusted their methods for calculating tobacco prices. Revising current minimum price laws to eliminate protections for manufacturer discounts, and implementing new and comprehensive minimum price policies could likely drive up prices and decrease tobacco use (42.) For example, a 2016 study found that pharmacies charged customers less for cigarettes and more for bottled water, compared with other stores. State and local policies aimed at promoting tobacco-free pharmacies would remove a significant source of discounted cigarettes (43).

Carefully crafted laws could avoid these undermining efforts, in line with the WHO FCTC Article 5.3. There is research to suggest that raising excise taxes will be more effective for reducing the availability of lower-priced products on the market, and decreasing income-based smoking disparities, if taxes adjusted to inflation and real income growth are designed to frequently and significantly increase prices for all products, combined with minimum price laws and bans on coupons, discounts and other promotions. Together, these three strategies limit the tobacco industry's ability to diminish the effects of higher excise taxes on consumer prices. Implementation of such a three-pronged strategy would likely overcome many limitations associated with focusing solely on excise tax increases (7, 44). Please refer to the information brief on banning incentives to retailers for further details.

Besides the limitations addressed above, the possibility of a larger black market should be taken into consideration, especially if internet sales controls are not in place. If this is not addressed in the policy and price mechanisms are not applied in a comparable manner across physical purchasing outlets and digital platforms, the consumer's switching behaviour will depend on price mechanisms. To ensure successful implementation of minimum price policies, jurisdictions may consider integrating pricing policies into tobacco retailer licensing laws by requiring compliance with these pricing regulations as a condition for obtaining or renewing a license. Since licensing fees elevate the operational costs for tobacco retailers, they can indirectly increase tobacco product prices. In areas without tobacco retailer licensing, pricing policies can be enacted through a separate law accompanied by a comprehensive enforcement strategy. Regardless of the approach taken, jurisdictions should impose stringent penalties for non-compliance.

Research indicates that underserved communities often face lower tobacco prices and greater tobacco marketing efforts. As a result, residents in these areas might experience more significant price increases when pricing policies are introduced. Nonetheless, these communities typically have the highest rates of tobacco-related illness and death and have been historically targeted by the tobacco industry. When combined with robust cessation resources, pricing strategies could provide substantial benefits to these populations, helping to reduce disparities in tobacco use and improving related health outcomes. While pricing policies can help reduce tobacco-related health disparities, it is crucial to enforce these policies fairly to avoid disproportionately affecting underserved communities. Jurisdictions should evaluate the impact of enforcement on various communities and ensure that neither the policy nor its implementation exacerbates existing inequities or creates new ones. Before implementing any tobacco pricing policy, communities should seek legal support and technical assistance to confirm they have the authority to adopt the policy and that the policy is effectively worded to minimize potential loopholes. For instance, communities should determine

whether their state pre-empts local governments from enacting certain types of tobacco pricing policies (3).

In the United States, proponents of minimum pricing contend that these prices are determined by percentage markups on wholesale prices. In the European Union, most minimum prices are set as a percentage, such as 95% of the weighted average price. As a result, minimum prices will increase alongside manufacturers' prices over time, helping to keep pace with inflation. In contrast, specific excise taxes like those on cigarettes in the United States lose their value as inflation rises. However, this issue can be mitigated when specific taxes are regularly adjusted for inflation and real income growth or when ad valorem taxes (applied to retail price) are additionally imposed, as required in the European Union. Opponents of minimum pricing argue that while excise taxes generate revenue for the government, prices raised through minimum price laws primarily benefit wholesalers and retailers. In this view, minimum prices advantage tobacco sellers rather than funding government programmes. This concern warrants further scrutiny, as minimum pricing policies may leave the industry with additional resources to invest in marketing research and innovative strategies to attract more customers (10).

It is important to prevent tobacco industry interference in formulating and implementing minimum price policies. For instance, in the European Union, Member States that implemented minimum prices on cigarettes – namely Austria, France, Italy, Belgium and Ireland – advocacy came from the ministries of finance due to high ad valorem excise duties and from manufacturers of premium brands, while the retail sector supported the measures because their margins are tied to maximum retail prices set by manufacturers. Only in Ireland was the initiative driven by the Ministry of Health, aiming to prevent price discounts (10).

Jurisdictions should be aware of the overarching treaties and laws governing minimum price policies to avoid negative court rulings and to design compatible price regulations. For example, in March 2010, the European Court of Justice ruled that setting minimum retail prices in Austria, France and Ireland violated European Union treaties, as it restricted producers' and importers' freedom to set prices, distorted competition, and primarily benefited cigarette manufacturers (10). The Court ruled that Member States can prohibit the sale of manufactured tobacco products at prices below the total cost, plus taxes, effectively preventing producers or importers from selling at a loss by absorbing tax impacts. Consequently, Belgium eliminated its minimum pricing rule, and another case was launched in Italy (10).

In summary, the implementation of an effective minimum price policy would require the following considerations:

- Implementation of the policy in combination with additional strategies to enhance its
 effectiveness, such as regular, large increases in specific excise taxes, bans on discounts
 and coupons, and other price-related incentives to consumers that the tobacco
 companies (or wholesalers or retailers) employ to reduce the ultimate selling price.
- Harmonization of policies across all products and widening the scope to cover the rapid development of alternative tobacco products.
- Ensuring that the policy significantly increases the tobacco product price as compared to the pre-policy period.
- Providing cessation services for lower-income people who smoke so that they can quit.

- Ensuring uniform and strong enforcement across physical and digital outlets, including strategies to combat illicit trade.
- Promote cooperation across jurisdictions to prohibit policy avoidance and reduce crossborder shopping.
- Designing minimum price policies that align with existing treaties and laws to ensure that the policies can withstand legal challenges.
- Carefully crafting and periodically revising laws to address emerging tobacco industry countertactics.
- Avoiding legal protection for tobacco manufacturer promotions.
- Prohibiting tobacco manufacturers from providing discounts that lower consumer prices below the legal minimum price.
- Preventing tobacco industry interference and lobbying to change policies and to insert the use of industry-generated language in proposed and enacted legislation.

Case study

Under the 2011 *Imposto sobre Produtos Industrializados* (IPI-Cigarro) tax reform (45), Brazil implemented two specific tax rates and one small ad valorem component for cigarettes, with scheduled annual increases over expected inflation rates. The Executive Branch was also authorized to set a minimum price per pack of cigarettes and increase it annually to adjust for inflation rates. These measures led to significant reductions in tobacco consumption between 2006 and 2014 (46, 47).

Since 2016, however, Brazil has not adjusted tobacco tax rates and minimum prices for cigarettes to account for inflation and income growth. A study using nationally representative 2019 survey data reported an increase in cigarette affordability, the introduction of illicit brands sold at or above minimum legal prices in the cigarette market, and the sale of legal cigarette brands below minimum legal prices (48). Cigarette minimum prices were recently increased in 2025, and further research is needed to monitor its impact.

Findings from Brazil demonstrate that minimum price policies for cigarettes can effectively reduce consumption. However, regular adjustments to both minimum prices and tax rates for inflation, along with strengthened tax administration to improve compliance and curb illicit trade, are essential to ensure sustained progress.

Summary

The minimum price policy for tobacco products aims to reduce consumption by making them less affordable, particularly for more price-sensitive groups like adolescents and people with lower income. It prevents tobacco companies from offering low-priced options, complementing tax increases when they are feasible and providing an alternative when tax increases are not feasible. Evidence suggests that setting higher minimum prices for all tobacco products could reduce rates of tobacco use and prevent substitution to cheaper alternatives, especially among low-income people who smoke. The policy should be regularly adjusted for inflation and real income growth and paired with other strategies such as pack size restrictions, promotion bans and cessation services. However,

challenges like price promotions, industry lobbying and enforcement issues must be carefully managed to avoid exacerbating health inequities.

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Appendix.

Table A1. An evaluation of evidence by the International Agency for Research on Cancer to support tobacco tax policies, including some items on increasing prices.

	Evidence	
Conclusion statement	Sufficient*	Strong
Increases in tobacco excise taxes that increase prices result in a decline in overall tobacco use.	1	
Increases in tobacco excise taxes that increase prices reduce the prevalence of adult tobacco use.		
Increases in tobacco excise taxes that increase prices induce current tobacco users to quit.	10	
increases in tobacco excise taxes that increase prices reduce the prevalence of tobacco use among young people.	10	
Increases in tobacco excise taxes that increase prices reduce the initiation and uptake of tobacco use among young people with a greater impact on the transition to regular use.	8	
Increases in tobacco excise taxes that increase prices lower the consumption of tobacco products among continuing users.	10	
Tobacco use among young people responds more to changes in tobacco product taxes and prices than does tobacco use among adults.	8	
In high-income countries tobacco use among lower-income populations is more responsive to tax and price increases than is tobacco use among higher-income populations.		1
Changes in the relative prices of tobacco products lead to some substitution to the products for which the relative prices have fallen.		1
Tobacco industry price discounting strategies price-reducing marketing activities and lobbying efforts mitigate the impact of tobacco excise tax increases.	1	
Tobacco tax increases that increase prices improve population health.	10	
Higher and more uniform specific excise taxes result in higher tobacco product prices and increase the effectiveness of taxation policies in reducing tobacco use.	8	
Tax avoidance and tax evasion reduce but do not eliminate the public health and revenue impact of tobacco tax increases.	10	
A co-ordinated set of interventions (a set of interventions that includes international collaborations strengthened tax administration increased enforcement and swift severe penalties) reduces illicit trade in tobacco products.		V
Increases in tobacco tax increase tobacco tax revenues.	10	
Increases in tobacco tax do not increase unemployment.	-	10

^{*} Sufficient evidence: an association has been observed between the intervention under consideration and a given effect in studies in which chance bias and confounding can be ruled out with reasonable confidence. The association is highly likely to be causal.

Source: Physicians for a Smoke-Free Canada, Coalition Québécoise pour le Contrôle de Tabac. Canada's cheap cigarettes. Why they are a problem. What can be done about them. [Internet]. 2017. Available from: https://www.smoke-free.ca/pdf 1/2017/CanadasCheapCigarettes-June2017.pdf (25)

[†] Strong evidence: there is consistent evidence of an association but evidence of causality is limited by the fact that chance bias or confounding have not been ruled out with reasonable confidence. However explanations other than causality are unlikely.

(iv) Birthdate-based sales restrictions (BSRs) ("tobacco-free generation")

Abstract

Policy description and background. This policy permanently prohibits sales of some or all tobacco products to persons born on or after a set date, regardless of age. This would have the effect of increasing the age of legal purchase annually, while allowing sales to all current legal purchasers in perpetuity, gradually reducing tobacco uptake and use. The policy was passed in New Zealand (but later rescinded before implementation), the Maldives (in force from 1 November 2025) and in numerous cities in the state of Massachusetts (United States); has been introduced (but not yet implemented) in the United Kingdom; and is under consideration in the state of South Australia and several Canadian provinces. Variations on BSR policies have also been proposed elsewhere, including Australia, Malaysia, the Philippines, Tasmania and three American states.

This FLM aligns with advancing Article 4.2(b) of the WHO FCTC, in particular in respect of measures to prevent the initiation of tobacco products in any form; Article 12, in so far as the measure is accompanied by effective public education; and Article 16, as its focus is on lifelong prevention of tobacco initiation by young people through establishing policies that make it illegal ever to sell tobacco products to those born after the date selected.

Evidence of impact. Modelling studies suggest that the policy could reduce smoking and, if effectively enforced, would lead to a significant reduction in tobacco use. Modelling commissioned by the previous New Zealand Government found that, if well enforced, the policy could halve smoking rates within 15 years. A subsequent analysis projected that a combination of policies, including a BSR policy, would rapidly reduce adult smoking prevalence. However, as a stand-alone policy, a BSR policy would take several decades to affect population health. United Kingdom Government modelling studies estimated that under the policy smoking prevalence would fall from 13% in 2023 to nearly zero by 2050 among people aged 14–30 years, and from 12.7% in 2023 to 1.5% in 2056 among those aged 18 years and over.

Benefits and strengths. The policy is politically appealing as it does not call for immediate changes to the retail environment. It establishes the idea that tobacco is a product too harmful to permit sales to continue indefinitely.

Implementation considerations. Effective, systematic monitoring and enforcement are required, particularly as affected cohorts grow older. The risk of product shifting, particularly among young people, could be mitigated by ensuring that sales of all tobacco and nicotine products are subject to the policy.

Conclusion. A BSR policy, if successfully implemented and enforced — supplementary to other measures under the WHO FCTC — could have the potential to reduce the initiation of use of tobacco products significantly and could thereby eventually contribute to ending the tobacco epidemic. It would have a long-term (in around 30 years) impact on the whole population as the age for legal sales would rise annually. This could eventually close off the pipeline of tobacco users, as the tobacco industry would no longer be able to target younger potential users to become consumers for their business, "replacing" smokers lost to death and disease. However, the policy does not benefit older people who smoke as they are not subject to the policy.

Description of the intervention

"Tobacco-free generation" or "smoke-free generation" policies (henceforth birthdate-based sales restrictions or BSR) permanently prohibit sales of some or all tobacco products to all individuals born on or after a set date, even after they reach full majority age. This would have the effect of annually increasing the age of legal purchase in perpetuity, gradually reducing tobacco uptake and use.

This FLM aligns with advancing Article 4.2(b) of the WHO FCTC, in particular in respect of measures to prevent the initiation of tobacco products in any form; Article 12, in so far as the measure is accompanied by effective public education; and Article 16, as its focus is on lifelong prevention of tobacco initiation by young people through establishing policies that make it illegal ever to sell tobacco products to those born after the date selected.

Availability of information/research evidence on the potential impact of the FLM

The "tobacco-free generation" policy was first proposed by researchers from Singapore in 2010, with the idea of creating an expanding cohort that could never legally be sold tobacco (1). The policy's rationale is that to end the cycle of young people initiation and addiction to tobacco products we must eliminate the notions associated with age-based restrictions that there is a "safe age" to begin using tobacco products, and that tobacco use is part of "coming of age" into adulthood. Proposed as an alternative to minimum-age laws, the policy is theoretically grounded in the mixed evidence on effectiveness of age restrictions, the tobacco industry's longstanding enthusiasm for framing tobacco use as an "adult" activity, and findings suggesting that "young people control" measures may actually inspire reactive defiance among young people and make them more inclined to want to do whatever is age-prohibited (2).

To date, no comprehensive pre-post evaluations of BSR policy impact have been conducted. As with many other forward-looking policies, the evidence must be drawn inferentially from studies of other somewhat similar policies or modelled on the basis of inferential assumptions. Raising the age of purchase for tobacco products to 21 years, or Tobacco 21 (T21) – see evidence brief (v) "Increase in minimum legal age for sales of tobacco products" – while not fully equivalent, is the closest tobacco-related parallel, and research on its effectiveness is mixed. After statewide T21 policies were enacted in California and Hawaii in the United States, monthly cigarette sales volumes dropped when compared with states without such a law (3). An analysis of national survey data in the United States reported that living in an area covered by a T21 policy was associated with an approximately 3.1 percentage point reduction in likelihood of smoking among 18 to 20 year olds (4). A 2024 modelling study suggested that comprehensive enforcement of T21 federal, state and local policies could avert up to 52,000 premature deaths, but noted that enforcement varied widely (5).

Retailer noncompliance is a major barrier to successful implementation of T21 policies. A study of retailer compliance in New Jersey found that underage decoys had their identification checked only 65% of the time, and were able to successfully purchase products in more than 40% of visits (6), and a California study using pre- and post-T21 survey data found similar results regarding purchases by minors and little change in tobacco product use (7). A national study in the United States found that only 17% of grade students in grades 6 to 12 who attempted to buy cigarettes after the policy was in effect nationally were unsuccessful in doing so (8).

BSR, however, is different from T21 and may have potential for de-normalizing tobacco. Berrick (9) draws a parallel with evidence about a different type of policy: motorcycle helmets, which vary in that some jurisdictions mandate all motorcyclists to wear them and some require them only for minors. He notes the findings of a meta-analysis reporting that there is greater compliance with a universal law requiring helmets for all motorcyclists, and less young people defiance compared to age-restricted laws, suggesting that a BSR tobacco policy might have similar effects on young people. It is logical to assume that given strong ongoing enforcement and retailer penalties, such a policy would reduce tobacco use by limiting consumer access to product purchases.

The policy's differential treatment of older tobacco users and those of succeeding cohorts is broadly consistent with other types of "grandfathering" provisions whereby some people or entities may

follow old rules instead of newly enacted ones. For example, many states in the United States changed the legal alcohol drinking age from 18 to 21 in the late 20th century, but those individuals who were already 18 to 20 at the time were "grandfathered" and permitted to continue (10).

There has been a surge of interest in BSR policies in recent years. A "tobacco-free generation" BSR has been enacted and successfully defended against court challenges in Brookline, Massachusetts, in the United States, and passed in at least 15 other Massachusetts communities; a statewide bill has been introduced (as of July 2025) (11). Legislation for a BSR policy was passed by Parliament in the Maldives on 13 May 2025, and will enter into force on 1 November 2025 (12). A BSR bill has been passed by one House of Parliament in the state of South Australia (13) and is currently being assessed by government staff.

New Zealand included a "Smoke-Free Generation" (SFG) BSR in its comprehensive Smokefree 2025 plan (14) (limited to smoked products). That policy, which was to have been accompanied by a comprehensive set of complementary FLMs aimed at achieving a goal of less than 5% daily smoking prevalence for all population groups by 2025, was subsequently repealed in full under a new government in 2024 and never implemented. Efforts continue to pressure the government to re-enact the policies, which are widely supported, including among young people (15, 16).

A BSR policy was introduced in the United Kingdom in 2023 but was not enacted prior to a change in government leadership (17). It has been reintroduced and appears to have public support, with 63% of respondents agreeing with the policy change (18). The United Kingdom policy plan includes smoked products, waterpipe tobacco, cigarette papers and herbal smoking products as subject to the new policy.

Two Canadian provinces also launched public consultations about BSR measures in 2024. Prince Edward Island proposes a BSR policy in conjunction with retail restrictions and expansion of cessation services (19). Newfoundland and Labrador have also launched a public consultation including a BSR policy, T21, and prohibiting vending machine sales (20). The province of British Columbia has started a campaign to promote adoption of the policy in combination with increased cessation support, denicotinization retail reduction, and banning flavoured vaping products (21).

This policy would, in the short term, affect only young people whose date of birth fell after the designated date. Longer term, it would grow to affect the whole population as it has the effect of raising the age for legal sales annually. Modelling commissioned by the New Zealand Government in 2021 found that a well-enforced BSR policy could halve smoking rates within 15 years, with greater health gains for Māori, New Zealand's Indigenous peoples, among whom smoking rates are higher and the population younger (22). Subsequent peer-reviewed published analyses (23) projected that the combination of denicotinization, retail reduction and BSR would rapidly reduce adult smoking prevalence from 31.8% in 2022 to 7.3% in 2025 for Māori, and from 11.8% to 2.7% for non-Māori. Compared with denicotinization and retail reduction as separate policies; however, BSR alone would avert far fewer deaths during 2020–2040. As a stand-alone policy, the BSR would not achieve New Zealand's goal of less than 5% smoking prevalence by 2025 for any portion of the population, and would take many decades to have an effect on health gains (23). This policy is likely to be most effective at the population level when enacted in combination with other policies, as in the New Zealand plan, particularly in countries where young people smoking rates are relatively low.

The Government of the United Kingdom modelling studies estimated that with a well-enforced BSR policy, smoking prevalence would fall from 13% in 2023 to nearly zero by 2050 among persons aged 14–30 years, and from 12.7% in 2023 to 1.5% in 2056 among those aged 18+ years. There are

relatively small projected short-term impacts on reducing disease cases and mortality, given the long trajectory for developing many tobacco-caused diseases. However, consistent with results of the New Zealand government modelling studies discussed in the preceding paragraph, under the modelled assumptions the number of premature deaths avoided would rise dramatically after 2044 in the United Kingdom. The United Kingdom's modelling study suggests that if the United Kingdom policy is successful, it will lead to public health benefits over 30 years, including improvements in the health outcomes of people who do not initiate smoking, reductions in healthcare costs, illness, and health inequalities, and increased spending in other sectors of the economy (18).

A recent paper (24) modelled a scenario in which sales were banned for individuals who were born between 2006 and 2010 in 185 countries to assess the impact on population lung cancer mortality through to 2095. With perfect enforcement, the study found that by 2095, the policy could prevent more than 1.1 million lung cancer deaths in people from this cohort.

BSR makes no immediate visible change to the tobacco retail environment; thus, even if fully implemented and enforced across several decades, it makes very gradual changes to the structural, political and social dynamics that sustain the epidemic. As the population to whom the products may be legally sold grows smaller and older, and the use of the products perhaps appears thereby less appealing to young adults, it may have a broader de-normalizing or signalling effect, contributing to reduced smoking prevalence (25). The policy is likely to be most effective in jurisdictions where smoking prevalence is low, other existing tobacco control measures in place, and where there is high capacity for ongoing effective monitoring and enforcement at the level of individual retailers. If well implemented, BSR could slowly close off the pipeline of "replacement smokers" (or other tobacco products users, if the BSR policy is extended beyond cigarettes) on which the industry depends.

Worldwide, over 93% of smoking-related deaths occur in those 50 and older. Even in low-income countries with larger proportions of younger people, 86% of smoking deaths occur among those aged 50+ years (26). Older smokers are less likely to benefit from the policy, which will initially have very modest effects but across several decades, will impact increasing numbers of people. Assuming projected estimates are correct, it will have high to significant population-level impact in 30 years. However, it is difficult to determine impact with much precision, given the very long trajectory of change.

As a stand-alone policy, BSR measures would take several decades to reduce smoking prevalence. Modelling conducted for the New Zealand government found that the smoke-free generation policy by itself would not achieve the smoke-free goal of prevalence at 5% or less for non-Māori until 2040 and for Māori until 2054 (22). The majority of the health-adjusted life years gained were after 2040.(23) A modelling study from Singapore found that a BSR type policy alone would achieve a smoking prevalence target of 5% or less only after 39 years, compared with combining nicotine reduction and a flavoured products ban, which were projected to achieve it within a decade (27). Another study examining the potential impact of such a policy in Solomon Islands found that BSR policy would take nearly 40 years to achieve a goal of prevalence less than 5% (28).

Awareness and profile of the FLM as a potentially promising intervention

In addition to the jurisdictions mentioned above, variations on BSR policies have also been proposed elsewhere, including Tasmania, Australia, the Philippines, Malaysia and three states in the United States, but have not yet been enacted (29–36). While some countries such as Denmark have used the "tobacco-free generation" language to describe their goals (37), we were unable to find others that had proposed or implemented a BSR policy.

Studies conducted in several countries have found substantial public support for BSR policies. A study from Tasmania, Australia found majority policy support among adults and students aged 12–17 years across all sociodemographic subgroups. Among adults, 75% supported the policy, including 72% of people who smoked. Among young people, there was 68% support, including 64% of those born after the proposed cut-off year (38).

Likewise, a study from New Zealand found strong support for "a law that prevents anyone who is currently 18 or younger from ever buying cigarettes or tobacco", with more than 75% of people who smoke and those who have quit smoking supporting it (39). New Zealand young people interviewed about the proposed policy supported it as a social good and viewed it as liberating rather than restrictive (40). A study conducted in Ireland found 56% support for a "tobacco-free generation" policy (41).

Other studies have found moderate to low levels of support, and interpretation is hampered by differences in how the questions are asked. In Hong Kong SAR (China), a 2015 survey found 71% of adults supported a BSR type policy, although the question referred to a birthdate-based "smoking" ban rather than a sales ban (42). A recently published cross-sectional representative study from the United Kingdom, however, reported that just 34.5% supported the policy, while 41.3% were opposed (43). A recent meta-analysis of multiple endgame policies (44) included four studies measuring public support for BSR and estimated an overall 54% level of support for a "tobacco-free generation" policy.

Policy-makers may find the BSR approach appealing as it makes very small changes in the status quo, thus minimizing opposition. A qualitative study in the United States with California legislators, staff and tobacco control leaders (45) found that a TFG/BSR policy was regarded favourably as feasible due to its very gradual approach.

Implementation considerations specific to this FLM

Overall, the research literature suggests that retailer non-compliance is a significant limiting factor in the effectiveness of T21 policies (8, 46). BSR policies, which require retailers to make behaviour changes, including checking identification universally (not only for those who appear young, but for everyone, to verify birth year), and refusing sales based on birth year regardless of age, would require additional dedicated resources for much more rigorous enforcement and substantial penalties for retailer non-compliance. As the age of legal sale gradually increases under BSR, retailers may find universal identification checks and compliance more challenging as, for example, after many years someone aged 36 may be legally sold tobacco products but someone aged 35 cannot. However, it is also possible that as the policy takes effect some retailers may find that with additional compliance checks, declining tobacco sales, and relatively low retail-level profit margins, tobacco sales are no longer worth continuing. If this occurs, it could further enhance the effectiveness of a BSR policy through retail reduction by attrition.

Many young people obtain tobacco from social sources (47–49). These sources may be difficult to

identify and control. However, social supply of tobacco often comes from peers who are close in age, so social supply channels are also likely to shrink as the policy advances over time. As the cohorts still smoking grow older, young people may find that tobacco use (or smoking) becomes a practice regarded as less desirable to emulate.

Depending upon the way the BSR is structured and what products are included, it could allow or promote product shifting among young people; for example, if only cigarettes or combustibles are included, young people vaping or other nicotine product use could increase. Since there is no public health rationale for allowing people not already addicted to a product to purchase it, this risk could be mitigated by ensuring that sales of all tobacco and nicotine products are subject to the policy.

Another caution related to this FLM is that if policy-makers feel passage of BSR has "fixed" the tobacco problem, it could unnecessarily delay for decades more rapidly effective and definitive measures, such as retail reduction or other changes to the tobacco-promoting environment that reduce exposure to tobacco-promoting cues (50). Consideration of this measure should take into account the political appetite for additional, complementary measures. BSR should not be considered instead of established WHO FCTC measures, but as a supplementary option for jurisdictions that have already implemented required WHO FCTC policies.

While modelling from New Zealand suggests pro-equity effects, a BSR policy may also have the effect of "locking in" existing health disparities in several ways. As BSR has no direct effect on reducing the accessibility, availability, and attractiveness of tobacco products for consumers born before the birthdate cut-off, without additional concurrent interventions it may entrench (or at minimum do nothing to ameliorate) already-existing tobacco-caused health inequities among the population groups now most likely to be tobacco users, namely older people and disadvantaged groups. Communities traditionally preyed upon by the tobacco industry, evidenced through high retail density, targeted marketing exposure, and higher prevalence and disease burden (51-53) also often have weaker tobacco control infrastructure. They may be less able to successfully implement additional initiatives to address ongoing tobacco use among residents born before the birthdate cut-off, and BSR enforcement may be more challenging due to social conditions in deprived communities, thus further exacerbating disparities (50). Combining a BSR policy with other FLMs, particularly retail reduction, as in New Zealand's previously-passed package of measures, would likely make enforcement easier and minimize the potential for negative consequences. A recent analysis suggests specific conditions that would maximize benefits and mitigate the potential for negative consequences of a BSR (50). These conditions include strong resources and authority for enforcement, education and monitoring of retail compliance, enacting the policy as part of a comprehensive package that includes measures that will also benefit the population not subject to the birthdate cut-off, and commitment of cessation resources, including direct assistance as well as ongoing motivating and supportive messaging through media and health systems to support people who use tobacco.

Summary

There has been a recent surge of interest in BSR policies, which have been implemented in numerous cities in Massachusetts in the United States, introduced but not implemented in the United Kingdom, passed and then rescinded in New Zealand, and are under consideration in the state of South Australia and several Canadian provinces. BSR-related policies have also been proposed in Tasmania, Australia, the Philippines, Malaysia and three states in the United States. While the policy would only have a short-term impact on people whose date of birth fell after the designated date, it would have a long-term impact on the whole population as the age for legal sales

rose annually. As the population to whom the products may be legally sold grows smaller and older and the use of the products perhaps appears thereby less appealing to young adults, it may have a broader de-normalizing or signalling effect. BSR makes no visible change to the tobacco retail environment, however, and thus would be expected to make only gradual changes to the social and structural dynamics that sustain the tobacco epidemic. BSR policies are politically appealing and, if rigorously implemented, could slowly close off the pipeline of "replacement smokers" (or other tobacco products users) on which the industry depends. Modelling studies suggest that if fully implemented and effectively enforced, the policy would have a dramatic positive impact on now-younger age groups, depending on their current smoking prevalence levels. Assuming projected estimates are correct, BSR could have high to significant population-level impact in 30 years.

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(v) Increase in minimum legal age for sales of tobacco products

Abstract

Policy description and background. This measure increases the minimum legal age for the sale of or access to tobacco products.

This FLM aligns with Article 16 of the WHO FCTC, which requires Parties to prohibit the sale of tobacco products to and by persons under the age set by domestic law, national law or eighteen.

Evidence of impact. As of 2023, 141 Parties have established a minimum legal sales age of 18 years, nine Parties have set it at 21 years, and only one Party (Sri Lanka) has set it at 24 years – the highest globally. Jurisdictions, primarily in the United States (including the federal government and individual states), have raised the minimum legal sales age for tobacco from 18 to 21 years – a policy commonly referred to as Tobacco 21. Studies from various American states indicate that increasing the minimum legal sales age has a significant impact on the targeted age group by: 1) limiting or eliminating access to tobacco products; 2) preventing retail and other outlets from selling tobacco to youth; and 3) reducing young people's ability to obtain tobacco from older peers who are close in age. Strong evidence for the effectiveness of Tobacco 21 in reducing youth tobacco use led to the adoption of a nationwide policy in the United States in 2019.

Benefits and strengths. Minimum legal sales age policies, such as Tobacco 21, target a specific age group. Raising the minimum legal sales age limits or eliminates this group's access to tobacco products. Furthermore, it prohibits retail outlets from selling tobacco products to the targeted age group.

Implementation considerations. The effectiveness of minimum legal sales age policies in reducing tobacco use depends heavily on compliance by retailers and other outlets, as well as consistent enforcement by governments. Young people may still be able to access tobacco products through alternative sources, such as social networks, online platforms or neighbouring jurisdictions without similar age restrictions. Additionally, evidence from the United States suggests that there may be differences in the capacities of states to enforce minimum legal sales age due to resources needed for implementation. The tobacco industry may also support such policies strategically, aiming to pre-empt the authority of local governments to implement more impactful regulations.

Conclusion. Raising the minimum legal sales age limits or eliminates access to tobacco products for the targeted age group and prohibits the sale of tobacco products to this demographic. Policy evaluations demonstrate that such policies effectively reduce tobacco use within the target population.

Description of the intervention

This FLM raises the minimum legal sales age (MLSA) for tobacco products. It establishes an age limit (or floor) below which retailers and other tobacco outlets are prohibited from selling tobacco products. The objective of this FLM is to prevent tobacco use initiation among youth, which would reduce overall tobacco prevalence. The scientific rationale for this FLM is grounded in the adverse effects of nicotine, the primary substance in tobacco products, on brain regions responsible for decision-making, reward processing and emotional regulation – areas that continue to develop until at least the age of 21 or older (1-11). Although jurisdictions that have implemented MLSA policies have experienced reductions in tobacco use among the target population (12), the evidence in support of the FLM is mostly from the United States.

This FLM aligns with WHO FCTC Article 16, which obligates Parties to prohibit sales of tobacco products to and by persons under the age set by domestic law, national law or 18 years.

Availability of information/research evidence on the potential impact of the FLM

Age limits for tobacco control have long been used to prevent young people from using tobacco products and continue to be implemented by a growing number of countries (12–14). As of 2023, 141 Parties have established a MLSA of 18 years, nine Parties have set it at 21 years and one Party (Sri Lanka) has set it at 24 years, the highest globally (14).

Among WHO FCTC Parties, the MLSA ranges from 18 to 24 years (14,15).

Diffusion of Tobacco 21

In 2005, Needham, Massachusetts (United States), became the first jurisdiction worldwide to raise the MLSA to 21 years (12), a policy now known as Tobacco 21 (T21) (16). In 2013, New York City passed the second Tobacco 21 legislation in the United States (17,18). California and Hawaii became the first states in the United States to adopt Tobacco 21, setting the foundation for the implementation of a national law in 2019 (19,20). As of 31 March 31 2024, 46 jurisdictions in the United States (42 states, three territories and District of Columbia) have enacted Tobacco 21 policies (21). Tobacco 21 laws have also been implemented by at least nine other countries as of 2023 (14).

Impacts of Tobacco 21

There is strong evidence for the positive impact of raising the MLSA for all tobacco products, particularly for decreasing tobacco use (22-24). A 2015 review by the Institute of Medicine (IOM; now National Academies of Sciences [NAS]) concluded that raising the MLSA to 21 or 25 years in the United States will lead to substantial reductions in tobacco use (25.) A 2024 systematic review (22) of 23 studies in the United States concluded that Tobacco 21 reduced cigarette smoking and sales. Case studies (13,26) and secondary analysis of United States national data (27,28) concluded that Tobacco 21 reduces tobacco use among youth aged 18-20 years (29). A 2023 analysis of United States national data found that Tobacco 21 decreased tobacco use among youth aged 18–20 years by 2-4%.(29) A study in the United States of smoking trends between 2006 and 2010 in Needham, Massachusetts, (Tobacco 21 law in effect), compared to 16 surrounding communities (without Tobacco 21 laws), found that while past 30-day smoking in Needham decreased from 13% to 7%, smoking in surrounding communities decreased less, from 15% to 12% (30). While a few studies suggest no association between Tobacco 21 and cigarette use or intention to use cigarettes (31), the majority of studies show that the Tobacco 21 policy significantly reduces cigarette use among persons aged 18-20 years who currently smoke or have ever smoked cigarettes (22,23,28,30,32-38).

Beyond its direct impact on decreasing tobacco use, studies have shown that Tobacco 21 reduces the perceived ease of access to tobacco products (39), risk perceptions of smoking (40,41), intentions to smoke or quit smoking (41,42), and cigarette sales (43). Additionally, Tobacco 21 policies have positive health and economic impacts (32). For example, a 2023 study of youth aged 16–19 years in Canada, England and the United States reported that a higher MLSA was significantly associated with lower perceptions of easy access to tobacco products among youth (39). These findings reinforce the value of Tobacco 21 as an FLM, if effectively implemented.

The overall population-level impact of MLSA policies depends on the targeted age range and the prevalence of tobacco use within that age group. This is informed by evidence on the age at which most regular users initiated tobacco use, and the adverse effects of nicotine on the developing brains of youth and young adults (1-11). Based on strong evidence that parts of the brain responsible for decision-making, reward processing, and emotional regulation continue to develop at least until the

age of 21 years and older, many studies (primarily from the United States) (22,29) have focused on assessing the effects of raising the MLSA to 21 years on the consumption of tobacco products (22,24). Additionally, like any policy instrument, the MLSA applies to all segments of the targeted population within specific political or geographic jurisdictions. The reach of this FLM could, however, extend beyond the targeted age range. For example, studies have reported that Tobacco 21 has residual effects on adolescents who are below the targeted age group (18-20 years) (36). In a comparison of tobacco use in Cleveland, Ohio (United States), which implemented Tobacco 21 in 2016, with neighbouring jurisdictions without such a policy, Trap et al. reported that Tobacco 21 was associated with a decline in tobacco use among youth (44). Similarly, other studies in the United States have found reductions in tobacco use after the implementation of Tobacco 21 laws (45,46). A national study in the United States found that the percentage of adolescents who perceive they can buy tobacco products from the store decreased from 67.2% in 2019 (pre-Tobacco 21) to 58.9% in 2020 (post-Tobacco 21). However, only 17% of young people who attempted to buy cigarettes were unsuccessful due to age, indicating that retailer compliance remains an issue (36). A California (United States) study found that Tobacco 21 decreased current and lifetime use of smokeless tobacco products in the general student population (47). MLSA policies not only affect the targeted population but may also have implications for the general population.

Differences in the impacts of Tobacco 21

The effect size of MLSA policies varies across subpopulations and geographic or political jurisdictions (22). For instance, an analysis of 2011–2016 national data in the United States found that the average 18- to 20-year-old who lived in metropolitan and micropolitan areas with Tobacco 21 laws exhibited a 1.2% point drop in their likelihood of being a current smoker, relative to those were not exposed to such laws (27). Another study in the United States concluded that statewide adoption of Tobacco 21 laws was associated with a 2–4% decline in smoking participation among 18- to 20-year-olds (48). However, there is evidence that the effect size for Tobacco 21 in reducing tobacco use may depend on tobacco use status (people who have ever smoked, currently smoke, or smoke daily). For example, a 2019 study found that exposure to Tobacco 21 laws yielded a 39% reduction in the odds of both recent smoking and current established smoking among 18- to 20-year-olds who had ever tried cigarettes (33). In a comparative study of the association in the United States between California's Tobacco 21 policy and smoking behaviour, Dove et al. (28) reported that the odds of daily smoking among 18- to 20-year-olds decreased by 8% before the policy and 26% and after the policy, compared to the referent states (i.e., those without Tobacco 21).

Additionally, there is literature on the effect of Tobacco 21 on the sales of tobacco products. A study of youth in the United States reported that Tobacco 21 reduced cigarette sales by 12.4 % in counties with the highest proportion of individuals under 21 years of age (45). Similarly, cigarette sales decreased by 13.1% in California (United States) and 18.2% in Hawaii (United States) after the implementation Tobacco 21 (49). Thus, while the magnitude of policy impact differs across studies, the evidence indicates that Tobacco 21 reduces cigarette sales, indicating variability in impacts of Tobacco 21 (50) that the WHO FCTC Parties should be aware of.

As a legal instrument, such as legislation, decree, or proclamation, MLSA policies would have an immediate impact on the target population when successfully implemented and enforced. However, compliance and enforcement are key barriers to the policy's effectiveness (23,36,51–54). For example, since the passage of Tobacco 21 by the United States Congress in December 2019, 46 states and territories have adopted the policy (21). Although the remaining jurisdictions have not adopted the policy, retailers are still required to comply with it (21). The main challenge lies in the extensive resources required for implementation, which could serve as barriers for low- and

middle-income WHO FCTC Parties. However, a case study in the United States of tobacco control in Missouri communities found that compared to other tobacco control policies, such as smoke-free laws, Tobacco 21 requires a considerably shorter timeframe and fewer resources for adoption (26).

The extent to which MLSA policies can have systemic and structural impacts is primarily impacted by tobacco industry marketing practices and strategies that target youth and young adults (55–57). Starting in the 1980s in the United States, the tobacco industry sought to undermine tobacco control by portraying smoking as an adult choice (55,58,59), especially through their youth smoking prevention programmes (55,59–61). The industry has promoted the idea that smoking is an adult decision and a "right" of adults to choose to smoke. Findings from studies suggest that framing tobacco use as an adult choice has negative repercussions for youth smoking initiation, given the tendency of youth to mimic adult behaviours.

Additionally, the systemic effects of MLSA policies are partially determined by the proportion of a country's population under the age limit. Given the evidence supporting the impact of MLSA in reducing tobacco use, the policy would potentially have a greater impact when a larger the proportion of the population is under the age limit, although it requires regulatory capacity to enforce it. The effectiveness of MLSA also depends on the age of smoking initiation in the country. For example, over 90% of people who smoke regularly in the United States started by 18 years (10,11,62), compared to about 80% in India (63). In this respect, the potential reach and impact of Tobacco 21 is expected to vary across different countries.

Awareness and profile of the FLM as a potentially promising intervention

The support and opinions of the public and policy-makers are essential to the possibility of developing and implementing public policies and programmes (64,65), including tobacco control. Reports on MLSA policies by the WHO (14,66) and the European Respiratory Society's Tobacco Control Committee (67), and studies from the United Kingdom (68), Ireland (69), Singapore (70), India (1), Bangladesh (2,3) and Pakistan (3) provide evidence of strong awareness of Tobacco 21. The vast proportion of studies in the extant literature has, however, focused on support for Tobacco 21 policies among the general population and subpopulations.

Legal age limits were introduced in the United States for tobacco control in the 19th century, and have been adopted by few countries (WHO FCTC Parties), such as Kuwait, Singapore and Sri Lanka in 2021 (67). However, fewer than 10 countries (both WHO FCTC Parties and non-Parties) have adopted Tobacco 21 policies as of 2023 (3,66).

Existing research has generally found strong support for Tobacco 21. Studies of support for Tobacco 21 among youth, young adults, and adults, across different jurisdictions and subpopulations (40,71–73) have found that the support for raising the MLSA is above 50% in most countries (73–78), with few exceptions such as Germany (43.3%) (79). A study of the support for raising the MLSA to 21 in Australia, Canada, England and the United States found that support ranged from 62.2% in the United States to 70.8% in Canada (74). A 2022 report found that raising the MLSA from 18 to 21 was supported by 63% of adults in the United Kingdom (68). Studies in the United States have found a high level support for Tobacco 21 among the general population (including people who use tobacco) across and within states (71). A study in the United States found that over 70% of adults strongly/somewhat supported raising the MLSA to 21 years in 2014, before the adoption of the 2019 national Tobacco 21 law (75). Public support for Tobacco 21 in the United States has remained consistently high over time (75.0% in 2014, 72.3% in 2015, 78.4% in 2016 and 75.2% in 2017) (76).

Research has also assessed support for Tobacco 21 laws among youth and young adults, who would be directly affected by such policies (41,51,77). An analysis of 2015 national data in the United States found 63.9% support for Tobacco 21 among youth aged 11–18 years, with higher support among respondents in middle school than high school, and higher support among females than males (41). Similarly, the support or favourability rate has been found to be high even in tobacco-growing states (57.9% among adults) (77). Studies conducted outside of the United States have also found strong support for raising the MLSA to 21 among young people in Singapore (80.3% of those aged 18–24 years)(70), the United Kingdom (54% for those aged 18–24 years, 59% of those aged 11–17 years)(68), and Ireland (70.6% of those aged 15 years and older) (69). Together, existing studies show that Tobacco 21 is supported by the targeted populations.

Across countries with Tobacco 21 policies, the main institutions responsible for implementation are retail outlets (52,53,63). Retailer support for Tobacco 21 has been minimally explored. A tobacco retailer poll found that 98.6% of tobacco retailers were aware of and 60.6% supported California's T21 law, at seven months after the law was implemented (72). Further research on tobacco retailer support may inform strategies to ensure effective enforcement and compliance (72).

Implementation considerations specific to this FLM

Studies have identified a myriad of barriers and challenges for the implementation of MLSA policies. The major challenge or barrier to MLSA policies is inadequate enforcement and non-compliance by retail outlets (23,36,51-54,67,72,80-84). For example, after the implementation of the national T21 law in the United States, only 17.0% of students in 6th through 12th grades who attempted to buy cigarettes were unsuccessful because of their age (36). A cross-sectional study in the United States found that underage decoys had their identification checked only 65.0% of the time and were able to successfully purchase products in more than 40.0% of visits, after the implementation of Tobacco 21 in New Jersey (81). These results are consistent with another study showing that 63.3% of retailers in New Jersey sold tobacco to underage buyers after Tobacco 21 (85). After the implementation of T21 in Pitt County, North Carolina (United States), retailers failed to request identity cards in 15.4% of purchase attempts and sold to an underage buyer 34.2% of the time, with 75.5% of retailers selling to an underage buyer at least once (83). In California (United States), 65.4% of youth under 21 years who used cigarettes were not refused purchase of cigarettes (65.4%) after the implementation of the T21 law; however, 54.3% felt it was harder to purchase cigarettes (34). Strong enforcement and compliance checks, therefore, will be essential to effectively implement MLSA policy.

Additionally, youth and young adults targeted with MLSA policies tend to obtain tobacco products from other sources, including social sources/networks (e.g., peers) (23,33,35,48,86), gas stations and vaping shops (34,82), neighbouring and adjacent jurisdictions without MLSA policies (35), and online (23,86,87). Given these implementation considerations, it is important that jurisdictions planning to adopt Tobacco 21 laws consider investment in supporting initiatives, for example: advance education of retailers and the public of the law, and resources for ongoing enforcement activity, including controlled purchase operations to test retailers' compliance with the Tobacco 21 law.

A potential negative consequence of MLSA policies is pre-emption (17,88), especially within a federal system of government. Pre-emption is a situation where higher tiers of government pre-empt or prevent lower tiers of government from enacting and implementing laws that are more stringent or differ from the higher tier of government (21,89–92). These pre-emptive laws could be explicit (i.e., the higher tier of government expressly indicates that it has absolute or complete control over policy issues and lower tiers of governments are prevented from making any stringent laws), or

implicit (i.e., inference from the law by the higher tier of government that indicates that lower tiers of government cannot make stringent or different laws).

Pre-emption of tobacco regulation has been used in the United States to stifle local regulation of tobacco efforts (92,93), with several negative ramifications such as impeding the ability of local governments to effectively protect their populations from the harm of tobacco use (91,94–96). Specific to MLSA policies, as of December 2019, 40 states in the United States enacted Tobacco 21 laws, seven of which expanded or introduced pre-emption when they increased the MLSA; a total of 26 states (52%) included pre-emption (88). Consistently, an analysis of Tobacco 21 policies in the United States, estimated that 20 states pre-empt local age restriction policies (97). With the potential of state pre-emption of MLSA policies such as Tobacco 21 to impede public health (27), such laws become potentially negative for tobacco control.

MLSA policies may also widen disparities in tobacco use, although the evidence is mixed. Some studies have reported that Tobacco 21 laws would mitigate disparities and inequities in tobacco use among youth and young adults (22,27,36,44,46,48,98) in rural—urban differences (99), across socioeconomic status (100–102), and among sexual and gender minorities (103). Simultaneously, the potential of Tobacco 21 policies to exacerbate disparities and inequities in tobacco use among youth and young adults, especially across race/ethnicity due to lapses in enforcement and compliance (52). For example, a study in the United States of retailer compliance with Tobacco 21 in Columbus, Ohio, found that after controlling for race- and age-based factors, retailers located in high- versus low-poverty neighbourhoods had lower compliance with age verification. This suggests that that low compliance with Tobacco 21 has the potential to widen disparities in tobacco use (52).

Summary

MLSA policies are broadly known among the WHO FCTC Parties, although there is a paucity of information on this policy in Africa, Latin America, the Caribbean and the Middle East. Evidence on the effectiveness of raising the MLSA on tobacco use and sales in the targeted population is limited to studies conducted in the United States. Nevertheless, as a policy instrument, MLSA has the potential to reach a large proportion of the targeted population, with studies showing positive effects of Tobacco 21 on subpopulations such as youth. MLSA would have an immediate impact on the target population and may be easier to adopt compared with other tobacco control measures, although resources required for implementation could be a barrier for low- and middle-income WHO FCTC Parties. Even though Article 18 of the WHO defines minors as "persons under the age set by domestic law, national law or 18", the existing evidence indicates that this age should be considered as the floor, not the ceiling for MLSA policies.

Inadequate enforcement and noncompliance by retail outlets are major barriers to the effective implementation of Tobacco 21 laws. Other challenges include the coverage of MLSA (either in terms of age, geography or jurisdiction, or product type), acquisition of tobacco products through other sources such as social networks, and influence of the tobacco industry, particularly in shaping the language of the MLSA. These challenges may be mitigated by enacting a policy with sufficient resources for strong monitoring and compliance checks, and substantial retailer penalties for noncompliance. MLSA policies may also have unintended consequences, including the use of preemptive regulations. and widening disparities and inequities in tobacco use.

MLSA holds a strong potential as a FLM for tobacco control, with growing awareness among the WHO FCTC Parties and broad public support. Further research is needed to explore the relationship (correlation and/or causal effects) between MLSA and increases in the age of initiation of smoking across countries and cultures.

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(vi) Ban/phase out sales of tobacco products

Abstract

Policy description and background. This policy involves phasing out or banning sales of some or all tobacco products within a jurisdiction. Many countries ban sales of some types of tobacco products. Some countries have banned sales and later rescinded their policies. Two cities in California (United States) have ended sales of all tobacco products.

This FLM could be viewed as building on measures considered under the following articles of the WHO FCTC: Article 8, if the measure included smoked products, and thus would be expected to reduce smoking; Article 12, informing the public that some products are too harmful to continue to be sold as everyday consumer items; Article 13, since such a sales ban would also eliminate all points of sale, as well as all tobacco advertising, promotion and sponsorship; Article 15 on the reduction of illicit supply of tobacco products; and Article 17, which refers to individual sellers as well as tobacco workers and growers in its focus on promoting economically viable alternative activities.

Evidence of impact. Eliminating sales of tobacco products would have immediate effects on the specific population groups still using or at greatest risk for initiating tobacco use, by de-normalizing tobacco sales, eliminating exposure to tobacco products and their advertising and promotion, and supporting those trying to quit by reducing access to the products. Depending upon the jurisdiction, the products subject to the sales ban, the phasing of the ban(s), and the situation regarding cross-border and illicit purchasing, this FLM could have an impact either immediately or within several years.

Benefits and strengths. Ending tobacco product sales makes visible, permanent changes to retail availability, advertising and product exposure, and accessibility. It reduces the number of industry allies and represents the ultimate de-normalization of tobacco products. It is also fully consistent, rather than incongruent, with public health messages about the harmfulness of tobacco products. High public support for ending sales of tobacco products has been documented in multiple countries – including in Australia, Bhutan, Germany, Ireland, the Netherlands (Kingdom of the), New Zealand, Pakistan, the Republic of Korea and England (United Kingdom) – for different age ranges and among groups of people who smoke and those who do not smoke. This support has also remained stable or increased over time, even among people who smoke in some of the studied cases and countries, despite the lack of campaigns promoting such measures.

Implementation considerations. Sales phase-outs are likely to be most successful in jurisdictions with the following in place: strong existing tobacco control policies; political commitment; already low tobacco use prevalence; capacity for effective implementation and enforcement; low potential for illicit sales of tobacco products; resources to support cessation of tobacco use; inclusion of bans on manufacture, transport and distribution of the products subject to the sales ban; consideration of retailer transition from tobacco sales; and enacted retail reduction policies. There is a gap in research on modelling the optimum pace for phasing out sales to minimize disruption to programmes supported by tobacco taxes while maximizing positive impacts. This may include identifying other potential taxes or sources of revenue.

Conclusion. If fully implemented and adequately enforced, a ban on/phase-out of sales of tobacco products would have a large effect on tobacco product availability, and could be expected to improve population health. Based on the extensive evidence on retail reduction, if well planned, phased, implemented and enforced, a sales phase-out would be expected to reduce tobacco initiation, increase cessation success and denormalize tobacco use.

Description of the intervention

This FLM would phase out or ban sales of some or all tobacco products within a jurisdiction.

This FLM could be viewed as building on measures considered under the following WHO FCTC articles: Article 8, Protection from exposure to tobacco smoke, if the measure included smoked products, and thus would be expected to reduce smoking; Article 12, informing the public that some products are too lethal to continue to be sold as everyday consumer items; Article 13, since such a sales ban would also eliminate all point-of-sales tobacco marketing and promotion; Article 15, on the reduction of illicit supply of tobacco products; and Article 17, which refers to individual sellers as well as tobacco workers and growers in its focus on promoting economically viable alternative activities. Such a sales ban could include resources or incentives to facilitate retailer transitions away from tobacco sales.

Availability of information/research evidence on the potential impact of the FLM

Several states in the United States banned or attempted to ban cigarette sales during the early 1900s (1). However, no ban persisted for more than a short time given the influence of the then-burgeoning commercial tobacco industry.

More recently, a small number of jurisdictions have banned sales of tobacco products. This includes Bhutan in 2004 (1–3), and South Africa in 2020 (4–6); however, tobacco sales bans in both countries were subsequently rescinded. Botswana and India also banned tobacco sales as a short term COVID-19-related measure; these policies were ended after 12 weeks and six weeks, respectively (4).

In Bhutan, all commercial tobacco sales, manufacture and supply were prohibited in late 2004 (7), but the policy was ended in 2021 to reduce illicit trade and as a COVID-19 transmission prevention measure (3). Bhutan, a country whose policies have been founded on the concept of Gross National Happiness (8), was the first modern nation to end sales of tobacco. The 2004 policy prohibited all sales of tobacco products and banned tobacco use in public places, but did allow for private consumption of products imported for personal use, while adding a 100% sales tax and customs duty (1).

While data on tobacco use in Bhutan prior to the 2004 ban are unavailable, tobacco use in the country is lower than in other Asian countries. A 2011 report found that the rate of smoking was 2.8%, with 97% public support for the tobacco sales ban (9). However, in 2019, overall tobacco use prevalence was estimated at around 24% (3), and seizures of smuggled tobacco reportedly increased after the policy (2). Although Bhutan had put in place a comprehensive smoke-free law in 2005 (9), no additional demand-side measures were implemented to complement the tobacco sales ban. During the early stage of the COVID-19 pandemic, when little was known about the disease and how it might be transmitted, concerns grew about cross-border transmission, as products were often smuggled from India, where COVID-19 was rising. In 2021, the Government ended the ban, stating that they were doing so to reduce SARS-CoV-2 transmission from those smuggling tobacco from India, and permitted sales of tobacco products in specific shops (3).

South Africa's cigarette sales ban was abruptly announced as a COVID-19 prevention measure during initial lockdown beginning in March 2020 (6). The measure lasted five months and appeared to result in a substantial fall in smoking prevalence. One survey conducted in South Africa during the sales ban found that 16% of people who smoked reported quitting during the lockdown, and 71% of those claimed that they would not return to smoking after the sales ban ended (6). However, other studies

have reported that less than 10% of people who smoked said they had quit, despite the prices of (illegally sold) cigarettes increasing dramatically during the ban (10). Later studies found that the ban had little impact on smoking cessation, and that the illicit market became even more entrenched (5).

Two California (United States) cities to date have successfully enacted bans on sale of tobacco products, both of which remain in effect. In both cities, smoking prevalence was already low, and the cities had previously enacted strong retailer licensing and smoke-free measures, including in public outdoor spaces. While there was some opposition from retailers, strong support among young people for the measures, support from public health groups, and a history of innovative tobacco control policy leadership in both communities played key roles in successful passage and implementation of the policies (11,12). These policies, which both came into force in 2021, were accompanied by offering free business consultations to help retailers make the transition away from tobacco sales.

Although no evaluations of the impact of these policies on tobacco use behaviours have been conducted, two studies have explored Beverly Hills and Manhattan Beach retailers' perceptions of the new laws. A 2021 survey of retailers' awareness of, compliance with, and support for the new laws at the time they went into effect found that all were aware of the laws, and most found compliance easy; however, most opposed them (13). Another study with in-person interviews conducted 22 months after policy implementation found that managers at most large chain stores had no complaints, while small retailers were more dissatisfied, primarily due to perceived revenue losses. Small retailers also objected to the limited geographic area covered by the laws, which they felt made it easy for customers to buy tobacco in immediately adjacent cities, and to exemptions for certain businesses in Beverly Hills. However, some retailers also pointed out advantages, such as reduced cigarette butt litter near their shops (14).

Compliance with the sales ban policy in actual sales practice was found to be 87.5% in an in-store purchase survey conducted about nine months after the ban came into effect (15). In addition, in-store marketing was almost entirely eliminated in the two cities. Further, there was no evidence of price gouging or greater presence of discounts in nearby cross-border stores.

A recent economic study examining sales data from a sample of retailers in Beverly Hills and Manhattan Beach found that in addition to finding high retailer compliance with the sales bans, tobacco sales ceased within three months in Beverly Hills and nearly ceased by December 2021 in Manhattan Beach. No significant cross-border shopping, and no significant effects on non-tobacco sales were found in either city (16).

Regarding tobacco use behaviours following sales bans, following the CVS Pharmacy (United States) chain's decision to stop selling tobacco, studies found a modest but significant increase in quit attempts (17), and reduced household and population-level purchasing of tobacco (18).

A 2023 systematic review examining the effect of various tobacco control policies on smokeless tobacco use reported that two studies evaluating the effects of sales bans showed significant reductions in smokeless tobacco sales (6.4%) and use (17.6%), but one study reported an increase in use among young people after a total sales ban (19).

Some jurisdictions have banned or phased out sales of specific tobacco products. For example, the Netherlands bans the sale of flavoured cigarettes, snus and nicotine pouches with levels above 0.035

mg/pouch, based on nicotine toxicity (and similarly 6-methylnicotine in pouches). Products with lower nicotine levels are considered to be below levels needed to sustain addiction (20,21).

As of 2024, 88 countries had banned sales of single cigarettes (22). The Vatican has had a cigarette sales ban since 2017 (23,24). To date, however, no countries appear to have ended the sale of all smoked tobacco products.

According to the Campaign for Tobacco-Free Kids (CTFK) policy database, 14 countries had water-pipe tobacco product sales bans as of 9 October 2024 (22). However, the Campaign's list still includes Bhutan, which reversed its sales ban policy in 2021 as a COVID-19 prevention measure. A 2018 report from the WHO FCTC Knowledge Hub for Waterpipe Tobacco Smoking found that 39 countries had regulations on water-pipe tobacco products and/or use, but identified gaps between policy enactment and implementation/enforcement; having a policy did not necessarily equate to affective implementation (25).

As of 2023, 16 Indian states or Union Territories had banned the sale of loose tobacco products, including *beedi* cigarettes (26). According to a 2017 report from the WHO FCTC Knowledge Hub on Smokeless Tobacco (27), 45 Parties to the WHO FCTC have implemented bans on sales of smokeless tobacco products, but most are only partial, allowing sales of some types of smokeless products. Fewer countries have banned manufacture and import of such products. Zaatari and Bazzi noted that while the WHO FCTC speaks to all tobacco products, regulations have tended to focus primarily on cigarettes (28). The CTFK policy database shows that 20 countries have bans on sales of smokeless tobacco products, but again the list still includes Bhutan, which reversed its previous sales ban policy. All European Union member states, except for Austria, Finland and Sweden, ban sales of oral tobacco products (not including chewing tobacco or nasal snuff).(29)

A study conducted in two Indian states assessing the ban on sales of *gutkha*, a particularly harmful form of smokeless tobacco, found differences between the states in consumer and vendor awareness of the ban, similar rates of self-reported use, and illicit market sales (assumed based on reported availability of banned products) appeared to continue in both, although in Kerala state, consumers reported less availability than before the ban *(30)*.

Countries have successfully defended in court their bans of some tobacco products, including gutkha, shisha, and snus. In most cases, countries have prevailed against legal challenges to their right to protect public health. A WHO publication summarizes this litigation (31).

There is also a substantial record of governments banning the sale of other types of products found to cause harm to the public, some of which have been challenged legally in international trade and investment fora. The right for sovereign nations to regulate or ban the sale of products to protect public health has been repeatedly affirmed, providing the policies are applied equitably. For example, France banned asbestos and asbestos-containing products. Canada, a major asbestos producer, unsuccessfully challenged the ban. The World Trade Organization panel found that the asbestos ban was justified by the health exemption under the General Agreement on Tariffs and Trade and the Appellate Body emphasized that member governments have the right to regulate to protect health and to determine their own level of protection (32,33). A phase-out of sales should apply to all affected products, whether domestic or imported.

Other products that have been phased out – and which arguably caused far less harm to the public – include leaded paint, leaded gasoline, chlorofluorocarbons and plastic bags, as well as many other individual consumer products known to harm health. Governments can and do act to phase out

many products that pose serious harm to health, particularly when they have no essential purpose. Further, in addition to the morbidity and premature mortality caused by tobacco products, the cost to society of allowing continued sales of tobacco as a normal consumer product is far greater for government and society than the tax revenue generated by its sale (34,35).

Awareness and profile of the FLM as a potentially promising intervention

Proposals to ban cigarette sales (or all tobacco product sales) have been discussed for decades. As early as the 1960s, a number of subnational jurisdictions in the United States proposed ending tobacco sales. Research using tobacco company internal documents (36) shows that the tobacco industry opposed such proposals, using the same arguments deployed against other tobacco control measures. Public health groups also opposed earlier proposals on the grounds that they were not evidence-based.

As endgame discourse and research advanced, however, the idea of ending sales began to generate more serious attention (37–41). The 2014 United States Surgeon General's report (42) included explicit reference to state and local bans on sales of some or all tobacco products as a potential endgame measure allowable under the federal law that gave the United States Food and Drug Administration authority to regulate tobacco products.

In 2019, Beverly Hills (California) became the first city in the United States to ban sales of most tobacco products, as the policy was now viewed as likely to have positive impacts on public health. Over the last decade, growing evidence has shown that retail reduction can reduce smoking initiation, improve cessation success, decrease marketing exposure, and de-normalize both tobacco sales and smoking (see information brief on Retail Reduction). A 2022 scoping review concluded that ending sales as a policy has progressed to the evidence synthesis stage (43).

Eliminating sales of tobacco products would have immediate effects on the specific population groups still using or at greatest risk for initiating use of tobacco, by de-normalizing tobacco sales, eliminating exposure to products and marketing, and supporting those trying to quit by reducing access. Depending upon the jurisdiction, the products subject to the sales ban, the phasing of the ban(s), and the situation regarding cross-border and illicit purchasing, this FLM could have an impact immediately or within several years if taking into account longer-term de-normalizing effects of reduced legal retail access and product exposure.

Public support

Substantial public support for ending sales of tobacco products has been documented in multiple countries and has remained stable or increased over time. This strong baseline support, despite the absence of any related public campaigns, suggests that the public may be more receptive to this measure than many in public health and policy circles assume. Table 1 summarizes the evidence.

Table 1. Support for a tobacco sales ban^a by country or region

		Per cent supporting tobacco sales ban				
Country/region	Time frame	Smokers ^b	Former smokers	Never smokers	Non- smokers	All
Ontario, Canada (ages 18+) (2003) (44)	Not specified	12.0		24.0		
New South Wales, Australia (ages 18+) (2004) (45)	< 10 years	37.2			59.0	
New Zealand (ages 18+) (2007-2009) (46)	10 years	46.0				

		Per cent supporting tobacco sales ban				
Country/region	Time frame	Smokers ^b	Former	Never	Non-	All
			smokers	smokers	smokers	All
New Zealand (2008) (47)	< 10 years	26.2	52.0	60.1		
United States (ages 18+) (2009/2010)	Current	19.0				
(48)	Current	19.0				
England (2008) (49)	< 10 years	32.5	40.5	49.4		
Europe (18 countries, ages 15+) (2010)	Not specified	25.6	29.4	41.2		34.9
(50)	Not specified	25.0	29.4	41.2		54.9
Victoria, Australia (ages 18+) (2010)	5-10 years	42.2				52.8
(51)	3-10 years	42.2				32.6
New Zealand (ages 15+) (2010) (52)	10 years					66.0
Bhutan (ages 18+) (2011) (9)	Current	88.0				94.0
United States (ages 18+) (2011) (53)	< 10 years	32.7			53.1	
New Zealand (adolescents) (2012)	10 40000	12.0	FO 0	CE O		F7.0
(54,55)	10 years	13.0	50.0	65.0		57.0
New Zealand (ages 15+) (2012) (56)	10 years	18.0			58.0	50.0
New Zealand (ages 15+) (2012) (57)	10 years	34.0	53.0	63.0		72.0
Hong Kong (ages 18+) (2013) (58)	< 10 years	45.4	59.4	68.0		
New Zealand (adolescents) (2014) (55)	Not specified	12.0				56.0
European Union (ages 15–24) (2014)	Not specified					16.0
(59)	·					
Germany (ages 14+) (2016) (60)	10 years	10.0				22.9
Netherlands (ages 15–16) (2016) (61)	Not specified	12.3				34.1
Queensland, Australia (university	10 years					51.6
students) (2017) <i>(62)</i>	10 years					31.0
New Zealand (university students)	10 years					53.3
(2018)(62)	10 years					33.3
European Union (6 countries, ages 18+)	10 years	40.4 ^d				
(2018) (63)	10 years					
New Zealand (2016-2018) (ages 18+)	10 years	44.9	60.3			
(64)	,					
Victoria, Australia (ages 18+) (2019)	Not specified	31.7	53.2	58.8		
(65)	·					
Australia (ages 18+) (2019) (66)	Not specified	32.9	62.3	67.2		61.6
Pakistan (ages 15+) (2019–2020) (67)	10 years	82.1				
South Korea (2020) (ages 19+) (68)	10 years	35.6				61.3
United States (ages 18+) (2021) (69)	Not specified	25.2			74.8	57.3
United States (2021) (70)	Not specified	36.3	54.4	67.6		
Ireland (ages 15+) (2022) (71)	Not specified	66.4			85.5	82.8

^a Question wording is not consistent across all studies

Source: McDaniel et al. 2024 (72)

A 2024 four country study measured support for banning sales of smoked products among people who smoked cigarettes in Australia, Canada the United States and England using two question scenarios: 1) banning sales with cessation support: and 2) banning sales with substitute products provided. Consistent with earlier studies (see Table 1), this study found that most people who smoked opposed a sales ban, but between 20% and 36% supported the idea, and opposition was reduced if the government provided cessation assistance. Support for a sales ban was highest among

^b Description of smoking status (smoker, nonsmoker, etc.) as employed in the studies, unless noted

^cThe category "non-smoker" could include former smokers, as distinct from "never smokers."

^d Includes both smokers and recent quitters

those wanting to quit smoking and those using or interested in using other nicotine products. People in England who smoke were equally supportive of both the ban with cessation support and the ban with substitution scenarios (73).

A 2024 systematic review and meta-analysis of 47 studies measuring public support for various forward-looking policies characterized as endgame measures concluded that while the majority of the general population supported these policies, overall support for a sales ban (53.7%) was lower compared to several other policies. However, it is noteworthy that even among people who smoked, support for a sales ban was 37.8% (74).

Implementation considerations specific to this FLM

The largest potential challenge to implementation of this FLM is controlling internet, Illicit and cross-border sales of tobacco products (75). If sales ban policies are implemented in jurisdictions where prevalence is already low, such illicit trade is reasonably likely to be manageable with adequate enforcement and monitoring. In jurisdictions where tobacco use is concentrated among disadvantaged groups, enforcement could worsen social injustice from inequitable policing practices. Especially during initial implementation, enhanced resources to help people quit may mitigate the risk of illicit sales. Since almost 70% of people who smoke say they want to quit (76), many may welcome the support of not having the products so easily accessible.

Although sales phase-out policies would likely be challenged by industry, it is currently unclear what form this opposition may take. To date, no tobacco manufacturers have taken legal action against the United States sales ban policies in Beverly Hills or Manhattan Beach. Legal challenges are always possible, but in the United States the 2009 Family Tobacco Control and Prevention Act specifically permits states and localities to adopt sales restrictions, including bans on sales of products altogether, and analysis of applicable laws suggests that local ordinances are likely to be upheld (77). The history of tobacco control suggests that each locality taking this step may enable others to do likewise (36).

Dsouza and Bhojani (78) discuss the tobacco industry's legal challenges to the innovative use of food laws by Indian states to support issuance of sales ban laws for various smokeless oral tobacco products. Any sales phase-out is likely to face legal challenges from the tobacco industry, as well as ongoing interference with implementation, and efforts to weaken or reverse the policy. Industry development of new products that circumvent the sales ban policy should also be anticipated, for example, as the industry changed to "concept flavours" (products with vague, evocative names that suggested flavours) to circumvent policies in the United States banning sales of specifically flavoured products (79,80).

Another potential challenge is dealing with governments' concerns over loss of tax revenue, particularly if the policy is enacted at state or national levels. There is a gap in research on modelling the pace for phasing out of sales to minimize disruption to programmes supported by tobacco taxes while maximizing positive impacts. This should include identifying other potential taxes or sources of revenue, since tobacco taxes are not the only major source of funding for government services.

The experience of South Africa discussed above suggests that how a sales ban policy is enacted is critical to its success. In the two jurisdictions in the United States that have successfully implemented sales phase-outs, the process included an extended transition period for retailers to sell off existing stock, access to business consultation for managing the transition, public awareness materials and pre-existing strong tobacco control policies, including cessation support.

Filby and colleagues (4) emphasize that both demand side (reduced prevalence, effective cessation support) and supply side (effective control of low level illicit trade and an accompanying ban on manufacture, transport and distribution of cigarettes) must be addressed for a sales ban to be effective. In addition, a phased approach such as enacting retail reduction policies (see information brief on Retail Reduction) prior to a full sales ban (such as banning sales in or restricting sales to particular types of stores) may help minimize potential negative consequences, as these measures further reduce prevalence prior to a full sales ban (81).

Difficulties in regulating non-cigarette tobacco products have been attributed to several factors, including the unique design of the products, the ways they are used, culturally specific practices associated with cottage industries that do not adhere to standard manufacturing processes, weak enforcement, exclusion of such products from existing tax schemes, and use of generic definitions for tobacco products that do not make explicit the inclusion of such products in regulations. Consideration of whether these are issues within the specific jurisdiction, and how to address them as part of the regulatory process, will be important.

Banning sales of only some types of tobacco products means that the basic supply system remains unchanged, since only certain products are not available legally. Such partial sales bans could have the effect of inadvertently reinforcing tobacco industry "harm reduction" narratives about deceptively marketed "reduced exposure/risk/harm" products, including those that lack long-term independent studies to support such claims. Consumers switching to other, also harmful forms of tobacco products could be a negative consequence of policies banning the sale of specific products. If switching (rather than quitting) is widespread, the policy impact on net health gains will depend upon the prevalence of switching, the types of products that people switch to and whether the switching behaviour leads to increased dual- or multi-tobacco product use, which could increase risks at the individual level. To mitigate this, policies should consider incentives for retailers who transition away from tobacco sales altogether, thus reducing exposure to other tobacco products and marketing.

Case studies

The linked case studies below of successful sales bans implemented in two cities in California in the United States provide more information on aspects of the policies' success (11,12).

https://endtobaccoca.ash.org/wp-content/uploads/2021/09/CS ManhattanBeach V1 Final.pdf
https://endtobaccoca.ash.org/wp-content/uploads/2021/09/CS BeverlyHills V1 Final.pdf

Summary

Ending tobacco product sales makes visible, permanent changes in retail availability, advertising and product exposure, and accessibility. It reduces the number of industry allies and represents the ultimate de-normalization of tobacco products. It is a standard practice for governments to phase out or ban sales of products that harm or kill consumers. Numerous countries have enacted bans on sales of some types of tobacco products, including single cigarettes, smokeless tobacco and water-pipe tobacco. The evidence on impact from such policies remains somewhat limited but given the well-documented harm profiles of these products, effectively banning sales could be expected to improve population health. Emerging evidence from analyses of both unsuccessful sales bans and successful ones suggests specific considerations that should be addressed when contemplating sales ban policies. These include a previous history of jurisdictional action to advance tobacco control, including smoke-free policies; political commitment; already-low tobacco use prevalence; capacity

for effective implementation and enforcement; low potential for illicit sales; and including in the policies bans on manufacturing, transport and distribution of the products subject to the sales ban. Policy-makers should also consider addressing the concerns of retailers making the transition away from tobacco sales, and planned pacing of the sales phase out to minimize potential negative effects. Further, if a sales ban applies only to particular products, the possible effects of switching behaviour must be considered.

Numerous studies from multiple countries suggest that a majority of the general public is supportive of ending tobacco sales, including more than one third of people who use tobacco. Based on the extensive evidence on retail reduction (see information brief on Retail Reduction), sales ban policies would, if well planned, phased, implemented and enforced, be expected to reduce tobacco initiation, increase cessation success and de-normalize tobacco use. Given the massive human and economic costs of the tobacco epidemic, which are borne by governments and society it is timely for countries with low tobacco use prevalence to begin planning to phase out tobacco sales.

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(b) Institutional structure/market

(i) Environmental controls ("producer pays")

Abstract

Policy description and background. The principle of "producer pays" would hold tobacco manufacturers financially accountable for preventing, managing and addressing the negative environmental and related health impacts of waste from the entire life cycle of tobacco production and consumption, including farming, manufacturing, distribution, and post-consumption product waste. This FLM applies the "producer pays" principle specifically to tobacco product waste, with the aim of addressing its environmental harms, ultimately contributing to long-term health benefits. There are several policy approaches to address this principle, including extended producer responsibility, which places the responsibility on producers not only to finance, but also to implement solutions that mitigate the environmental harms of tobacco product waste.

Legislation to hold tobacco manufacturers accountable for the environmental harms of tobacco product waste has been implemented at different levels across countries in the European Union, where the Single-Use Plastic Directive imposes extended producer responsibility on producers of tobacco products with plastic filters.

This measure aligns with Article 18 of the WHO FCTC, which calls on the Parties to have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.

Evidence of impact. Evidence from other sectors highlights the potential application of the "producer pays" principle, through extended producer responsibility policies (holding producers responsible for financing and implementing policies). These measures also reduce tobacco product waste litter, and generate revenue that can be used for tobacco control.

Benefits and strengths. This FLM has the potential to reach the majority of the population. Reduced exposure to environmental toxins would contribute to long-term health benefits. Shifting the cleanup costs to the tobacco industry would reduce the taxpayer burden.

Implementation considerations. Operational relocation by the tobacco industry from strictly regulated regions to regions with weaker regulatory measures may undermine regulatory efforts. Greenwashing by the tobacco industry through adopting superficial measures and continuing harmful practices is possible if not monitored and acted upon. In light of its long history of deceit and efforts to distance its image from the lethal nature of the product it produces and sells, the tobacco industry may use producer responsibility programmes as part of activities it describes as "corporate social responsibility". Therefore, it has been suggested that the producer-pays principle should be implemented purely as a producer tax, without granting the industry a stakeholder role for the implementation of solutions, in accordance with Article 5.3.

Conclusion. This policy would support public health by generating revenue, which can be reinvested in tobacco use prevention, education and cessation programmes. This would reduce the environmental footprint of the tobacco industry and promote equity and health.

Description of the intervention

The adverse health impacts of tobacco use are well known. However, tobacco not only impacts the health of individuals involved in the lifecycle of tobacco, from those who farm tobacco to those who consume manufactured tobacco products, it also poses significant threats to environmental health. Tobacco farming contributes each year to the loss of 22 billion tonnes of water, 600 million trees, 84 million tonnes of carbon dioxide emissions and 200 000 hectares of deforestation globally (1,2).

Additionally, the excessive use of pesticides and fertilizers harms biodiversity (3). Manufactured tobacco products, such as cigarettes and smokeless tobacco, are the most littered items (4,5), leeching over 7000 toxic chemicals into the environment when discarded. Worldwide, countries spend billions of dollars to clean up tobacco waste, with much of the cost falling on taxpayers (2).

This FLM holds tobacco manufacturers financially accountable for preventing, managing and addressing the negative environmental and related health impacts of waste from tobacco production and consumption. There are several policy approaches to address this principle, including extended producer responsibility (EPR), which places the responsibility on producers to implement solutions that mitigate the environmental harms caused by the lifecycle of tobacco product production and consumption, including soil and water pollution, deforestation and tobacco product and packaging waste. Shifting the financial burden of environmental damage from taxpayers to the tobacco industry ensures that the industry pays the costs of harms, without being granted a stakeholder role for implementing solutions, thereby minimizing the risk of greenwashing.

Availability of information/research evidence on the potential impact of the FLM

Research has examined the potential impact of applying EPR, product stewardship and the principle of "producer pays" in environmental laws for the management of hazardous wastes from other sectors (for example, automotive, consumer electronics, textiles) (6) to policies for tobacco product waste production and management (1,6–11).

In the United States, the non-profit Product Stewardship Institute works with governmental, private sector and non-profit partners to implement the 89 EPR responsibility/product stewardship-based state laws that have been enacted in 33 states (7). These laws address 12 types of waste products including appliances with refrigerants, switches, batteries, carpets, cell phones, electronics, fluorescent lighting, mattresses, mercury thermostats, paint, pesticide containers and pharmaceuticals. For example, the statewide PaintCare law in Oregon requires paint manufacturers to fund and operate a system for the retrieval, transport and processing of paint waste, which contains toxic substances. In 2012, over 70% of the latex paint waste collected under this programme was used to produce recycled-content paint (12). However, a product stewardship is designed to manage the adverse impacts of products that are otherwise beneficial to society, but that through their development or manufacture, their use in certain ways, or their disposal, create negative externalities. Product stewardship does not align well as a strategy for the management of a product such as tobacco which causes significant harms at all stages of its manufacture and use and where that use is being actively discouraged by governments around the world.

In France, since the implementation of the EPR system in 1992, waste management outcomes have improved. Recycling rates for household packaging waste increased from 18% to 70 % in the past 28 years; the collection rate of household packaging waste increased from zero to 53% in the past 13 years, with 74% of collected waste recycled into new materials; and the collection rate for batteries increased from zero to 49% in the past 20 years, with 80% of collected waste recycled into new materials (13). A proposed model based on the well-established principles of EPR and producer pays, as applied to measures that have been adopted in the United States and the European Union, would hold the tobacco industry accountable for tobacco product waste management (7). However, it is important to note that the tobacco industry may use EPR to promote corporate social responsibility, which could undermine regulatory efforts. This vulnerability is discussed below.

In the European Union, the 2019/094 Directive requires tobacco product filter (TPF) producers to contribute to the costs of managing their waste in public collection systems, including litter, in proportion to the amount of product waste generated (14). An appropriate output-based cost model

was proposed to assess TPF quantities in relevant waste streams (14). A 2024 study (15) developed a sampling method to examine TPF quantities in residual waste from four German district types and in waste from public collection systems for three settlement structures within Trier City. The study quantified average specific TPF quantities in residual waste as 277.7, 271.8, 193.3, and 204.5 gi^{-1a-1} in the selected city district, urban district, densely populated rural district and sparsely populated rural districts, respectively. Findings support the development of a cost model based on EU Directive 2019/904, which may assist in cost calculations, verify the success of the measures, and contribute to TPF litter reduction in Germany (15).

The potential public health impacts of this FLM include:

- (1) further de-normalization of tobacco use and increasing anti-industry sentiments;
- (2) increasing the cost of tobacco products;
- (3) supporting the implementation of new regulations, such as banning all cigarette filters, requiring eco-friendly packaging, implementing warnings on the environmental harms of cigarettes on product packaging (as implemented by the European Union), and restricting unsustainable farming practices, to make tobacco products less marketable and mitigate its significant environmental footprint;
- (4) strengthening existing anti-litter and outdoor smoking prohibitions; and
- (5) forging new alliances with environmental advocacy, tobacco control and regulatory groups.

This FLM has the potential to reach the majority of the population. Cleaner public spaces with reduced tobacco product waste would improve the quality of life. Reduced exposure to environmental toxins would contribute to long-term health benefits. Shifting the clean-up costs to the tobacco industry would reduce the taxpayer burden and is an important step towards addressing the environmental harms caused by tobacco consumption and production. Moreover, the overall economic burden of tobacco product waste management may encourage the tobacco industry to increase the cost of tobacco products (7), which could help reduce tobacco consumption. Hence, this FLM would yield multiple community benefits, both directly and indirectly, to the majority of the population. Direct effects would be most evident to vulnerable populations such as youth and adolescents, women and children, low-income individuals, individuals suffering from diseases, and rural and marginalized groups (16,17).

This FLM is expected to have a significant impact over time, if implemented effectively. Environmental improvements may be observed in the short term, while deeper cultural and systemic transformations are likely to develop over an extended period. In the short term, key outcomes may include the adoption of new regulatory frameworks, such as enhanced waste management systems and mandated funding mechanisms, such as tobacco industry fees, for clean-up initiatives. Public awareness campaigns that highlight the environmental hazards of tobacco product waste can encourage changes in behaviour. Over time, this may lead to broader behavioural and market changes. Systematic environmental benefits – such as cleaner public spaces, reduced pollution and improved waste management – will become increasingly evident. Anticipated long-term environmental gains include ecosystem recovery, a substantial reduction in global plastic and non-biodegradable tobacco waste and enhanced public health outcomes. These efforts will contribute to broader climate change mitigation, reinforcing sustainable environmental practices worldwide.

Implementation of this FLM may also shift public perception and amplify criticism of the tobacco industry by calling attention to the environmental harms caused by tobacco production. This could magnify the social unacceptability of the tobacco industry, especially among youth and environmentally conscious individuals. Research has also shown that accountability measures, by reducing tobacco industry profits, can weaken the industry's capacity to lobby against tobacco control and public health policies (18).

Under the producer-pays principle approach, a levy on tobacco companies could be used to fund the implementation of WHO FCTC measures (8). In the European Union, the Single-Use Plastic Directive requires producers of tobacco products with plastic filters to cover the costs of waste management (8). The Government of the United Kingdom suggests that the funds raised from this approach could be used to fund stop-smoking services, in particular for those groups in most need (for example, pregnant women, social renters, people living in mental health institution, and those in deprived communities) and to supress the illicit tobacco market by improving trading standards enforcement (8).

Implementation of an EPR legislation for tobacco product waste management could increase the price of tobacco products to make them less affordable, which would lead to a substantial reduction in tobacco use. Moreover, the revenue collected from the tobacco industry may be utilized to fund tobacco control initiatives, including smoking cessation programmes, and campaigns to educate the public about tobacco product waste and the tobacco industry's responsibility, which may motivate cessation and encourage anti-industry sentiments (7). This may then lead to reduced tobacco sales, and the discontinuation of tobacco product sales by some retailers, although others may lobby for exemptions or alternative waste management solutions.

Some retailers might stop selling tobacco products altogether, while others could lobby for exemptions or alternative waste management solutions. This could undermine the programme's effectiveness, result in continued improper disposal of tobacco waste, and even shift consumer behaviour, possibly reducing legal sales or encouraging black-market alternatives.

It is important to consider that the EPR model has some potential liabilities. Recent commentaries have noted that EPR programmes in tobacco waste have been used by tobacco companies as part of their "corporate social responsibility" objectives (19), citing experiences in the European Union in which EPR programmes have provided tobacco companies with high-profile opportunities to demonstrate their willingness to work with health and environment authorities in environmental clean-up. The casting of industry collaboration with government is in violation of Article 5.3. Indeed, because of these risks, it has been suggested that producer-pays principle should be implemented purely as a producer tax, without allowing the industry to engage in environmental clean-up activity, as they would be doing in an EPR programme (20).

Awareness and profile of the FLM as a potentially promising intervention

Studies suggest that there is strong support for this FLM among policy-makers and the public. A 2023 United Kingdom study found that stakeholders favoured the addition of the polluter pays principle to tobacco control policies, and considered its implementation to be acceptable and feasible (8).

Several countries, including France and Spain, and cities such as San Francisco (California, United States), have adopted the environmental aspect of producer-pays principle in relation to tobacco control (8,21). In Europe, the Single-Use Plastic Directive covers tobacco with plastic filters, requiring Member States to establish EPR schemes (8).

A 2020 New Zealand study of people who smoke and those who do not smoke found that most respondents perceived cigarette butt litter to be toxic to the environment and held smokers primarily responsible for creating tobacco product waste. However, when knowledge of butt non-biodegradability increased, the proportion of those who held tobacco companies responsible for tobacco product waste also increased. Changes to product design, fines for littering, and expanded smoke-free spaces were considered most likely to reduce tobacco product waste (9).

A 2016 survey of 65 members of the Framework Convention Alliance (FCA), a global network of civil society individuals and organizations focused on tobacco control, now known as the Global Alliance for Tobacco Control (GATC), assessed their knowledge, attitudes and perceptions of tobacco product waste. Findings showed that the majority of respondents (57%) were unfamiliar with the EPR and Product Stewardship as possible environmental intervention strategies. Respondents expressing opinions agreed that adding a litter fee to fund tobacco product waste (TPW) programmes would aid in reducing tobacco use and reduce the environmental impacts of tobacco product waste, with 100% agreeing that TPW is harmful to human health, natural environments, drinking water supplies, animals and aquatic organisms. All except one respondent agreed that EPR and product stewardship should apply to tobacco product waste (22).

Studies (9,23) have also found that increasing awareness among the general population about the tobacco companies' role in creating tobacco product wastes is associated with greater support for the FLM.

Implementation considerations specific to this FLM

Potential barriers to the implementation of this FLM include:

- Policy and regulatory limitations: The effectiveness of this FLM could be undermined by weak regulatory frameworks or inconsistent enforcement. Due to the lack of international coordination, the tobacco industry may take the opportunity to hinder the uniform implementation of this FLM across borders, creating regulatory loopholes. Implementation of a policy that balances both economic feasibility and environmental goals may be challenging in the low-resource regions. Promoting global agreements to standardize the implementation across borders may reduce the regulatory loopholes. Industry interferences can be prevented establishing penalties for non-compliance and ensuring oversight. Implementation in low-income countries may need additional support, such as subsidies or international aid, to prevent excessive economic strain.
- Market distortion: Tobacco companies may face competitive disadvantages in regions that implement strict environmental control (producer-pays) regulations. Hence, uneven global adaptation of this FLM could drive tobacco industries to relocate to less regulated regions, causing market distortion.

Implementation of minimum environmental levies across multiple countries could prevent relocation of tobacco companies to less regulated regions. Imposing environmental compliance requirements on imported tobacco products may help to discourage the relocation of tobacco production to jurisdictions with more lenient regulations. Requiring tobacco companies to disclose environmental impact data that is available to the public may encourage responsible practices.

Potential unintended consequences of this FLM include:

- Lobbying: The scope and enforcement of FLM policies to limit the environment impact may get diluted by strong industry lobbying.
- Administrative challenges: Governments may face significant upfront costs for the design, implementation, and enforcement of this FLM, which would divert resources from other critical areas of focus. Consistent enforcement, surveillance, and monitoring are also required for successful implementation.
- Greenwashing: Tobacco industries may adopt superficial measures to greenwash and appear compliant, while continuing harmful practices, such as introducing new and emerging products (for example, electronic nicotine delivery systems, heated tobacco products, nicotine pouches and other nicotine products), which could reduce the overall impact of the FLM. Consistent monitoring and penalties could help to prevent greenwashing and ensure compliance. It should be noted that recent commentaries (19,20,24) have warned that EPR clean-up programmes, in which tobacco manufacturers become stakeholders with government, may well constitute a violation of Article 5.3.

Case studies

Spain: On 24 October 2024, Spain implemented environmental regulations (Royal Decree 1093/2024) that require tobacco companies to cover the costs for the clean-up of discarded cigarette butts (25). Under this regulation, tobacco manufacturers are required to cover 100% of the costs associated with the management of cigarette butt waste. However, the regulation lacks specific provisions for implementation or enforcement mechanisms. This has raised concerns regarding effective policy implementation among both supra-municipal and municipal administrations (24).

Cigarette manufacturers are also obliged to remind consumers not to discard cigarette butts in public areas. A 2023 report estimated that local authorities in Catalonia were paying between €12 and €21 (US\$ 13–22) per inhabitant per year on street cleaning of discarded cigarette butts, with higher rates in coastal areas (26). In addition, there are direct costs for clean-up of other areas where cigarette butts accumulate, such as sewage and water treatment plants and indirect costs linked to their impact on ecosystems, human health, tourism and other economic activities. These findings support the inclusion of an EPR approach for cigarette butts in Spain's environmental regulations (26). Cigarette companies are likely to transfer the cost to the consumer by increasing product prices, which could also work out as another incentive to quit. To reduce smoking in public areas, Spain designated 525 beaches as smoke-free in 2021, which could help reduce tobacco waste pollution on beaches and increase public awareness about the issue. However, a key limitation of such a measure is that it primarily addresses the location of smoking rather than the behaviour itself — potentially leading to the displacement of tobacco waste to other locations rather than its elimination.

France: In 2020, France passed an EPR law that requires tobacco producers to contribute or pay for their waste management, either by running their own waste management system or by paying an eco-contribution to a producers responsibility organization, which uses the funds to manage and recycle tobacco-related waste on their behalf. The circular economy law, adopted on 10 February 2020, introduced 10 new EPR schemes from 2021 to 2025 under Article L541-10-1 of the Environmental Code, including those for plastic-tipped tobacco products. As per the EPR scheme for cigarette butts from 2021, producers have to contribute to clean the city streets (13). EPR schemes in France for cigarette litter not only generated funds for clean-up but it also prompted various public awareness campaigns linking environmental harm due to tobacco use (13). It should be noted, however, that the French EPR law was used by the tobacco companies to partner with the Government, which raises risks associated with the industry's corporate social responsibility

objectives, and is contrary to Article 5.3 (18). Moreover, the organization responsible for the EPR scheme in France, for which the tobacco manufacturers are stakeholders, has been fined more than €1 million for failing to meet its objectives (20,23,27–29).

Summary

Tobacco causes numerous health and environmental harms at every stage of the product life cycle, from cultivation, curing, processing, trading, manufacture, distribution, use and disposal.

Implementation of an environmental control (producer-pays) regulation would hold tobacco manufacturers financially accountable for managing and preventing the negative environmental and health impacts of tobacco production and consumption, serving as a dual-purpose strategy to achieve sustainable economic and public health goals. This FLM aligns with the decision adopted at the Tenth session of the COP in 2024 to protect the environment from the harms of tobacco.

Tobacco industry resistance would be one of the major roadblocks for implementation of this FLM as these industries often found lobbying against regulations and imposing resistance to policies on financial liabilities to dilute the enforcement mechanisms. Besides, potential arguments from tobacco industries on increased operational costing, impacting profitability and higher product prices from consumers can hinder the implementation.

Revenues generated from fines, taxes or environmental impact charges on the tobacco industry can provide significant financial resources. These funds can be allocated to support tobacco control initiatives, such as public awareness campaigns, cessation services, reforestation efforts in tobacco-growing regions and assisting tobacco farmers in transitioning to alternative crops. Reduced tobacco consumption would also decrease the economic burden of treating tobacco-related illnesses and improve overall health-care efficiency. Additionally, imposing financial disincentives for environmentally harmful practices may help regulate tobacco industry corporate behaviours and promote sustainable practices.

The environmental controls (producer-pays) framework promotes environmental stewardship by holding the tobacco industry accountable, and it integrates environmental, financial and health strategies to into reduce the global impact of tobacco on both the planet and society.

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(ii) End of any government support for tobacco farming

Abstract

Policy description and background. Ending government support for tobacco growing aims to phase out tobacco farming, making it more difficult for the tobacco industry to obtain tobacco leaf, and yielding better outcomes for farmers – freeing them to grow more profitable and less exploitative crops, while still receiving support for their activities.

This FLM supports Article 17 of the WHO FCTC, which requires Parties to promote economically viable alternatives for tobacco growing; and Article 18, providing for the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture.

Evidence of impact. Government support for tobacco farming is often based on the perception that tobacco growing benefits national economies. However, economic analyses generally show that tobacco growing does not provide economic benefits for countries or for farmers, and that such government support does not positively contribute to economic growth. Given this lack of economic benefit, and the health harms of tobacco farming both to the farmers and via the products that are created from tobacco, reducing or ending such government support for tobacco farming would be a policy step to consider. In fact, evidence from Sri Lanka, the United States and the European Union indicates that ending government support has led to substantial declines in tobacco cultivation.

Benefits and strengths. Ending government support for tobacco growing would most directly and immediately affect tobacco farmers, who are exposed to health risks and subjected to exploitative contracts and pricing. In theory, if adopted by enough countries, ending government support for tobacco farming might contribute to decreasing the supply and increasing the cost of tobacco leaf, provided a sufficient number of farmers stop growing tobacco.

Implementation considerations. This FLM would need to be accompanied by support to tobacco growers in raising their awareness about the negative health and economic impacts of tobacco farming and in substituting tobacco growing with economically viable alternative activities. The tobacco industry response might be to attempt to provide so-called solutions in lieu of government support, while continuing with exploitative contracting and pricing approaches that leave farmers impoverished. To avoid this, governments should regulate industry practice, contracting and pricing of tobacco leaf, and should support transition to economically viable alternative activities.

Conclusion. Widespread adoption of this FLM could decrease the supply of tobacco leaf, leading to price increases and ultimately to decreased tobacco use.

Description of the intervention

Governments provide direct and indirect support for tobacco growing in many forms. While some countries have ended this support, many countries have continued to provide support to tobacco farmers because they believe it yields economic benefits for the country and supports livelihoods for these farmers. However, studies on the economic impact of tobacco growing have concluded that, taking into account all relevant variables, tobacco growing does not provide economic benefits for countries or for farmers (1,2).

Many tobacco farmers suffer from exploitative tobacco industry contracting and pricing approaches. Tobacco farming often involves children. Tobacco growing exposes farm labourers to toxic chemicals that are associated with skin and eye irritation, nerve damage and respiratory symptoms. Wet tobacco leaves can also cause green tobacco disease (3).

Ending government support for tobacco growing aims to decrease tobacco farming, making it more difficult for the tobacco industry to obtain tobacco leaf. This yields better outcomes for farmers and frees them to grow more profitable and less exploitive crops. As many tobacco farmers have predatory loans from the tobacco industry to pay back, this FLM should include support to relieve such indebtedness.

The purpose of this FLM is to end tobacco farming while providing support for tobacco farmers. This FLM aligns with principles of WHO FCTC Article 5.3 to prohibit government support for the tobacco industry. While the definition of "tobacco industry" in the WHO FCTC does not include tobacco growers, tobacco manufacturers depend on growers for their products. Further, Article 17 calls for replacing tobacco growing with alternative activities, and Article 18 references measures in respect to tobacco cultivation considering the health of persons.

Governments in many parts of the world have been providing support for tobacco growing since the 1800s. Lencucha and Drope (2022) describe how tobacco growing was globalized by European colonial powers to decrease reliance on tobacco grown in America (4). "For example, the British empire sought to supplant its reliance on the US for tobacco by commandeering and allocating large swaths of fertile land in sub-Saharan Africa for tobacco growing," they conclude (4). By the late 1800s many governments were providing support for tobacco growing, and "these institutional arrangements, including longstanding tobacco governing boards with tobacco industry representation, and agricultural research agencies with mandates to improve the quality and quantity of tobacco being produced, serve to perpetuate both material support for tobacco growing and a normative environment that unquestioningly views tobacco as an important economic commodity" (4).

While some jurisdictions, including Australia, Canada and the European Union, have eliminated or significantly diminished tobacco growing, many other countries, including a number of LMICs, continue to provide support to tobacco growers. More than 124 countries grow tobacco (5). The top tobacco growing countries are Brazil, China, Indonesia, Malawi, Mozambique, Türkiye, the United Republic of Tanzania, the United States and Zimbabwe. As of 2023, China and Brazil accounted for more than 50% of all tobacco grown in the world. Notably, high-income countries (HICs) have substantially reduced tobacco growing while LMICs have increased production. LMICs grow more than 90% of the tobacco leaf that is used globally for tobacco production (6).

Many countries, including WHO FCTC Parties, continue to provide both direct and indirect support for tobacco growing. Direct support includes subsidy payments to farmers, including "cash to farmers for growing a particular crop and/or crop loans on softer lending terms, crop insurance, etc." (5). Indirect support is provided by artificially decreasing the price of inputs such as seeds and fertilizer. Indirect support can also be provided in the form of supportive infrastructure including roads, irrigation and loans (6). Some countries, including the Philippines and Argentina, use tobacco tax revenues to fund these types of support (6). A 2023 World Bank report provides specific examples of government support for tobacco growing in Argentina, the European Union, Lebanon, North Macedonia, the Philippines, Switzerland, the United States and Zimbabwe (5).

Availability of information/research evidence on the potential impact of the FLM

Governments provide support for tobacco growing because they believe that it benefits their economies. However, recent analyses demonstrate the pitfalls in this belief (7) and a 2023 WHO report concludes that government support for tobacco growing does not actually contribute positively to countries' economies. In fact, "Tobacco is erroneously perceived to be a highly

profitable cash crop, as the tobacco industry exaggerates its economic importance. In most tobacco-growing countries, the contribution of tobacco leaf imports and exports is small." (5)

There is some evidence that ending government support for tobacco growing in HICs can lead to benefits in reducing tobacco farming. A 2016 report found that decreased government support for tobacco growing in the United States led to a reduction in the number of farms growing tobacco due to decreased profitability (6). The European Union has not provided support for tobacco growing since 2010. While tobacco growing has decreased substantially, the tobacco farmers in the European Union still "received nearly US\$ 52 million in direct payments between 2015 and 2020."(5) A 1990 review of the tobacco growing industry in Australia found that tobacco farming "was by far the most subsidized agricultural activity in Australia, receiving assistance at around six and a half times the rate of other horticultural activities, and over 12 times the average rate for all agricultural activities."(8) A buy-out scheme resulted in the end of all commercial tobacco growing in Australia by the year 2017 (8).

There is limited action, or available data, on the impact of ending government support on tobacco growing in LMICs. A 2019 WHO report indicated that Bangladesh "dropped tobacco from its cash crop list and the Ministry of Industry stopped giving subsidies on fertilizers to BAT [British American Tobacco]" (9); however, the effects of these measures for tobacco farming in Bangladesh are unknown. A 2023 report in Sri Lanka found that after substantial reductions in government support for tobacco growing from 1990 to 2020 in that country, land devoted to tobacco growing decreased from 8920 hectares to 1143 hectares over this time period, translating to a decrease in proportion of agricultural land from 0.47% to 0.04% (10). In Brazil, decreased government credit for tobacco growing resulted in a decrease in government provided loans for tobacco growing from 87% in 1999 to 1% in 2017, and in significant reductions on tobacco growing (11).

Government involvement in supporting tobacco growing is one of the most explicit ways in which governments continue to cooperate with the tobacco industry. This FLM would disrupt this part of the system.

Awareness and profile of the FLM as a potentially promising intervention

Some jurisdictions have eliminated or significantly diminished tobacco growing (for example, Australia and the European Union), or reduced support for tobacco growing (for example, Sri Lanka and Brazil), as previously discussed. However, governments continue to provide direct and indirect support for tobacco growing in many countries. Ending government support for tobacco growing is very much on the global agenda as evidenced by the call in the WHO 2023 No Tobacco Day report to end government support for tobacco growing, in alignment with Article 17 of the WHO FCTC.

Implementation considerations specific to this FLM

Some tobacco growers may oppose the end of government support, as it could directly threaten their livelihood. Implementation of WHO FCTC Article 17 measures to support tobacco growers to substitute with alternative activities, could mitigate this opposition, especially if accompanied by education on the negative health and economic impacts of tobacco growing. Tobacco industry incentives are a major barrier to the implementation of measures to support tobacco farmers in transitioning to alternative activities. According to the WHO, "In most countries, farmers have had trouble shifting away from tobacco because of the incentives provided by the industry, such as seeds, financing, access to agricultural training, and an assured market. Despite typically yielding net economic losses overall, tobacco is an assured market that generates small windfalls of cash, which makes moving away from tobacco challenging from a farmer's perspective." (12)

To avoid this, governments should regulate industry support, contracting and pricing of tobacco leaf and support transition to alternative activities as called for in Article 17. This could, for example, involve funding to tobacco farmers to repay loans owed to the tobacco companies.

Case studies

The Portuguese settlers started growing tobacco in Sri Lanka in the 16th century. Over time, various governments promoted tobacco growing. By 1990, 8920 hectares (0.47% of agricultural land) was being used for tobacco cultivation (10).

A 2023 report by the Institute of Policy Studies Sri Lanka notes that in light of sharply decreased government support for tobacco growing, from 1990 to 2020 land devoted to tobacco growing decreased from 8920 hectares to 1143 hectares translating to a decrease in proportion of agricultural land from 0.47% to 0.04% (10). Data collected and analysed for this report demonstrate that tobacco farming is not particularly profitable "for most smallholder tobacco farmers in Sri Lanka" and that several food crops are more profitable. Those who continue to farm tobacco do so "because of easy crop management, drought tolerance, contract benefits and an assured market". Notably, the study found that young people are less likely to be involved in tobacco farming than older farmers (10).

The Government of Sri Lanka had indicated its intention to ban tobacco growing altogether by 2020. While this has not occurred, support for tobacco growing has been stopped and measures introduced to help farmers move to alternative activities. Justification for the ban was rooted in an effort to decrease tobacco use in Sri Lanka (10).

Summary

Ending government support for tobacco growing aligns with the principles of the WHO FCTC Article 5.3 prohibition of support for the tobacco industry, the Article 17 call for replacing tobacco growing with alternative activities and the Article 18 call for measures implemented in respect to tobacco cultivation considering the health of persons. Adopting this FLM would close an obvious gap in the WHO FCTC's efforts to end government involvement in the tobacco enterprise.

Many countries, including WHO FCTC parties, continue to provide both direct and indirect support for tobacco growing. Government support is rooted in the perception that tobacco growing benefits their economies. However, economic studies refute this claim (5).

Eliminating and decreasing government support has led to substantial declines in tobacco growing in Brazil, the European Union, Sri Lanka and the United States. Over 90% of tobacco growing occurs in LMICs, and the bulk of this is done on small farms by impoverished farmers suffering at the hands of exploitative practices of the tobacco industry. Ending government support for tobacco growing together with strong supports for helping farmers transition to alternative activities, could potentially reduce inequities in tobacco farming and production.

Alongside the WHO No Tobacco Day report call for ending government support for tobacco growing, Sonja von Eichborn, Director of the Unfairtobacco project, stated that, "tobacco farmers are not the enemy, but the weakest actor in the tobacco trade system, and they need support from governments and rich countries to step away from growing tobacco." (13)

Ending government support for tobacco growing will not, on its own, disrupt the supply of tobacco leaf. Additional steps will be necessary to prevent the tobacco industry from stepping in to replace government support and continue its exploitation of small tobacco farmers. Implementation of

Article 17 measures to support tobacco growers in transitioning to alternative activities would help to ensure successful implementation of this FLM. Minimally, ending government support should increase the cost of tobacco leaf which could increase the price of finished product to consumers, decrease tobacco industry profitability, or both.

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(iii) Measures to reduce tobacco supplier profits and pricing power

Abstract

Policy description and background. This FLM comprises two components: a cap (a maximum level) on the wholesale price of tobacco (the manufacturer price) the tobacco industry is able to charge, based on product production costs plus a modest, regulated profit margin; and a substantial increase in tobacco excise taxes and/or the application of a new "polluter pays" levy to ensure that retail prices remain high. It would limit tobacco industry using differential pricing strategies to undermine tobacco tax policies, thereby leading to decreased industry profits, increased government tax revenues and, ultimately, reduced tobacco consumption.

This FLM supports Article 6 of the WHO FCTC, requiring Parties to adopt or maintain measures including implementation of tax policies and, where appropriate, price policies, on tobacco products as effective and important means to contribute to the health objectives aimed at reducing tobacco consumption.

Evidence of impact. A wholesale price cap and concomitant tax strategy have been recommended as a policy by several organizations in the United Kingdom. However, this FLM has not been implemented by any jurisdiction to date. The measure is justified based on its potential to effectively limit tobacco industry monopoly power that creates very high profit margins, and to support public health by limiting price-based sales tactics and increasing government tax revenues.

Benefits and strengths. Implementation of this FLM would be likely to lead to substantial reductions in tobacco industry profit incentives, to limit tobacco industry price-based sales tactics that undermine tax policies, and to generate substantial additional government tax revenues that can be used to support public health and other goals. This measure would have the potential to raise the cost of the cheapest tobacco product brands, which could reduce tobacco consumption and increase cessation – particularly among low-income groups who are more price sensitive.

Implementation considerations. Effective implementation of this FLM will require a regulatory body to set and periodically adjust price caps based on production costs, and tailored to the unique context and needs of individual jurisdictions. Safeguards to protect this regulatory body from any influence by the tobacco industry are essential, in accordance with Article 5.3 of the WHO FCTC. Policy-makers should also consider whether this FLM should be applied across all tobacco products, to avoid tobacco industry transitioning to other products outside the FLM. Investing additional tax revenue to fund cessation support for disadvantaged groups should be considered to prevent financial strain on those unable or unwilling to quit.

Conclusion. This FLM aims to control tobacco product prices in order to reduce significantly the industry's ability to segment markets and manipulate prices (such as by offering cheap "starter" brands or luxury "premium" brands). The measure would make existing tobacco taxes more effective and hence reduce tobacco consumption, while the accompanying tax increase/polluter pays levy to offset the reduction in wholesale prices would prevent unintended reductions in retail prices. The government revenue could be reinvested in tobacco control efforts, public health and other initiatives.

Description of the intervention

The tobacco industry has produced products that have caused the premature deaths for over 100 million people in the 20th century, and tobacco is projected to cause up to one billion deaths in the 21st century. It has also been identified as the most profitable industry during the 20th century (1). The juxtaposition of these two extraordinary facts about the tobacco industry has been noted, with

measures being proposed to reduce tobacco use and other measures proposed to reduce the profitability of the tobacco industry.

Tobacco excise tax is widely regarded as one of the most effective tobacco control measures (2.) The resulting increases in retail price discourages consumption, both by existing people who smoke and by deterring initiation by potential new consumers (3). They are also a win—win policy for public health in that tobacco taxation can raise considerable sums of government tax revenue (some of which can be spent addressing tobacco use).

Tobacco excise taxes are therefore a powerful instrument for reducing consumption. However, tobacco companies can still use pricing strategies (for example, differential shifting of taxes, introduction of new brands or products, price-related promotions, among others) to undermine tobacco tax increases (4).

This FLM consists of two components, which together would: (a) decrease the profitability of the tobacco industry; and (b) transfer a proportion of that profitability to the governments. This FLM would also fulfil the objective of limiting tobacco industry pricing behaviour.

The first component of the FLM would be to impose a cap on the wholesale price of tobacco based on the cost of production. The cap would be set by a regulatory body with no direct involvement of the tobacco industry beyond government mandated provision of data, consistent with WHO FCTC Article 5.3 and its guidelines (5). This first component of capping wholesale prices would then be combined with the second component: a substantial tax increase (for example, an increase in existing excise taxes, or as a new polluter-pays levy). These two components in combination would limit the ability of the tobacco industry: (a) to use differential pricing strategies to undermine tobacco tax policies; (b) to remove the profit incentive for the sale of tobacco products; and (c) to redirect the vast majority of the tobacco industry's substantial profits into government revenue through the implementation of that second tax component. Ultimately, this FLM would reduce tobacco consumption, generate government revenue for tobacco control initiatives, and reduce the health burden of tobacco use.

Availability of information/research evidence on the potential impact of the FLM

This FLM is grounded in two key characteristics of the tobacco domain. The first – common across industries – is that the tobacco industry passes on the cost of excise taxes to consumers. Notably, it does so through differential pricing strategies: under-shifting tax increases for lower-priced cigarettes while over-shifting for higher-priced ones, thereby softening the overall impact of tax increases on demand (4). As a result, these demand-side taxes tend to have minimal impact on industry profits, and lead to modest reductions in tobacco consumption.

The second characteristic is the exceptionally large profit of the tobacco industry. A 2021 analysis by Branston (6) reported that in 2018 the six largest global cigarette manufacturers made pre-tax profits exceeding US \$55 billion, which is higher than the US\$ 51 billion combined profits of major multinational corporations such as Coca-Cola, PepsiCo, Nestlé and others (7–9).

Branston (6) went on to report that tobacco companies can achieve such massive profits as a result of very high profit margins. In 2018, Imperial Brands reported a global operating profit margin of 46% (10), rising to 63% in the market in the United Kingdom, where it increased to 71% in 2019 (11) This means for every £100 in revenue (after paying excise taxes), £46 was profit. Such margins are substantially higher than those of other global industries, which generally have operating profit margins of around 15-16% (7-9,12-17).

This inordinate profit drives industry behaviour as it would be difficult, if not impossible, for the industry to earn similar profits from other commercial activities. As profit-seeking commercial companies, the global tobacco industry naturally fights all measures that might disrupt their ability to continue to make such profits. As such, a policy designed to impact industry profitability would reduce the profit-focused incentives that drive the industry's behaviour. If selling tobacco products is no longer profitable, the industry would lose interest in selling such products (at least in those markets where no profits were possible). As such, the key to the success of any such measure is the extent to which it reduces industry profitability over time. A slight reduction or a one-off reduction in profitability is unlikely to change incentives enough to make a meaningful difference. Furthermore, such a policy would be far more attractive if it could have wider public benefits beyond just reducing industry profit.

The following models have been suggested/utilized to prevent tobacco industry pricing strategies and limit their profits: (1) a surcharge on corporate profits; (2) a novel tobacco tax based on the value and/or volume of tobacco sales; (3) minimum unit pricing; and (4) direct tobacco price controls with a concomitant tax increase.

1. Surcharge on Corporate Profits

An additional tax (as compared to other industries) could be applied to the standard rate of corporate profit taxation each country charges. It could be applied at various parts of the tobacco supply chain, from manufacturers to distributors (18). The problem with this approach is that the global tobacco industry is internationally structured to minimize their corporate tax liabilities. As such, any attempt by a single country to increase taxes on tobacco industry profits will likely result in the tobacco industry simply reorganizing their corporate structures to make sure their future profits are reported elsewhere (19). For example, Canada implemented the Tobacco Manufacturers Surtax (TMS) as a temporary surtax of 40% additional corporate tax income on tobacco manufacturers in 1994, with the tax being made permanent and increased to 50% in 2001 (20). However, between 1994 and 2012, the relocation of cigarette manufacturing from Canada to Mexico, together with reductions in general corporate income tax rates by the Canadian Government (in 2006 and 2009), significantly reduced the tax burden on tobacco manufacturers operating in Canada – resulting in an estimated 60% decrease in the profits from domestic tobacco sales between 2005 to 2012, and costing the federal treasury US\$ 86 million in 2012 (18). As such, a profit tax surcharge would only be effective if implemented at the global level (for example, through the WHO FCTC) or if applied as a windfall tax (21). A sudden one-off windfall tax, if implemented without prior notice, would be virtually impossible for companies to avoid or circumvent. However, as a time-limited form of taxation, it would not change industry behaviour in the desired manner.

2. Novel sales-based taxation

A second option would be to apply a levy or charge on the tobacco industry based on its historical market share. This approach is used in the United States through Food and Drug Administration (FDA) user fees (22), and a similar scheme has recently been introduced in Canada (23,24). Such tax charges create a fund that is based on the value/volume of tobacco sales in the previous year. This approach can effectively raise revenue, particularly if hypothecated for health-related purposes. However, such schemes are a more complex variation of tobacco excise tax, where the tax is applied retrospectively rather than at the time of sale. The industry can plan for such taxation, and as with other forms of excise tax, they would pass the cost on to people who smoke in the form of higher

retail prices. As such, this approach will neither curb the excessive profits of the industry nor produce broader benefits through shifts in industry behaviour.

3. Minimum unit pricing

A third option would apply a minimum unit pricing (MUP) strategy to tobacco products. This approach has been adopted in a limited number of markets for alcohol, where the government sets a floor price per unit to be sold that applies to all forms of alcohol products. While it has been suggested that this could be applied to tobacco products (25), there are several implementation challenges to consider. First, as both the weight of tobacco and nicotine content absorbed by consumers varies between products, there is no clear standard "unit" for tobacco products as there is with alcohol. Second, MUP requires setting higher retail prices for the cheapest products/brands. While this can effectively deter tobacco use, any increase in sales revenue would benefit manufacturing companies through higher profit per unit, rather than increasing government tax revenues. Additionally, since MUP only sets a lower threshold for prices, it allows the continued use of price as a selling tactic above the minimum level.

4. Wholesale price control and concomitant tax increase strategy

The fourth possibility is the one that forms this FLM, which combines two components that, if implemented together, would reduce industry profits and increase government tax revenue, with the overall impact being to limit tobacco industry pricing strategies.

The first component would be to introduce a cap (maximum level) on the wholesale tobacco price (manufacturer price) the tobacco industry is able to charge. Such a price cap could be based on an assessment of the cost of producing the product, including an allowance for a small return on capital/rate of profit in line with other manufacturing industries. A cap of this type would explicitly limit the profit the industry was able to achieve by lowering the wholesale price.

An additional benefit of capping wholesale prices is that it would make it difficult for the industry to segment the market as they currently do. Wholesale price caps could be applied to specific products (that is, one price cap for factory-made cigarettes, another price cap for fine cut tobacco for roll-your-own cigarettes, etc). With a single price cap per product type, the industry would not be able to apply such huge price differentials between their discount and premium brands. All brands would have to comply with the price cap, so any price differentials could only be created by pricing below the cap, and the limited level of profitability allowed would severely curtail the space for doing so. Essentially the price caps would remove price from being a key marketing strategy, as the industry would no longer be able to offer some very cheap brands to encourage uptake/prevent cessation and some very expensive brands to maximize profits. By removing this tactic of price, excise tax increases would also be made more effective as the industry would have very limited capacity to engage in the over- and under-shifting that currently happens when taxes increase in many tobacco markets.

To set the wholesale price caps for a given market, a government department or independent regulatory body would need to be tasked with the responsibility. This body would assess the production costs faced by the tobacco industry when producing/importing each tobacco product (either within that country or overseas and again at the border if imported) and make an assessment as to what wholesale price is required to cover those costs, including the tobacco excise duties to be paid. A small uplift would then be added to allow the industry a small amount of profit in line with that earned by other manufacturing companies. The result would then be the wholesale price cap

to be applied. This cap could be set annually or for a two-year period given that forward planning is not required in the tobacco industry in the same way it is for capital intensive utility industries where price caps are generally applied for several years at a time to give the industry clarity to facilitate investment decisions.

Such price caps would need to be set on a country-level basis to account for the individual nature of the market and the tobacco excise tax applied therein. However, groups of countries could work together to assess production costs to make it easier for an individual country to set the appropriate caps. For example, in the European Union, where tobacco production is concentrated in several member states, the assessment of production costs could be shared among the relevant countries, who would then account for additional costs incurred, such as transportation costs and domestic excise taxes.

Capping wholesale prices at a low level would, by itself, result in lower retail prices, which would lead to the undesirable consequence of increasing tobacco use. To rectify this, the proposed policy would require a second component: the imposition of a concomitant and matching increase in tobacco product taxation when the price caps are applied to ensure that the retail price does not decrease. This second component could be applied as a one-off increase in existing tobacco excise taxes or as a new 'polluter pays' levy introduced at the same time (and updated as needed if the price caps change over time)(26–28). The latter has the option of more easily allowing the additional tax revenue to be hypothecated for specific health purposes, and it can be presented to the public as a scheme to capture what was previously tobacco industry profit as new tax revenue. Such a new tax could be applied to the tobacco manufacturing companies in the same way as existing excise taxes, and as such could be a part of tobacco taxation, alongside any existing taxes.

This FLM of wholesale price control and concomitant tax strategy has not yet been introduced in any market. However, it has been proposed in academic research and has been adopted as a recommended policy by several organizations in the United Kingdom (29–31). Studies by conducted by Action on Smoking and Health (United Kingdom) has found the majority of the public would support the introduction of this FLM.

This two-part strategy is supported by two main justifications. First, it recognizes the monopoly power that exists in many tobacco markets, such as the United Kingdom. While there are four global transnational tobacco companies, all of which operate in the United Kingdom, the market for tobacco is not one where intense competition is visible (32.) Well-intentioned tobacco control measures, such as advertising and product display bans, remove traditional avenues for firms to compete against each other. Furthermore, the extreme level of profit and profit margins identified earlier on are not possible in a dynamic competitive market.

The United Kingdom market is not unique with the industry reporting enormous profits in many of their global markets. In regular product markets where a lack of competition has been identified, governments (or government-appointed bodies) generally look to enhance competition where it is possible to do (33). However, with tobacco, more competition would mean lower retail prices and hence more tobacco use. As such, governments may need to consider an alternative approach. In markets where competition is not possible, such as markets economists identify as natural monopolies like centralized water supply, price-based regulation is often used instead (34). The application of price-based regulation in the tobacco market thus represents an extension of conventional economic approaches used in markets where firms have monopoly power.

The second justification can be made based on the substantial health benefits that would be realized from this two-part FLM that both removes industry price-based selling tactics and directly and substantially increases tax revenue for government. Accordingly, this FLM may be viewed favourably from the perspectives of both economics and health.

Awareness and profile of FLM as a potentially promising measure

This FLM has the potential to help address the public health challenges and the societal costs of tobacco use. Tobacco tax measures at the expense of industry profits may help advance the United Nations Sustainable Development Goals (SDGs) to ensure health and well-being, and reduce inequality (35), by providing a funding mechanism for public health programmes and universal health coverage, while holding the tobacco industry financially accountable for its role in causing non-communicable diseases.

The revenue generated through the tobacco tax measures that reduce industry profits can be invested in public health infrastructure including health education and social marketing campaigns and tobacco cessation programmes leading to the overall improvement of preventive health care. In the Philippines, implementation of the 2012 Sin Tax Reform Act raised over US\$ 3 billion in the first year of implementation. A significant portion of the generated revenue was allocated to fund universal health coverage and public hospitals (36).

Canada has integrated tobacco surtax proposals into its public health and legislative policy in response to the economic impact of tobacco use and its potential to strengthen health-focused policies (see previous section for details).

Implementation considerations specific to this FLM

The nature of the price caps set/new levy to be introduced could vary to account for the market conditions and political environment of the particular national or regional market in question. For instance, the FLM could be introduced in a way that either increases the price of the cheapest brands up towards the more expensive brands, or in a way that keeps the mean retail price the same (but with a much lower spread of prices around it). Furthermore, the price caps could be introduced in a phased approach over several years or introduced at a single point in time. The selection of one of these approaches, which each present unique opportunities or issues, should be based on the specific context and needs of individual countries.

To implement this FLM effectively, a regulatory body would need to be established to set the initial price cap and to periodically review and adjust it. This body would periodically need to receive information from the tobacco industry to assess their production costs as part of the process for determining the price cap. There is a risk that such a body could suffer from what is known as regulatory capture – adopting the world view of the companies to be regulated (37,38). This is a well-known risk with any form of regulation but is unlikely to present a major challenge given that tobacco industry regulation is far less complex than regulation of industries more traditionally subject to price controls, such as public utilities like water or electricity. Furthermore, this regulatory body could exist either as a direct part of government (for example, a department of health) or as an independent regulator either given the role as part of wider regulatory responsibilities or created just for the specific purpose. The regulatory body tasked with setting the price caps would need to be diligent in adhering to the requirements of WHO FCTC Article 5.3 and its guidelines, to minimize the risk of regulatory capture.

The nature of the price caps applied might also address wider industry health harming behaviour. When assessing the cost of production for use in determining the price cap, expenditure on "especially undesirable" activities might be disallowed. For example, marketing expenditures or legal expenses incurred when fighting future public health measures are unlikely to be considered as legitimate costs of production. Engaging in such actions would therefore be discouraged.

Policy-makers must also consider whether this FLM should be applied across all tobacco products. Any products for which this FLM would not be applied might create incentives for industry transitions to those other highly addictive products. Parties would need to consider the impact of those incentives in their tobacco control strategies.

The implementation of this FLM is likely most feasible in countries with strong tobacco control measures, including high taxes, which have already led to substantial declines in tobacco use. It is also important to note that in many low- and middle-income countries, the tobacco industry has deliberately kept the wholesale prices much closer to the production costs to grow consumption and prevalence. In such countries, the strategy of capturing excess profits through a cap on wholesale price would not achieve the same kind of financial benefits as it would in high-income countries, where the wholesale prices are significantly higher than the production price.

There is one other scenario in which this FLM may not be feasible or effective in reducing industry profit. In countries where the tobacco manufacturing industry is a state-owned enterprise (SOE), there is no real distinction between the SOE financial surplus (that is, profits, being the difference between production cost and wholesale price) and tax revenue, since both accrue to the government. As such, this scheme would not generate additional government revenue, although there would still be the wider benefits from controlling the range of prices available in the market.

One of the key benefits of this FLM is that it would raise the price of the least expensive tobacco brands. This would aid in preventing smoking uptake and encourage greater cessation from existing consumers. However, as with tax increases this would come with socioeconomic implications. The least expensive tobacco brands are those most likely to be consumed by individuals in lower socioeconomic groups. These individuals are frequently the most sensitive to price so would therefore have a greater incentive to quit (and not start), and hence the measure would have a positive equity element to the policy (39). It might also increase the financial burden on individuals who are unable or unwilling to quit. As such, it would be important to allocate a portion of the additional tax revenue for smoking cessation services to support those in disadvantaged groups who continue to smoke.

A related although distinct benefit of treating all brands equally is that this would reduce variability of prices across brands – an effect similar to changes in tax structure (from ad valorem to specific), which has been shown to lead to lower consumption (40).

It is not clear how the industry might respond to the first imposition of such a FLM. There are several possible areas where industry action might be foreseen. First, the industry might reorganize their activities to claim as costs of production, profit that is being made in other countries using similar tactics to those adopted to avoid profit based taxation (for example, charging domestic subsidiaries fees to use particular brand names). Such tactics should be possible for the regulator to identify and combat using historical data and by, for example, only allowing limited profit on the cost of using particular brand names or if needed, encouraging the sale of products with generic brand names (particularly in markets where plain/standardized packaging has been introduced). Second, existing companies might threaten to withdraw from any market introducing this FLM. This seems unlikely

as some low profits are better than none. Third, tobacco companies may adopt a low-price strategy, by selling at least some of their products below the price cap. Not only would they have limited ability to do this because of the low rate of profit allowed by the cap, but if such behaviour was observed, the industry regulator could be given "urgent review" powers to tighten (that is, lower) the price cap and increase the polluter pays levy at the next periodic review. This would effectively lower the industry profit going forward so would be a counterproductive strategy for the industry to adopt. Finally, it might be that the industry would want to feed the illicit tobacco market to make more profit on illicit sales then they were able to do on legal sales. Such an incentive likely already exists in markets with high tobacco taxes. Existing tools for industry monitoring (for example, track and trace) and enforcement of other tax measures could be deployed in response. Indeed, with more tax revenue raised, enhanced funding for enforcement would increase the potential to reduce the size of the illicit market.

The wholesale price control and concomitant tax increase approach would be implemented in addition to existing excise tax rather than replacing it. Removing cheap tobacco from the market would limit the ability of the industry to use such brands to minimize the impact of tobacco tax increases, thereby increasing the effectiveness of future tobacco taxation measures.

This FLM can be implemented in conjunction with other existing and future tobacco control measures, including other FLMs such as changes to the retail environment. The FLM proposed herein may reduce industry resistance to future measures, as the impact of new measures could be considered as part of the price-capping process. The costs of fighting these measures would simply reduce profits, if they were not considered to be an allowable cost of production.

The tobacco industry has traditionally used other parts of the tobacco supply chain to fight against tobacco control measures. However, with this FLM the other parts of the tobacco supply chain should not be significantly impacted. By setting wholesale prices charged by the tobacco manufacturers, retailers can still be allowed to make their current profit margins on each sale, while those supplying raw materials to the industry (for example, tobacco leaf) would have their costs allowed for as part of the price capping process so the industry would not be able to sustainably increase profits by reducing inputs costs.

Summary

This FLM aims to control tobacco product prices to simultaneously reduce the profitability of the tobacco industry and redirect its previous excess profits to government taxation, which could be reinvested in public health and other initiatives. The proposed policy includes two synergistic components: 1) a regulatory cap on the wholesale price of tobacco products based on actual production costs plus a modest, regulated profit margin; and 2) a concomitant increase in tobacco taxation to ensure retail prices remain high, thus maintaining the deterrent effect on tobacco consumption.

This intervention addresses two structural characteristics of the tobacco industry: its use of differential pricing that undermine tax increases; and its abnormally high profit margins – ranging from 40–70%, which is far above the global industrial average of 15–16%. These profit levels not only incentivize continued tobacco sales but also make the industry highly resistant to standard public health interventions.

Capping wholesale prices would significantly reduce the industry's ability to segment markets and manipulate prices (for example, offering cheap starter brands or luxury premium brands). This would make existing tobacco taxes more effective and hence reduce tobacco consumption. The

accompanying tax increase to offset the reduction in wholesale prices would prevent unintended reductions in retail prices.

The combined cap-and-tax strategy offers a unique solution to reduce tobacco industry profit incentives, limit its ability to undermine tax policy and increase government revenue to fund tobacco control efforts. Implementation would require independent regulatory oversight and country-specific adaptation. However, this FLM is a scalable and impactful policy innovation with both economic and public health benefits.

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(iv) End the commercial sale of tobacco industry products

Abstract

Policy description and background. This FLM eliminates what has been described as the "perverse incentive" tobacco product manufacturers and, to a certain extent, retailers/distributors currently operate under, whereby the more products they sell, the more profit they make. These increased sales lead to higher tobacco use, and consequently increased health harms. This model requires tobacco industry products to be supplied by not-for-profit enterprises that operate under a strict public health mandate, overseen by a not-for-profit authority. This FLM would reduce and subsequently eliminate profits that can be made by the tobacco industry and, as the case may be, retailers and distributors. The policy has the potential to rapidly reduce tobacco harms in the population.

The model complements implementation of price and tax measures under Article 6 of the WHO FCTC, and prevention of illicit trade in tobacco industry products under Article 15, as it takes over the supply chain, thereby allowing greater oversight and record-keeping, and eliminating potential avenues for supply of illicit tobacco industry products through retailers. The not-for-profit authority would have the ability to exert controls in line with Articles 9 and 10 on the regulation of contents and disclosure of tobacco products and Article 11 in respect of packaging and labelling of tobacco products. Lastly, the model would facilitate effective implementation of Article 13 by banning tobacco advertising and promotion through product packaging and in retail outlets.

Evidence of impact. No jurisdictions have implemented a model where commercial sales are banned, and products are supplied through not-for-profit enterprises with a public health mandate. Evaluations of government-owned alcohol monopolies document public health benefits of governments taking over the supply of a dangerous product, even when none were operating with a public health mandate as a priority. Implementation of the proposed model under a strict public health mandate would be likely to lead to significant improvements in public health.

Benefits and strengths. The strength of this FLM is that it dismantles the current tobacco product supply chain that underpins many of the barriers and delays that Parties may face when implementing articles of the WHO FCTC. The model would eliminate the ability of the tobacco industry to recruit and addict new users to their tobacco products. Benefits to those already addicted to tobacco industry products are significant: individuals would no longer have to overcome the temptation and triggers that ubiquitous commercial access to tobacco industry products currently burdens them with when trying to break their tobacco dependence.

Implementation considerations. With the right political will and with expert and careful development and implementation of the model, any barriers to implementation could probably be overcome. A key consideration is that the implementation of this model, if applied to tobacco products only, could lead to tobacco users switching to nicotine products such as electronic nicotine delivery systems (ENDS) and nicotine pouches. This would mean that their nicotine addiction would be maintained, and the tobacco industry would continue to profit from this addiction, while users face the health, social and economic consequences of their continued addiction.

Conclusion. The proposed FLM can be seen at the end of a continuum under which many countries have already introduced restrictions on supply of tobacco products, and surveys show there is strong public support for banning the sale of tobacco products. The model helps to overcome barriers to the implementation of the WHO FCTC, and accelerates the elimination of tobacco industry interference and use of tobacco industry products.

Description of the intervention

It has been described as a "perverse incentive" that the tobacco industry has been allowed to operate under a model where subject to some constraints on its conduct, its profits increase with the number of people it addicts and the volume of products it sells – a dynamic that underlies the health, economic and social devastation caused by tobacco, which led to the creation of the WHO FCTC (1). Corporations that supply tobacco products are designed, managed, governed and mandated to maximize profits, even when doing so results in human harm (2). It is within a government's power to change this corporate model in the public's interest and remove the ability for corporations to profit from selling addictive and potentially lethal products.

The tobacco industry remains one of the most profitable industries in the world with revenue of US\$ 912 billion in 2022 from global tobacco sales (3) and projected revenue of US\$ 988.4 billion in 2025 (4). In addition, between 2014 and 2018 the value of the global e-cigarette market more than doubled from US\$ 6.8 billion to over US\$ 15.5 billion, and by 2021 it had increased to almost US\$ 22.8 billion (5). These high levels of profit provide the tobacco industry with significant resources to block, delay, and undermine tobacco control measures. In addition, profits are utilized to develop and launch new products in markets where sale of traditional tobacco products are declining, while at the same time pursuing increased market growth for traditional products in regions where prevalence is still increasing (3).

This FLM proposes a model to eliminate the ability for the tobacco industry, including retailers and distributors, to profit from the commercial sale of tobacco industry products. Instead, supply of tobacco industry products would be strictly controlled through a non-for-profit authority that has a public health mandate and would appoint not-for-profit enterprises to supply products. The primary aim of the FLM is to reduce nicotine addiction to the point that: a) tobacco industry products no longer need to be supplied; and b) users who require support for nicotine addiction have access to evidence-based measures that are proven safe and effective by the relevant medical authority and which do not provide the tobacco and related industries with an alternative source of profits.

While this FLM proposes a major structural change to how tobacco industry products are supplied, it can be seen at the end of a continuum under which many countries have already introduced restrictions on supply of products, such as minimum age purchase regulations and tobacco sales licensing frameworks. Measures further along this continuum, such as greatly restricting the number and type of retailers are expanded in other FLMs included in this report (see Retail Reduction information brief). Taking complete control of the tobacco supply chain by removing commercial profits and supplying under a public health mandate is a potential final step on this continuum.

The proposed model would most likely be appropriate for countries that are advanced in their WHO FCTC implementation and would be introduced as part of an existing comprehensive suite of tobacco control measures. Importantly, to successfully eliminate commercial profits, the model would ideally be applied to not only traditional tobacco products, but all tobacco industry products that may be introduced into the market in the future by the tobacco industry or their vested interests.

Prohibiting commercial sale of tobacco industry products through the proposed model aligns with WHO FCTC Article 5.3, which obligates Parties "in setting and implementing their public health policies with respect to tobacco control … to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law" (6).

The model removes the commercial and other vested interests from the supply side of tobacco industry products. At the same time, it greatly diminishes the tobacco industry's ability to interfere in tobacco control demand reduction measures as articulated in other WHO FCTC articles and supports a Party's ability to properly implement or expand or intensify these demand reduction measures.

The model complements implementation of taxation measures under WHO FCTC Article 6, and illicit trade measures under Article 15, as it takes over the supply chain, thereby allowing greater oversight and record-keeping, and eliminating avenues for supply of illicit tobacco products through retailers and distributors. The not-for-profit authority would have the ability to dictate controls on product content, ingredient disclosure, and packaging and labelling, providing a mechanism for Parties to fully implement, and if they choose intensify, implementation of Articles 9, 10 and 11. Lastly, the model would facilitate effective implementation of Article 13 by prohibiting advertising and promotion via packaging and in retail outlets, and as the not-for-profit authority would be retaining sales margins on supply of the products, it would provide a revenue stream to support the implementation of public education measures under Article 12 and evidence-based cessation measures under Article 14.

Availability of information/research evidence on the potential impact of the intervention

Although models suggesting the re-structure of the supply of tobacco products have been in the public arena since the early 2000s there has been little progression beyond the original conceptual models (7,8). Of these models, only one explicitly proposed an option for not-for-profit supply of tobacco products that would eliminate commercial sales (2,9). No country has yet transferred the supply of tobacco industry products from for-profit companies to not-for profit entities with a public health mandate.

While there has not been significant additional development of a not-for-profit model since it was proposed in the early 2000s, what has changed significantly is the extent to which the tobacco industry is tightly regulated within existing market structures (10), reduced prevalence of tobacco use in many countries (11), and the range of new products that generate substantial profits for the tobacco industry and retailers (5).

As a result, many assumptions underpinning the previous model are outdated and elements likely obsolete (for example, the requirement for governments to acquire tobacco industry operations and take over manufacturing, as well as supply, of tobacco industry products). In addition, some of the regulatory elements that the original model would oversee (1,2,9) have progressed globally and are covered under articles of the WHO FCTC, such as Article 13 (Tobacco advertising, promotion and sponsorship) and Article 11 (Packaging and labelling of tobacco products). Tobacco use prevalence has also decreased significantly in countries that are advanced in their implementation of tobacco control policies (11), so previous assumptions that not-for-profit supply would have to ensure uninterrupted and unchanged supply of products for tobacco users, at least in the short term, are likely no longer relevant (2). Lastly, tobacco manufacturers are embarking on a major global public relations campaign to reframe themselves as concerned about the health of their customers. Tobacco industry claims that they want to reduce use of traditional tobacco products have not stood up under scrutiny and evidence shows these claims are more of a marketing strategy to promote their diversified range of products to addict new users and convince existing users to use alternative products rather than quit altogether (12,13). The current environment is far more complex with the addition of new products that provide a significant new profit stream to manufacturers as increasing numbers of the population, particularly young people, try and then become addicted to the

diversified product offerings (5) The development of an updated and more appropriate not-for-profit model is needed.

The new model of prohibiting commercial sale of tobacco industry products and eliminating profit-driven behaviour proposes a complete structural change in the way tobacco industry products are supplied and has the potential to radically disrupt the current commercial institutional systems that perpetuate and entrench use of these products. The proposed model is described in detail at the end of this document. Tobacco industry products would no longer be available through private retailers so retailers would no longer be able to profit from their sales. The tobacco industry would still be able to manufacture products, but the entire supply chain would be taken over by a not-for-profit authority that has a public health mandate. The model would allow the not-for-profit authority to dictate the price they are willing to pay manufacturers for the wholesale purchase of their products if they wish to supply not-for-profit enterprises – the result would be greatly reduced profits to manufacturers. This would not mean that the retail price of products would decrease, as retaining high tobacco prices is crucial to tobacco control success (14). However, sales margins made by the not-for-profit enterprises would cover the costs of running the enterprise, and remaining income would be used for evidence-based tobacco control measures to reduce nicotine addiction within a population. Any taxes previously levied on products could also remain and still flow to government.

To be effective, the model would be introduced as part of an existing comprehensive suite of tobacco control measures such as high taxes; price controls; tobacco product packaging, labelling and contents regulations; and strict regulation of supply of all tobacco products, as well as cessation support for nicotine addiction. The result would be greatly accelerated cessation and ultimately no uptake of tobacco products or other nicotine products manufactured by the tobacco industry, their subsidiaries or companies in which they have a vested financial interest. This would ultimately mean there is no longer a profitable retail market for tobacco and alternative nicotine products.

The positive outcomes of this FLM are twofold: firstly, it would effectively eliminate the tobacco industry's ability to profit from the sale of their products within a country and use those profits to undermine tobacco control and further its business globally. Secondly, it would reduce nicotine addiction in a population, thereby reducing the health, social, economic, and environmental harms caused by nicotine addiction. The FLM would therefore have a large effect size on the general population. The model can also be structured to impact specific population groups to a greater degree, with the potential to reduce use of tobacco industry products in higher prevalence groups, and thus reduce the health, social and economic inequalities that result from their use.

Because this proposed model is new, no real-world evidence exists of its impact. A useful comparison, however, is provided by a 2019 narrative review of government monopolies as an instrument for public health that looked at the evidence of impact of government owned alcohol monopolies (15). While the structure of government-owned monopolies and their objectives differed over time and between countries that had implemented them, the review identified a range of positive public health outcomes. Public health advantages included: limiting the number of outlets; limiting hours and days of sale; product selection and pricing determined by public health interests; better adherence to conditions of supply; political lobbying diminished as private interests are removed; and most importantly, they hold down levels of sale of the harmful product and reduced alcohol-related problems (15). This evidence provides useful insight into the positive health impacts that would be expected when implementing a model that prohibits commercial sale of tobacco industry products.

Because the model proposes a major structural change, it would need an appropriate lead-in time to provide notice to consumers, retailers and distributors, and the tobacco industry of the intended change and to establish the not-for-profit supply authority and mechanism. If implemented in countries with advanced tobacco control measures in place, such as strict retailer licensing and policies that have greatly reduced the number of retailers, then the changeover to a not-for-profit supply model could happen more readily. Lower prevalence of tobacco use would also facilitate implementation more quickly as a lower level of demand for products would require a fewer number of not-for-profit enterprises to be authorized to supply products.

Once the not-for-profit supply mechanism was in place, Parties could expect to see decreases in prevalence of tobacco use and nicotine addiction.

Awareness and profile of the measure as a potentially promising intervention

Different models that propose a radical restructuring of how tobacco products are supplied are described in most compilations of FLMs or "endgame measures" (16–18). There is only one conceptual model, originally proposed by Callard and Collishaw in 2005, that specifically provides for the supply of tobacco products to be through not-for-profit enterprises (2,9). A model that would end the commercial sale of tobacco industry products and replace it with a not-for-profit model has not been included in any country's tobacco control strategic plan or similar strategic documents to date.

There have been several surveys that assess public support for a tobacco sales ban. While the wording of questions was different across the surveys, the more recent surveys indicate encouraging levels of public support for such measures (8). Studies have also found support among adults who smoke for a ban on cigarettes within 10 years, with cessation support from the government – 43.6% support in Canada (19) and 39.2% in the Republic of Korea (20), and without cessation support, 45.4% in Hong Kong SAR (China) (21), 32.% in England (22) and 46.0% in New Zealand (23).

Implementation considerations specific to this intervention

Potential challenges/barriers to adoption of the intervention

a. Political and public perception of the right to engage in commerce

Tobacco manufacturers have over decades manipulated both political and public perception through carefully crafted messaging that tobacco products are "just like any other consumer products", they are "legal" and that tobacco corporations are "legitimate businesses manufacturing a legal product". Likewise, tobacco retailers have continued to legitimize their businesses by claiming that they are "selling a legal product" and that they "have the right to make a living selling a product that is legal". The tobacco industry has reinforced these perceptions by downplaying the harm of the tobacco products while simultaneously asserting that they are among the most highly regulated industries in the world (1). This messaging has unfortunately been successful, embedding the misperception that prohibiting the sale of tobacco products is not feasible due to legal barriers or concerns about regulation of "legal products".

Liberman (1) describes how this tobacco industry messaging is misleading and not supported by legislative interpretation. He states that products themselves are neither legal or non-legal, it is only "conduct" in relation to those products such as sale or manufacture that can be legal or illegal. Similarly, industries are neither legal or illegal – the tobacco industry is not a "legal industry" but one that is regulated and it is its "conduct" in relation to those regulations that is either illegal or legal.

Educating policy-makers and politicians on these principles will go some way to reversing the misleading perceptions that have been manipulated by the tobacco industry and retailers.

The perception that there is somehow a "legal right" that tobacco products can be supplied for a profit can also be challenged by citing examples of products/services previously considered "legal" being restricted or prohibited from supply because of their fatal impact on the health of those who are exposed to them. There are many examples from around the world where certain industries have had their products prohibited from being supplied altogether or supplied only through highly regulated and authorized suppliers. When the evidence of asbestos causing the deadly cancer mesothelioma became clear, many countries introduced a ban on the supply of products containing asbestos, and currently there are 72 countries who have such a ban in place (24).

Similarly, it has recently become clear that most silicosis cases (a serious, irreversible lung disease that causes permanent disability and can be fatal) are in people who work with engineered stone. Engineered stone, such as that used in kitchen benchtops, when undergoing processes such as drilling, grinding, sawing or polishing, generates very small sized crystalline silica dust that can penetrate deep into the lungs and cause irreversible lung damage. To protect workers, the Australian Government has introduced a prohibition on the manufacture, supply, processing and installation of engineered stone in all Australian jurisdictions from 1 July 2024 (with minor exceptions) (25).

In another example of public health outcomes being put ahead of corporate and retail profits, as of June 2020, 24 countries prohibit sunbed use in persons aged under 18 (or younger age limit) and three countries (Australia, Brazil, and the Islamic Republic of Iran) have an outright ban on commercial solaria, also known as sunbeds, tanning beds, sunlamps or artificial tanning devices. Exposure to ultraviolet radiation (UV) is the predominant environmental cause of skin cancers and the incidence rates of melanoma are still increasing around the globe. Solaria by design emit high or extreme UV levels; accordingly, in 2009, the International Agency for Research on Cancer classified UV-emitting tanning devices as carcinogenic to humans (26).

b. Potential need to compensate tobacco retailers

The original model to supply tobacco through not-for-profit enterprises contemplated that governments would acquire the operations of tobacco manufacturers through purchase at fair market value to shareholders (2). Acquiring tobacco manufacturers is unlikely to be feasible, acceptable and most importantly necessary, in the context of modern-day tobacco control strategies. The new model proposes that manufacturers could supply not-for-profit enterprises with tobacco industry products that meet strict criteria for as long as there was a market for the product in that country. Once that market no longer exists, either because demand for tobacco industry products has diminished to a point that the products are no longer in use or governments decide to end their supply completely on public health grounds, then like any other corporation who find themselves with products for which there is no longer a market, manufacturers would have to make business decisions about their future. Governments have no responsibility to support or protect the commercial and vested interests of the tobacco industry and doing so would contravene WHO FCTC Article 5.3.

In an ideal scenario for implementation of this FLM, tobacco industry product retailers would already be highly regulated, with high licensing fees and strict regulation in place governing where, when and who can supply products. This would mean there were already a significantly lower number of retailers within that country. Whether a country would need to provide compensation for no longer allowing these retailers to supply tobacco industry products will depend on domestic laws that are

in place and policy decisions made when developing the FLM. Countries may decide to give retailers notice to allow them to diversify or close their business or they may decide to offer some form of compensation, if required under law, or if this makes implementation more feasible and avoids delays.

c. Not-for-profit enterprises are not willing to supply tobacco products

It is anticipated that some not-for-profit enterprises, particularly those who are already involved in the public health field, may be reluctant to supply tobacco products for ethical and legal reasons. However, given public health enterprises are those most likely to be in contact with tobacco users and able to provide cessation services, reassurance and protection will likely be necessary. To overcome legal concerns, governments could limit the liability of directors and employees of a new not-for-profit authority as well as any not-for-profit enterprises who supply tobacco industry products for previous wrongs committed by the tobacco industry, as well as any future health conditions that result from use of tobacco industry products. To overcome ethical concerns, it would be made very clear that the mandate of not-for-profit enterprises is to contribute to meeting the public health objectives of decreasing use of tobacco industry products to eliminate the need for these products to be supplied at all in the future.

Potential negative consequences of FLM

a. Tobacco industry increases profits from non-tobacco products

The greatest negative consequence of implementing this model is that if it is restricted to only removing the ability of the tobacco industry and retailers to make a profit from selling traditional tobacco products, rather than all tobacco industry products, this FLM will facilitate and encourage a market for alternative nicotine products manufactured by the same companies and sold by the same retailers for significant profit. Making a profit, through whatever legal means is available to it, is a fundamental mandate of corporations and small businesses (9). As implementation of the WHO FCTC has accelerated and prevalence of use of tobacco products has reduced in many countries, the tobacco industry has responded by diversifying their product offerings so that profits can continue to flow from sale of products that are less regulated such as electronic nicotine delivery systems (ENDS) and nicotine pouches (5). Profit from whatever source, ensures tobacco manufacturers continue to have the funds to undermine, obstruct and delay global implementation of regulatory measures to reduce addiction to their products for as long as they possibly can.

In 2003, it was recognized the risk that "Effective regulation of tobacco with a view to minimizing its harmful effects cannot be genuinely achieved if it is not integrated with regulation of the product's alternatives and competitors" (1). It is crucial that in undertaking structural change to minimise or stop profits that the tobacco industry and retailers can make from selling tobacco products, that a country does not inadvertently shift addicted nicotine users to alternative tobacco industry products that continue to provide profit to the tobacco industry. To maximize reductions in the health, social, and economic harms caused by tobacco use and nicotine addiction, and to eliminate industry profits from the sale of its products, countries will need to consider using this model to control all products manufactured by the tobacco industry and sold by tobacco retailers. At a minimum, in order to be effective at reducing or eliminating tobacco industry profits, this model must be implemented alongside measures that tightly regulate supply of alternative tobacco industry nicotine products to ensure addiction from their use is also minimized, as called for under decisions from the Sixth session and Seventh sessions of the COP (27,28).

b. Not-for-profit enterprises develop a perceived need to continue supply of tobacco industry products to justify their own existence or support other work they do

This model contemplates major structural change requiring the creation of a new authority and supply infrastructure. It has been noted that when establishing such new institutions, there is a risk that they may develop incentives to sustain themselves beyond their usefulness or in ways that might prove harmful, or that might quickly become redundant (29). Care should be taken so that not-for-profit enterprises do not develop a perceived need to maintain some use of tobacco industry products in order to justify their own continued existence (2).

This risk could be mitigated by ensuring there are no incentives to prolong product supply and that measures are in place to stop conflicts of interest. Examples include independent control and oversight of not-for-profit suppliers; criteria for who can and cannot be a not-for-profit supplier; public health mandates for not-for-profit suppliers being comprehensive and with clear targets and timelines that must be met; incentives for meeting targets and timelines early; and an end date/point being set so that all not-for-profit suppliers understand when their function will cease to exist.

A proposed model for prohibiting the commercial sale of tobacco industry products and replacing it with a not-for-profit model is provided in the Appendix to this brief.

Summary

This FLM introduces a mechanism where tobacco industry products can only be supplied by not-for-profit enterprises that operate under a strict public health mandate overseen by a not-for-profit authority. It would remove the ability for tobacco retailers to supply and profit from tobacco industry products, and greatly reduce profits tobacco manufacturers could make from supplying their products via the not-for-profit authority/enterprises, which would then decrease profits to negligible levels as users of tobacco industry products quit and demand for them ceases or governments decide to end their supply altogether.

Not-for-profit supply of tobacco products would be feasible in countries that are advanced in tobacco control implementation and that already have low tobacco use prevalence. It assumes that evidence-based measures such as high excise taxes and prices, strict regulation of the supply chain, regulation of product packaging and design, restrictions on tobacco retailers, and evidence-based cessation programmes are already in place.

If implemented, this FLM would impact the entire population and could be structured in a way to provide additional incentive and support for population groups with high rates of tobacco product use to quit.

Barriers and potential negative consequences of this FLM could be overcome with expert and careful development and implementation of the proposed model.

A key consideration is that the implementation of this FLM, if applied to tobacco products only, could lead to tobacco users switching to nicotine products such as ENDS and nicotine pouches. This would mean that their nicotine addiction would be maintained, and the tobacco industry would continue to profit from this addiction, while users face the health, social and economic consequences of their continued addiction.

Prohibiting the ability of the tobacco industry to continue to generate excessive levels of profit through commercial sale of their products would diminish the limitless funds they currently have that enables them to aggressively block, delay and undermine tobacco control measures. The tobacco industry also utilizes their profits to develop and launch new products in markets where sale of traditional tobacco products are declining, the result being the alarming global increase in uptake of ENDS among youth and people who do not smoke, which Parties noted and agreed to take action on in meetings held at the Sixth session and Seventh session of the COP. The profits also allow them to pursue increased market growth for traditional products in regions where prevalence is still increasing.

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Appendix

Proposed model for prohibiting commercial sale of tobacco industry products and replacing it with a not-for-profit model

This model proposes a framework for how this FLM could be implemented by countries. Individual elements would be considered and adapted to suit country specific circumstances.

1. Rationale

It has been described as a "perverse incentive" that the tobacco industry has been allowed to operate under a model where subject to some constraints on its conduct, the more people they addict, the more products they sell and more profit they make, with the unparalleled toll of death and disease being a direct consequence (1). It has also been acknowledged that it is problematic that supply of tobacco products is managed by corporations that are designed, managed, governed and mandated to maximize profits even when doing so results in human harm (2).

The tobacco industry remains one of the most profitable industries in the world with revenue of US\$ 912 billion in 2022 from global tobacco sales (3) and projected revenue of US\$ 988.4 billion in 2025 (4). Global revenue is projected to have a compound annual growth increase of 2.59% from 2025 to 2029 (4). Analysis also indicates that currently the global tobacco industry's aggregate profitability remains historically strong, at a level which has been driven by higher product pricing and structural changes in their product mix (3). As companies transition away from traditional cigarette products into alternatives such as e-cigarettes and smokeless offerings, analysis also indicates that tobacco companies are likely to see underlying profitability supported by the comparatively higher gross margins of these new products relative to traditional cigarettes (a result of excise generally not being levied on these new products) (3).

It is a political choice to allow corporations to supply tobacco industry products under this commercial incentive – there is no such thing as a "legal right" to sell a product. Therefore, it is within a government's power to decide to change this model in the public's interest and remove the ability for corporations to profit from selling addictive and potentially lethal products. The public interest rationale could be grounded in any or all of the following frameworks:

- a. consumer protection
- b. human rights
- c. the obligation of corporations to do no harm
- d. criminal negligence or reckless/unconscionable conduct endangering life.
- 2. Pre-conditions for optimum context into which to introduce this FLM
 - e. low prevalence of use of tobacco industry products (individual countries will determine what is appropriate for their context);
 - f. part of a comprehensive tobacco control strategy;
 - g. products highly regulated packaging, labelling, ingredients, etc.;
 - h. high excise taxes and price controls on products;

- i. Retailers licensed and strict controls on who, where and when products can be sold (see Retail Reduction information brief for further information);
- j. strong mechanisms in place to enforce existing legislation, in particular measures to secure the supply chain and prevent illicit trade; and
- k. evidence-based not-for-profit cessation supports in place, including those specific and appropriate for population groups who may have higher prevalence of tobacco use (for example, low-income earners, people with mental health conditions, First Nations communities, etc.).
- 3. Non-exhaustive options for the type of not-for-profit enterprises who could supply (2)
 - I. nongovernmental not-for-profit organizations
 - m. publicly owned enterprises
 - n. community interest companies
 - o. private not-for-profit enterprises
 - p. cooperatives.
- 4. Criteria for not-for-profit suppliers
 - q. must be appointed by not-for-profit authority;
 - r. directors/staff must have no conflicts of interest and the organization must comply with relevant sections of WHO FCTC Article 5.3 Guidelines (acknowledging that supplying tobacco products will conflict with some aspects of WHO FCTC Article 5.3 Guidelines); and
 - s. must adhere to public health mandate and conditions set by not-for-profit authority.

5. Not-for-profit definition

A not-for-profit (NFP) authority and enterprises as envisioned in this model does not mean that tobacco would be sold to users at cost price. Tobacco prices would be set in line with best practice tobacco control and the profit margin between the cost price and the retail price that used to be retained by retailers would now be retained by the NFP authority/enterprise and used to cover their running costs, the costs of providing education campaigns, as well as evidence-based support and services to eliminate nicotine addiction. Any excise or other taxes already levied on the products could remain and be collected by government. Tobacco manufacturers would at first be able to derive a small profit by supplying to the NFP authority if they choose, but this would be greatly diminished as the NFP authority would determine the price it was willing to pay manufacturers for their products. Any profits the tobacco industry could make in the future from supply would reduce even further as the NFP authority realizes its mandate of eliminating nicotine addiction, so the use and supply of tobacco industry products is no longer needed.

Suggested steps for implementation of the model (to be adapted for country specific circumstances)

a. Government decides to adopt the model.

- b. Establishment of the NFP authority within health department/agency (experience warns that if an authority is in, or reporting to, a government agency/department with primary responsibility for state revenues, consumer affairs or trade that it may be subject to weakening by political pressure from economic interests over public health interests) (15).
- c. Criteria for which NFP enterprise(s) can supply products are determined and an evidenced-based framework for supply that includes limitations on the number, type, location, etc. of suppliers is established (see Retail Reduction information brief for further evidence to inform supply framework).
- d. NFP authority determines protocols for minimum standards and conflict of interest criteria for cessation services. Services wishing to be considered as a cessation service must apply to the NFP authority for accreditation. Cessation services must be NFP.
- e. Decide whether retailers' ability to sell will be phased out or they will be compensated.
- f. Retailers are given notice of date for which their ability to supply will end.
- g. Manufacturers are given notice of date for which supply of products through tobacco retailers will end and supply through NFP authority only will begin.
- h. NFP authority issues tender/guidelines to tobacco manufacturers for products it will purchase for supply (price willing to pay, product controls labelling, ingredients, branding etc., distribution chains the not-for-profit authority will administer etc.)
- i. NFP authority determines which manufacturers are chosen to supply products to/via the NFP authority.
- j. Protocols for NFP enterprises determined including which individuals they can supply tobacco industry products to, the price of these products, how often and what quantities they can supply to individual users (to help prevent illicit trade of products), cessation services they must provide or refer to, and targets for quit rates they must meet, etc.
- k. NFP enterprises who will be authorized to supply determined (those who apply and meet approved criteria and protocols) in line with supply framework limiting the number, type and location, etc. of suppliers
- I. Accredited, evidence-based cessation support in place either directly through the NFP enterprise or through referral to accredited cessation service.
- m. Individuals addicted to nicotine can purchase products through appointed NFP enterprises while at the same time being offered evidence-based cessation support and subsidized/free nicotine replacement therapy products that have been approved for therapeutic cessation by the relevant government medicine/drug oversight authority.

(v) Quota on tobacco manufacture and imports, followed by regular reduction ("sinking lid")

Abstract

Policy description and background. This policy involves government intervention to reduce the amount of tobacco products released to the market for sale (a "sinking lid") regularly, leading to a reduced supply and higher prices – which would increase requests for tobacco cessation services and decrease tobacco consumption.

The aim of reducing tobacco supply through this FLM aligns with and builds on Article 15 of the WHO FCTC, requiring Parties to implement measures with a view to eliminating illicit trade in tobacco products; Article 16, requiring to prohibit the sales of tobacco products to persons under the age set in a given jurisdiction; and Article 17, promoting economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers; while the resulting price increase aligns with the aims of Article 6 to reduce tobacco consumption through the application of price and tax measures.

Evidence of impact. There is no real-world evidence for the impact of sinking lid quotas on tobacco products. Reviews of similar cap-and-trade systems for carbon emissions find that they are effective at reducing carbon emissions and are cost-effective.

Benefits and strengths. If implemented with sufficient quota reductions in a reasonable period of time, tobacco products would become unaffordable, leading to large numbers of people quitting and to ever smaller numbers initiating. This could disrupt the tobacco supply chain, potentially making the for-profit manufacture and distribution of tobacco products untenable.

Implementation considerations. Implementation of quotas/sinking lids requires data on tobacco sales. Jurisdictions without the capacity to collect valid sales data would probably be unable to adopt this policy. Similarly, where substantial parts of the tobacco market are in home-made or small-scale manufactured products (such as *beedis*), the supply of tobacco products would be difficult to track. It is possible that the tobacco industry would, at certain stages, adjust prices to mitigate the impact of reduced supply on purchases. To prevent such manipulation, minimum price regulation may be necessary.

Conclusion. Imposing a sinking lid quota to reduce the amount of tobacco products released regularly would be aimed at disrupting the tobacco supply market. This FLM could be considered in light of the success of quota systems in other areas. It has the potential to have a substantial impact on the tobacco epidemic, and strong public support.

Description of the intervention

This FLM involves government intervention to regularly reduce the amount of tobacco released to the market for sale (a "sinking lid") with the outcome being that as supply is reduced, prices increase as a result of continued demand. Ultimately, as per tobacco control evidence from tax increases, higher prices would drive increased cessation and reduced uptake of tobacco product use (1). The aim of reducing tobacco supply aligns with and expands the guiding principles of WHO FCTC Article 15 (measures to eliminate illicit tobacco trade), Article 16 (measures to prohibit sales of and access to tobacco products to and by minors), and Article 17 (measures to support economically viable alternatives for tobacco growers), while the resulting price increase aligns with the aims of Article 6 (price and tax measures to decrease demand).

The model is based on schemes used to reduce carbon emissions (cap-and-trade schemes) and to control the catch taken from fisheries. Manufacturers and importers would bid at government-run

auctions for shares of the market. Revenue from share auctions (as well as tax revenue) could be used to fund tobacco control programmes.

Availability of information/research evidence on the potential impact of the FLM

The quota and sinking lid idea in the domain of tobacco control was first introduced in 2010. The theory of change is quite straightforward, being based on the law of demand. By decreasing the supply of tobacco products available for purchase, price would increase, which would lead to a decrease in both tobacco consumption and prevalence of use, similar to the effects to tobacco tax increases (2). Two possible sinking lid approaches have been proposed that "could involve government-mandated set percentage point reductions in annual tobacco sales/import quotas from either: 1) the market share of each tobacco company at a baseline year; or 2) available tradeable quotas to either tobacco companies or to wholesalers (e.g., that could be auctioned off regularly in declining amounts by a government agency)"(3). It is important to note that this quota and sinking- lid strategy, which aims to reduce tobacco use from the supply side, could well be implemented in conjunction with the more familiar, and extensively used strategy of increasing tobacco taxes, which seeks to achieve the same goal from the demand side.

To date, no country has implemented this FLM, so there is no direct evidence of its impacts (4). However, there have been two modelling studies that have estimated the effects of implementing this FLM in New Zealand, with set target dates for decreases in tobacco sales and ending tobacco sales altogether (5,6). Both studies set tobacco sales to be reduced to zero over the course of 14 years.

While the quota/sinking-lid approach has yet to be applied for tobacco, there is extensive experience with similar interventions in environmental protection and in control of fisheries. A 2017 review of cap-and-trade systems concluded that they are both "environmentally effective and economically cost-effective (lead phasedown, SO_2 allowance trading)"(7). A 2024 review also concluded "... that carbon pricing policies have caused emissions reductions. Statistically significant emissions reductions are found for 17 of the reviewed carbon pricing policies, with immediate and sustained reductions of between -5% to -21% (-4% to -15% when correcting for publication bias)"(8). Three prominent successful implementations of quota/sinking lid interventions in reducing emissions are:

- 1. The Acid Rain Programme in the United States of America, which was the first national cap-and-trade programme in the United States, achieved, by 2021 a near total elimination of sulfur dioxide (SO₂) emissions (96% reduction from 1990 levels) at lower-than-project cost since its implementation in 1995 (9) (10) (11).
- 2. California's statewide cap-and-trade programme in the United States, established in 2012, is among the largest multisectoral emissions trading systems globally. The programme reached its goal of reducing greenhouse gas emissions to 1990 levels by 2020 four years ahead of schedule, in 2016 (11,12).
- 3. The European Union Emissions Trading System (ETS) established in 2005) is the first carbon market in the world to use a cap-and-trade system to curb greenhouse gas emissions. As of 2023, the ETS has led to an estimated 8–15% decrease in overall carbon dioxide (CO₂) emissions in some European Union countries, and a 47% reduction in CO₂ emissions, compared to 2005 levels, by power plants and industrial facilities (12,13) (14) (15).

A more recent example of a quota or sinking-lid approach is the gradual reduction in the proportion of combustible engine automobiles allowed for sale, aimed at increasing electric vehicle adoption and lowering carbon emissions. Several jurisdictions have adopted policies to phase out the sale of combustible engine automobiles with sinking-lid stipulations that set a decreased supply level by target years culminating in zero sales. Canada, several states in the United States, the European Union), the United Kingdom, Iceland, Norway, Costa Rica, Chile, Ethiopia, and three Australian states have set deadlines for zero sales by the year 2024 through 2050, with 2035 being the most common target year (16).

If well implemented with sufficient quota reductions in reasonable period of time, tobacco products would become increasingly less affordable, leading to increases in quitting among those using tobacco products, reductions in consumption among those who continue to use tobacco products, and decreases in people initiating tobacco use and progressing to regular use.

If quotas were reduced substantially and at a sufficiently rapid rate, there would be great potential for disrupting the chain of tobacco supply, eventually making for-profit manufacture and distribution of tobacco untenable.

Awareness and profile of the FLM as a potentially promising intervention

Sinking-lid/quota impositions on tobacco supply have been included in compilations of tobacco endgame measures since its introduction into the literature in 2010. While it has yet to be adopted in any country, this FLM remains on the agenda of endgame proponents. A 2019 study of adults in Hong Kong SAR (China) found that 80% supported imposing a quota on combustible cigarettes with an annual reduction in the number of cigarettes made available for purchase. This measure received the highest support among the endgame measures tested, including the smoke-free generation policy, which 52% of respondents supported (17).

Implementation considerations specific to this FLM

Implementation of quotas/sinking lids requires data on tobacco sales. Jurisdictions that do not have the ability to collect valid sales data would likely be unable to adopt this FLM. Similarly, where substantial parts of the tobacco market is in homemade or small-scale manufactured products (for example *beedis*), the supply of tobacco products would be difficult to track. At the same time, jurisdictions where prevalence is low and the market is not well established may encounter fewer barriers to adoption and implementation.

This FLM might face opposition from those concerned about the consequences for people who are addicted to tobacco products and have been unable to quit. To address this challenge, it has been suggested that this FLM should be accompanied by large-scale public education campaigns and support for tobacco cessation (3).

This FLM leaves tobacco industry growing, production and manufacturing intact, at least in its early stages, and the industry would maintain its economic and political clout. It is possible that the industry would adjust prices to mitigate the impact of reduced supply on purchases. To prevent such manipulation, it may be necessary to implement minimum price regulation (3). While higher prices may result in greater profits for the tobacco industry (to the extent that the higher prices would adequately compensate for the reduced sales volume that would result from this FLM), there would still be a potential substantial public health benefit from reducing consumption and prevalence.

Case study

The European Union Emissions Trading Scheme (ETS) was introduced in 2005 with an aim to gradually reduce carbon (CO_2) emissions. Currently, the ETS is set to decrease emissions by 62% of 2005 levels by 2030 (15). The programme sets a cap on total carbon emissions from some 12 000 power and manufacturing plants across the European Union (15). As a cap-and-trade initiative, each emitter receives permits for each tonne of carbon determined by the amount of carbon equivalent to its past emissions minus the reduction target for the given period. These permits are tradeable such that an emitter that uses less than its allotment of carbon can sell permits to other emitters who exceed their carbon emission cap. The permit price is determined through a European-wide market (15).

The ETS is now in its fourth phase. Studies estimate that the ETS has achieved a 2.5–5% total emissions reduction during Phase I (2005), a 6.3% reduction in Phase 2 (2008–2009), and a 2.9% reduction in Phase 3 (2015–2016 compared to baseline emissions (12,13,18). A 2022 review found that the ETS has led to increases in the prices of emission-intensive goods that provide incentives to reduce CO₂ emissions, and has driven development of carbon-reduction technologies (14).

As of 2023, the ETS has led to a 47% reduction in total greenhouse emissions from 2005 levels from EU power stations and industrial facilities (19). An added benefit of the ETS is that since 2013, it has generated revenue of more than 175 billion Euros (19).

Summary

This FLM involves government intervention to regularly reduce the amount of tobacco released to the market for sale (a "sinking lid"), with the outcome being that as supply is reduced, prices increase as a result of demand. Ultimately, as per tobacco control evidence from tax increases, higher prices would drive increased cessation and reduced uptake of tobacco product use. Two possible sinking- lid approaches have been identified: 1) decreasing quotas based on baseline market share of each tobacco company; and 2) cap-and-trade of available quotas.

There are no real-world applications of this FLM at this time, and therefore no direct evidence of its impacts. However, modelling studies indicate the feasibility of implementing this FLM. Research evidence shows that similar interventions are effective for environmental protection and the control of fisheries. Many governments have successfully implemented quota systems to prevent overfishing, and quota cap-and-trade systems to decrease carbon emissions.

Imposing a quota on tobacco manufacture and imports and the reducing over time (sinking lid) would be a bold measure aimed at disrupting the tobacco supply market. Imposition of a sinking-lid quota system for tobacco supply has strong potential for decreasing the number of people who use tobacco by sharply increasing cessation and decreasing initiation. There is some evidence of strong public support for this measure, albeit from just one jurisdiction.

Success of this measure requires that it be accompanied by price controls to prevent industry from reaping profits from price increases, and cessation campaigns to support tobacco users who have trouble quitting due to their strong addiction to nicotine. Governments would face challenges rooted in freedom of commerce arguments from the tobacco industry and would be subject to ongoing pressure to set unambitious tobacco supply reduction targets and to do so over extended periods of time.

This measure deserves careful consideration in view of the success of quota systems in other areas, the strong potential to substantially reduce tobacco consumption and prevalence, and the strong public support for this measure.

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(c) Product

(i) Low/very low nicotine content levels in combustible tobacco products

Abstract

Policy description and background. Nicotine is responsible for the high addictiveness of tobacco products. This FLM would lower nicotine in cigarettes and other products to minimally or non-addictive levels – very low nicotine content (VLNC). This FLM would establish guidance for nicotine regulation, and would make tobacco products less appealing, less addictive, less toxic and less harmful, protecting the full spectrum of the population.

Promoting tobacco use cessation and adequate treatment for tobacco dependence is an obligation in Article 14 of the WHO FCTC and its Guidelines for implementation.

This FLM aligns with the aim to prevent and reduce tobacco consumption, nicotine addiction, and exposure to tobacco smoke under Article 5.2; measures to regulate the contents, emissions, design features, and disclosures of tobacco products under Articles 9 and 10, guidance for countries under the 2015 WHO Tobacco Regulation Group Advisory Note on a Global Nicotine Reduction Strategy; acknowledgement that modification of tobacco products is a strategy to prevent nicotine addiction and promote cessation by Parties in decision FCTC/COP7(14), and the supplementary document to the Eighth session of the COP in 2018 based on a WHO Global Consultation on tobacco addictiveness measures.

Evidence of impact. This FLM has not yet been implemented by any country. Legislation requiring this FLM was passed in New Zealand in 2022, but repealed in 2024, before implementation; it was also issued in the United States in 2025 as a proposed rule and is currently undergoing the required rule-making process. While in principle this FLM is applicable to all tobacco products, all available evidence to date has focused on cigarettes. Randomized clinical trials conducted in high-income countries, have found that VLNC cigarettes significantly reduce consumption of cigarettes, with no evidence for sustained increased compensatory smoking; some trials also found increases in smoking cessation. Modelling studies conducted in high-income countries, suggest that this policy could reduce cigarette smoking prevalence by decreasing smoking initiation and increasing smoking cessation, with the potential for substantial decreases in smoking-related mortality over time. There is moderate to strong public support for VLNC cigarettes, even among people who smoke.

Benefits and strengths. As nicotine is a powerfully addictive substance, a regulatory policy that would reduce the nicotine levels in tobacco products could lead to substantial public health benefits from decreases in initiation that would reduce the demand for tobacco and increases in cessation. If implemented across all tobacco products (as well as being considered for nicotine products), this FLM would increase the public health benefits.

Implementation considerations. Research suggests that implementation of this policy is technically feasible but depends on countries' regulatory capacity, including the ability to test products; however, greater reductions in nicotine are likely to produce greater impact of this FLM. This FLM would require market surveillance and product testing, as well as enforcement mechanisms with appropriate penalties. Strengthened surveillance systems would also provide the necessary information to either respond to, or counter, any industry claims and arguments. Consideration should be given to the implementation of measures preventing product substitution, including comprehensive regulation across all products. Public education campaigns and warning labels that emphasize that VLNC tobacco products are less addictive, but still harmful, would inform the

population and address misperceptions. Nicotine reduction policies should take place within the context of comprehensive tobacco control. International collaboration, including sharing of laboratory resources and technical expertise, could further support countries with limited testing capacity. The burden of proof should be on manufacturers of relevant products, and the cost of implementation of this policy measure should be borne by the manufacturer.

Conclusion. Significantly reducing levels of nicotine in tobacco products – especially cigarettes – is technically feasible and could lead to substantial public health benefits in reducing initiation of smoking and potentially increasing cessation among those who smoke.

Description of the intervention

This FLM will be referred to as a "very low nicotine content (VLNC)" regulation or policy. While this FLM proposes lowering nicotine levels in all combustible products, the available evidence has been focused on combustible cigarettes. While this brief discusses the evidence available for VLNC cigarettes, lowering nicotine levels across a range of tobacco products to reduce addictiveness would have the greatest public health benefits.

Over one billion people smoke cigarettes, and smoking is responsible for about 8 million deaths per year (1). Addiction to cigarettes is primarily caused by nicotine (2,3). Nicotine dependence is a chronic disease, and it is often a barrier for successful cessation of tobacco use. Given the role that nicotine dependence plays in the persistence of smoking, the concept of lowering nicotine in cigarettes to levels that would be minimally or non-addictive has been discussed since the 1990s (4,5).

Preventing and reducing nicotine addiction is an explicit goal of the WHO FCTC, (Article 5.2 (b)), as is the promotion of tobacco use cessation (Article 14 and its implementation guidelines (6)). Partial guidelines for implementation of Article 9 (Regulation of the contents of tobacco products) and Article 10 (Regulation of tobacco product disclosures) (7) were adopted by the COP at its Fourth session in 2010 in decision FCTC/COP4(10), with amendments adopted at the Fifth session in 2012 in decision FCTC/COP5(6) (8). At the Seventh session of the COP, in 2017, in decision FCTC/COP7(14) (9), Parties acknowledged that modifying tobacco products is a strategy to prevent addiction to nicotine and may support cessation efforts. This FLM also aligns with guidance for countries to implement WHO FCTC product regulations under the 2015 WHO Study Group on Tobacco Product Regulation (TobReg) Advisory Note on a Global Nicotine Reduction Strategy (10), which concluded that "A nicotine reduction strategy could decrease the acquisition of smoking and progression to addiction among experimenters, limit the number of cigarettes smoked by some proportion of addicted smokers and both increase the number of addicted smokers who stop smoking and reduce the number of those who relapse."

In 2018, the WH held a consultation on tobacco addictiveness reduction measures. The final report, which was submitted as a supplementary document to the Eighth session of the COP), acknowledged that the ability to implement and enforce a VLNC policy would vary by countries' technical, financial and human resources available, with LMICs less likely to benefit from such a policy, but acknowledging that in other countries, where such capacity was present, a VLNC policy could be beneficial (11).

A VLNC regulation would lower nicotine to minimally addictive or non-addictive levels. The technology necessary to achieve this lowering of nicotine in the cigarette is well-established. The nicotine content in regular cigarettes varies – in a surveillance study conducted by the United States Centers for Disease Control and Prevention, nicotine concentrations ranged from 16.2 to 26.3 mg

nicotine/g tobacco with a mean of 19.2 mg/g of tobacco (12). A VLNC policy would substantially reduce this quantity. The vast majority of clinical trials that have examined the impact of VLNC cigarettes, which have been cited in literature reviews, for example, Donny & White 2022 (13) have used VLNC cigarettes with 0.4 mg per gram of tobacco, although the two countries that have advanced discussions on VLNC regulations for cigarettes — New Zealand and the United States — proposed limiting nicotine in cigarettes to 0.8 mg and 0.7 mg/g of nicotine, respectively, equivalent to a reduction of about 95% of the nicotine in cigarettes. The limits on nicotine established by countries may differ based on their regulatory capacity, including the ability to test products; however, greater reductions in nicotine are likely to produce greater impact of this FLM.

Availability of information/research evidence on the potential impact of the FLM

There is a wealth of research demonstrating the feasibility and public support for the implementation of regulations to reduce nicotine in cigarettes to non-addictive levels. Reducing nicotine in cigarettes to VLNC levels is technically viable (11). If a regulation for VLNC cigarettes is to be implemented, however, it should be the only standard available (that is, all cigarettes should be subjected to the same, or lower, nicotine limit).

Over the past decade, many randomized clinical trials (RCTs) have been conducted examining the impact and safety of VLNC cigarettes. These trials, which have been reviewed in several articles (13–15) have been conducted among adults representing a range of population groups and demonstrate that VLNC cigarettes were acceptable and did not create additional harm when compared with regular nicotine level cigarettes (16–19).

Most existing studies of VLNCs have been conducted in the United States (20) and other high-income countries (Canada and New Zealand). Thus, the impact on people who use combustible tobacco products in LMICs remains unknown (11).

A number of other clinical trials in the United States and other high-income countries assessed the impact of VLNC cigarettes on smoking behaviour. Most trials examined whether VLNC cigarettes led to decreases in consumption – the number of cigarettes smoked per day. These trials have found that those smokers who were randomly assigned to smoke VLNC cigarettes reduced the number of cigarettes they smoked per day (13,14,16,19,21–23).

A 2024 trial found that reduction in the number of cigarettes smoked per day among those who used VLNCs was achieved even in the presence of other nicotine products in the market, but not cessation (24).

Although most trials were not designed to measure the impact of VLNC cigarettes on cessation, some have assessed cessation among participants at follow-up period. For such trials (18,19,22–24), findings showed higher rates of cessation among those who were randomly assigned to the VLNC cigarette condition compared to other nicotine delivery conditions.

Importantly, in several trials participants were also offered cessation support – nicotine replacement therapy (NRT) and behavioural support – at the end of the trial period (15), which increased cessation rates across a range of characteristics, including those who are experiencing severe mental illness, those experiencing mood or anxiety disorders, and/or those experiencing socioeconomic disadvantage (21,23,25) and those not motivated to quit (21,23,26,27).

While these clinical trials have limitations, overall findings point to a potential for cessation, especially when combined with NRT and behavioural support. Moreover, these trials confirm that

those smoking VLNC cigarettes would not engage in compensatory smoking — smoking more — due to a desire to maintain their levels of nicotine (16,19,23,28,29). Although some trials show a brief period of increased smoking, this is not maintained over time.

A recent summary of what would be expected under a VLNC cigarette regulation from leaders in this research area is provided by Denlinger-Apte et al. (2025) (30).

Awareness and profile of FLM as a potentially promising intervention

For over 30 years, there has been discussion of the possible positive impact of setting limits on nicotine levels on cigarettes. The United States engaged, in 2018, in a regulatory process to establish a rule requiring VLNC cigarettes, but it has not been implemented (31). In December 2022, New Zealand became the first country to pass legislation to reduce nicotine in cigarettes to non-addictive levels, along with other significant measures (including substantial reductions in retail availability and smoke-free generation). This legislation, however, was repealed in February 2024 (32).

Some WHO FCTC Parties have implemented nicotine limits in non-combustible products, although the impact for these policies is yet to be evaluated. Existing policies and current discussions on reducing nicotine concentration in e-cigarettes do not focus on establishing non-addictive levels, except in the context of proposals for a complete ban on nicotine in these products.

While there is some evidence that there would be no increase in disparities associated with this policy (26), research on a range of population groups and from LMICs is missing.

The potential impact of this FLM would likely be even greater in countries where the VLNC limits are applied to other combustible tobacco products, since it would preclude transitions from cigarettes to other dangerous products (11).

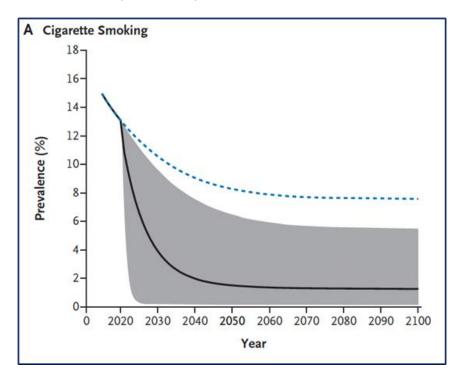
Evidence of potential impact of a VLNC regulation from modelling studies.

Modelling studies have estimated the potential impact of a VLNC regulation at the population level over time (33,34). These modelling studies of the impact of VLNCs in the United States (9) and in Aotearoa/New Zealand (33,34) conclude that the impact of a VLNC regulation would be very pronounced on reducing smoking prevalence, due to a combination of reduced initiation and progression to regular smoking among young people who do not smoke, and substantial increases in cessation among those who smoke.

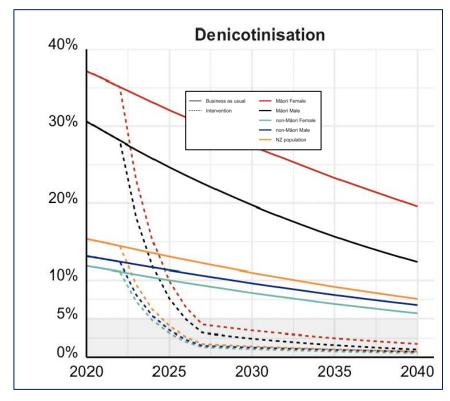
The United States Food and Drug Administration's population health model predicts that VLNCs could lead to a sharp decrease in smoking prevalence, and by the year 2100, could prevent 48 million young people from starting to smoke, lead 12.9 million people to stop smoking, and avert 4.3 million deaths (35).

Fig. 1 shows the estimated time trends in smoking prevalence in the United States under an VLNC cigarette standard implemented in 2020 (solid line) versus no VLNC standard (dotted line) from 2020 projected to 2100. Smoking prevalence is projected to be reduced by half within five years, and by over two thirds within 10 years (36).

Fig. 1. Estimated time trends in smoking prevalence in the United States under an VLNC standard (solid line) vs.no VLNC standard (dotted line).



Source: Apelberg et al., 2018 (36)



Source: Ait Ouakrim et al., 2024 (34)

Fig. 2 shows similar time trends in smoking prevalence in Aotearoa New Zealand, for the overall population and for Māori and non-Māori males and females with and without a VLNC regulation implemented in 2022. There would be significant reductions in smoking prevalence. Importantly, the model projects a substantial positive equity impact, with the reductions in smoking being even greater among Māori, leading to a very significant reduction in the equity gap, and projecting that the smoking prevalence for all population groups would achieve the target of less than 5% prevalence in less than five years after the implementation of the VLNC cigarette regulation (34).

Fig. 2. Estimated time trends in smoking prevalence in Aotearoa New Zealand under an VLNC standard (solid lines) vs. no VLNC standard (dotted lines) for the NZ population and for Māori and non-Māori males and females.

The modelling studies do not address the issue of switching to other tobacco products. Although the definition of tobacco products differs across countries, to the extent that other products not covered by this FLM are available and are a source of nicotine that is more potent (either in nicotine content and/or nicotine delivery), there could be transitions away from cigarettes to these other products. The extent to which that would happen would depend on the products available (11).

Implementation considerations specific to this FLM

Although evidence from clinical trials, and modelling studies of projected impact demonstrate that this FLM could have substantial impact on reducing smoking, there may be significant challenges to its implementation. As with other FLMs, tobacco industry opposition will be a barrier. Statements of the New Zealand Government elected in November 2023, which repealed the broad Smokefree Plan of the prior government, which included VLNC requirement for cigarettes, were entirely consistent with those of the tobacco industry (37).

The potential impact of this FLM may depend on a range of factors, including the overall tobacco control and regulatory environment, availability of other nicotine products, and whether the policy would be accompanied by other measures that aim to phase out certain types of tobacco products. The industry might be able to manipulate the intention of this policy through cigarette design and additives that enhance or maintain addiction. Thus, accompanying regulatory measures, such as use of nicotine analogues, and availability of other products with high nicotine content, in addition to ongoing support for cessation, would reinforce the impact of VLNCs (11,38). More generally, it is important for a VLNC regulation for cigarettes to cover all cigarettes, or possibly other combustible tobacco products, depending on the desired scope of the regulation. However, there may be significant technical challenges in extending VLNC regulation beyond cigarettes, the product on which nearly all nicotine reduction research has been focused.

Effective implementation of any product regulation measure will require robust regulatory capacity to test cigarettes for compliance with nicotine standards, as well as the ability to counter the likely threat of illicit full-nicotine cigarettes. The impact of this FLM will largely depend on a country's ability to enforce the policy and consistently measure nicotine content. Collaboration among Parties could enable those without testing facilities to have their products tested by others with such capacity. The WHO Tobacco Laboratory Network (TobLabNet) could play a key role in supporting this effort.

A significant concern is related to communication on the policy and availability with these products, with evidence that people may misperceive them as being safer or less harmful(11,32,39–44). Messages need to be carefully develop to ensure that these misperceptions are addressed (44,45),

such that there is public awareness that VLNC cigarettes are no less harmful than regular-strength nicotine cigarettes, only less addictive.

Another implementation consideration is the level of support for a VLNC regulation. The research assessing support among the population and among smokers has found a high level of public support for VLNC cigarettes among adults and among youth, mostly in high-income countries (39–43). This suggest that Parties developing this FLM would be generally supported by the public. However, given the likely very strong resistance by tobacco industry, which would include communications to the public to reduce support, efforts by governments and health stakeholders to counter those industry attempts to reduce public support would be an important component of a Party's plan toward developing a VLNC regulation.

The participants of the 2018 WHO/WHO FCTC Consultation on Tobacco Addictiveness Reduction Measures identified nine challenges to VLNC regulations, which include those that are relevant to other FLMs (11):

- 1. "Political/regulatory challenges such as adequate political support, risk of going first and possibly failing, length of time for implementation, risk of a negative impact on tax revenue, need for regional treaties to regulate trade of new products, need of country strategy for policy, risk of distraction from other policies (opportunity costs) and social acceptance of new products."
- 2. **"Behavioural/acceptability challenges** such as consumer acceptance of products and the need to develop a communication strategy." Acceptance would be easier if as a standard, no other cigarette is available in the market and non-acceptance would lead to decrease in use.
- 3. "Health challenges smokers could try to maintain the same levels of nicotine which they are accustomed to getting from other sources, including illicitly traded... This may lead to unforeseen behavioural implications, unanticipated market effects, and in some cases, unexpected health effects." Otherwise, there is no reason to believe that health effects of VLNC cigarettes would be any different, and if they lead to cessation, it would be an improvement.
- 4. **"Capacity challenges** such as the requirements for a suitable country strategy and infrastructure for the policy, potential for distraction from other policies in terms of opportunity costs, the need for clarity over the rules governing the process of transitioning to manufacturing of addictiveness reduction products, potential increased costs in general, need for capacity and know-how, and lack of monitoring capacity." The cost of tobacco product regulation is sometimes wrongly assumed to be higher than it really is. Therefore, opportunity costs should be calculated realistically and always consider potential additional sources of funding from tobacco control, such as charging costs to tobacco companies or manufacturers (nicotine content is not hard to determine).
- 5. **"Scientific and country specific evidence challenges** which include the choice of approach to reducing addictiveness, translation of research into real life, the definition of the addictiveness term, classification of products with reduced addictiveness potential, lack of country-specific evidence and lack of product specific evidence." Discussion and decisions of the COP could facilitate addressing some of these challenges.

- 6. **"Legal challenges** such as the response of the tobacco industry to such a policy, the role of regional treaties and trade agreements, constant industry innovation to reinvent itself." Industry legal challenges are expected across the board and are not unique to this FLM.
- 7. **"Economic challenges** such as the potential increase of illicit trade of combustible tobacco products, possible decrease in tax revenue [which the industry will exploit], lack of coordination and differentiated regulatory treatment between neighbouring countries which may lead to cross-border illicit trade." This is a risk with a range of FLMs, and not unique to a VLNC policy. Having an agreed upon global policy would facilitate mitigation of this challenge.
- 8. "Agricultural/feasibility challenges given the complexity and magnitude of intervention requiring adequate growing and production capacity, which could impede the timely implementation of tobacco addictiveness reduction measures. Furthermore, this may involve genetic engineering of tobacco plants which may be the subject of differing legislation in different countries, in the light of the environmental impact and consumer perception of genetically modified organisms (GMOs)." The burden of these measures would fall on the tobacco industry.
- 9. **"Ethical challenges** such as the possible impact on highly addicted smokers affected by tobacco addictiveness reduction, particularly if alternative lower-risk nicotine products were not readily available." It will be important to provide cessation support in tandem with this FLM, in addition to ensuring that there is clear communication about the advantages of quitting, not starting, versus switching to other, high nicotine products, if available.

Case study

New Zealand

The 2021 Smokefree Aotearoa 2025 Action Plan set out a comprehensive strategy aiming to minimize smoking prevalence rapidly by reducing uptake of smoking by young people and increasing smoking cessation among people who smoke. The 2022 Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act (SERPA) introduced three key measures included in the Action Plan: greatly reducing the number of retail outlets able to sell smoked tobacco products, limiting nicotine in smoked tobacco products so they are non-addictive, and introducing a 'Smokefree Generation' policy. The new Government repealed SERPA in February 2024, so none of the measures were implemented.

Although the SERPA was ultimately repealed, its development involved the accumulation of substantial evidence and analysis by the government in support of the proposed nicotine reduction measure, along with its other components (46).

Summary

This FLM would require tobacco products to be produced and sold with significant limits on the nicotine content – (VLNC). Most of the available research has focused on cigarettes, hence this brief only addressed VLNC cigarettes, although it is possible to reduce nicotine content in other tobacco products. There has been a substantial body of research studies on the impact of VLNC cigarettes from clinical trials, which have found that VLNC cigarettes could lead to significant reductions in consumption and significant increases in cessation of smoking. Modelling studies have concluded that the implementation of a VLNC cigarette regulation would lead to reductions in overall smoking prevalence due to substantially reduced rates of those who would initiate and then progress to regular smoking and thus substantially increased rates of cessation among those who smoked

cigarettes. This would lead to health gains that were estimated in New Zealand/Aotearoa to also significantly reduce the current equity gap in smoking prevalence between Māori and non-Māori peoples. Less studied, but a potentially strong impact, is the reduction of initiation by young people.

There would almost certainly be very strong resistance by the tobacco industry to this FLM. In addition, other challenges include the need to educate the public that VLNC cigarettes would be no less harmful than regular-strength nicotine cigarettes, only less addictive, the importance for regulatory capacity for product testing to assess compliance with the regulation (either in the country or in collaboration with other countries with that capacity), the need to consider the possible (or likely) illicit market of regular-strength nicotine cigarettes, and to have the capacity to address that significant challenge.

New Zealand and the United States have proposed regulations for VLNC cigarettes, and the evidence that each country has gathered in the development of those regulations provides a rich and detailed source for Parties considering this potentially impactful FLM.

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(ii) Ban on all flavouring agents and other additives in tobacco products

Abstract

Policy description and background. This policy calls for a ban on all additives and flavouring agents in tobacco products, including flavour accessories that may be used to increase their palatability and appeal, thus promoting initiation and sustained tobacco use – particularly among young people. Additives have no beneficial effects on health. Furthermore, additives can be toxic or can lead to toxicants created by pyrolysis.

This FLM aligns with the aim to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke under Article 5.2. It is also consistent with the Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC, which propose to Parties measures to reduce the attractiveness of tobacco products as part of effective tobacco product regulation, as this has the potential to contribute to reducing tobacco-attributable disease and premature death. In relation to attractiveness, guidance is provided as follows: "Tobacco products are commonly made to be attractive in order to encourage their use. 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." Further, this FLM builds on the WHO Study Group on Tobacco Product Regulation's technical report series, which has recommended banning or regulating flavours and restricting other additives since 2015.

Evidence of impact. A growing number of countries have implemented bans on ingredients that may be used to increase attractiveness or to mask tobacco smoke harshness (such as flavouring agents) in several types of tobacco products, particularly in cigarettes, and an increasing number of countries have extended flavour restrictions to heated tobacco products. Studies show that cigarette flavour bans are effective for decreasing tobacco use among adults and young people, and – contrary to industry claims – some studies indicate no increase in the use or purchasing of illicit cigarettes after menthol cigarette bans. A small number of countries and jurisdictions have banned the use of other non-flavouring additives such as cooling agents in tobacco products.

Benefits and strengths. Bans on flavouring agents in tobacco products will lead to higher cessation rates and lower initiation rates, with similar outcomes expected for other tobacco additive bans. Existing research suggests that bans on flavouring agents in tobacco products will have a significant population-level impact, with high reach (the entire population) and strength (large effects on decreasing initiation and supporting cessation). Tobacco additive bans are expected to have similarly positive effects. There is a strong conceptual foundation supporting the idea that a complete ban on flavouring agents in all tobacco products and accessories would optimize intended public health outcomes, prevent tobacco industry workarounds, and facilitate compliance and enforcement. Such forward-looking legislation would also reduce the need to revise laws in response to market developments and industry strategies to undermine regulation.

Implementation considerations. Obligations for the submission of ingredient information to regulators, and use of non-targeted laboratory methods for broad screening of product composition, may help to ensure compliance. The establishment of global or central laboratory capacity and banning of flavour accessories that may be used for tobacco products may support successful policy implementation. As tobacco products can be produced with only very few or no additives, it is proposed to ban all additives — if needed with a few exceptions, such as preservatives. Therefore, a limited and comprehensive list of allowed additives, comprised of these few exceptions, rather than a negative list of banned additives, could simplify and enhance implementation. Parties may also consider guiding principles for regulation of flavouring agents and other additives: 1) legislation needs to be comprehensive, to minimize the potential for loopholes; 2) legislation needs to be

flexible enough to adapt to developments and for changes to be made easily; and 3) to the extent possible, legislation should apply across all tobacco products (and nicotine and related products) to avoid consumer switching and thus undermining of the impact of the policy.

Conclusion. A comprehensive ban on flavouring agents and other additives in all tobacco products, including flavour accessories, will reduce initiation use and encourage cessation, and thereby decrease tobacco demand and use prevalence.

Description of the intervention

This policy would ban all flavouring agents and other additives in all tobacco products, as defined by the WHO FCTC. This FLM aligns with the aim to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke under Article 5.2. It is also consistent with the WHO FCTC Partial guidelines for the implementation of Articles 9 and 10, which call for measures to reduce the attractiveness, addictiveness and toxicity of tobacco products, as this has the potential to contribute to reducing tobacco-attributable disease and premature death. In relation to attractiveness, guidance is provided as follows: "Tobacco products are commonly made to be attractive in order to encourage their use. 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." (1)

Additive bans can be too narrow, whereas a ban on specific compounds, irrespective whether they are added or already naturally present in tobacco leaves, can be considered as forward looking. One prominent example of such a compound is sugar, which can be naturally present in tobacco leaves at up to 20% by weight. For the effects on a consumer it does not matter whether a compound is added or was already present in tobacco leaves. A ban on specific compounds thus removes the burden of proof on whether a compound is added or already present in harvested tobacco leaves.

Availability of information/research evidence on the potential impact of the FLM

Flavouring agents

Ample evidence is available on the impact of tobacco flavour bans.8 which have been implemented by a growing number of countries. Studies show that cigarette flavour bans are effective for decreasing smoking prevalence. For example, in the United States, a ban on flavoured cigarettes except for menthol in 2009 substantially reduced youth smoking (2). However, substitution to other flavoured products was also observed, and one study showed a 6% overall decrease in the probability of using any tobacco product among youth at four years post-ban (3). For menthol cigarette bans, studies from Canada (4) and the Netherlands (5) have found that such bans were significantly associated with increased quitting among adults who smoke menthol cigarettes. A 2025 systematic review and meta-analysis concluded that menthol cigarette bans promote smoking cessation among adults who smoke menthol cigarettes. However, pooled analysis showed that 24% of adults who smoke menthol cigarettes quit smoking after a menthol ban, 50% switched to nonmenthol cigarettes, 12% switched to other flavoured tobacco products and 24% continued smoking menthol cigarettes (6). Vice-versa, when flavoured molasses came on the market in the 1990s, instead of the previously used unflavoured tobacco, this was associated with increased consumption in women (7). Among countries that have considered e-cigarettes to be tobacco products, or to be regulated in a similar way as cigarettes, some have implemented bans on flavoured e-cigarettes. Three out of four studies included in a systematic review published in 2024 showed that regulations that ban or limit flavoured e-cigarette products were associated with decreased use of vaping

⁸ In this information brief, the term "flavour ban" is used, which is another commonly used term for "flavouring agent ban."

products in youth (8). All of these studies featured restrictions that banned various sweet flavours but retained flavours such as menthol and tobacco. One study found that banning flavours increased the use of a permitted flavour (mint).

It is important to note that a characterizing flavour ban is not the same as a ban on all flavourings. Under such a ban, products without a characterizing flavour may still contain flavouring additives. Most of the flavour regulations worldwide ban selling, importing, and manufacturing tobacco products with characterizing flavours (9). Flavour bans based on sensory assessment of characterizing flavours are difficult to enforce (10,11), lead to the marketing of products with levels of flavouring that would be close to or below sensory detection, thus possibly not being a product with "characterizing flavours" (12,13), and are subject to potential legal challenges that have not yet been tested in any court (14). Furthermore, flavourings at levels not clearly noticeable can still increase attractiveness. For example, menthol at levels not clearly noticeable has still been found to improve taste, facilitate initiation, and possibly convert people who smoke non-menthol cigarettes to menthol cigarettes (15). A complete ban on all flavourings will eliminate the need to develop analysis of each additive impact and attempt to regulate which levels would or would not be allowed. Thus, an optimal flavour product standard would include a complete ban on additives that have flavour properties, and be applied to all tobacco product categories as well as all components or parts of the tobacco product (that is, the tobacco, filter, wrapper or paper), including separate flavourings that can be added to the product (14).

Other types of additives

Worldwide, 62 countries have tobacco product additive-related regulations at the regional, national or subnational levels. While most of these regulations focus on flavour, especially bans on selling, importing, and manufacturing tobacco products with characterizing flavours, some countries have implemented partial or complete bans that include other types of additives (9.) For example, Canada does not permit the use of flavourings, sweeteners or several other compounds that increase the appeal of tobacco products, with a few exceptions (guar gum, alcohol flavours) (16,17). Germany (18), Belgium (19) and the Netherlands (20) have banned menthol and other activators of the cold receptor, as these facilitate inhalation of smoke, which is not allowed by the European Tobacco Products Directive (21) Germany and the Netherlands have banned many other classes of additives as well.

To the best of our knowledge, no evaluations of the impact of these (partial) bans on additives other than flavourings have been conducted to date. Given that in many cases their effects are similar to flavourings, that is, to facilitate use, it is expected that banning such additives will also decrease use. There is evidence that additives, such as sugars, synthetic cooling agents, and humectants, can make cigarette smoke easier to inhale, for example by decreasing its harshness. This may improve the smoking experience, making it easier for young people to start smoking and harder for those who smoke to quit (16).

A total ban on the use of additives in all types of tobacco products will impact the entire population of people who currently use tobacco, people who have quit using tobacco and those who have never used tobacco. The policy may have a greater impact on people who are just starting to use tobacco by reducing its appeal. Early aversive experiences (for example, exposure to harshness and bitterness of tobacco smoke) could potentially deter continuation of use, and limit the amount of nicotine inhaled and exposure to nicotine's addictive effects (16). Additionally, the policy may have a stronger impact on groups, such as young people and women, who may be more inclined to initiate smoking due to additives that facilitate inhalation (22).

Overall, existing research suggest that tobacco flavour bans will have a large population-level effect, with high reach (the entire population), and strength (significant effects on initiation and cessation). Tobacco additive bans are likely to have similar population-level impacts. For other additives, the reach will also be the entire population, but no data are available on strength. To the best of our knowledge, no impact assessments have yet been carried out on (partial) bans on additives other than flavourings. However, given that most additives have similar mechanisms to facilitate use, banning such additives is expected to decrease use via decreased initiation and increased cessation. Once implemented and properly enforced, they will be effective immediately. Banning all additives, especially those that make the use of tobacco products more attractive and addictive, will strengthen the message that sale of such highly toxic and addictive products is not normal. Additives, especially flavourings, lead to misperceptions about the risks of using tobacco products. For example, many smokers, including young smokers, incorrectly believe that menthol products are less harmful because they are less harsh and easier to use (23).

Awareness and profile of this FLM as a potentially promising intervention

Worldwide, 62 countries have already implemented tobacco product additive-related regulations, showing awareness and recognition as a promising intervention (see evidence section for details). Regulations that prohibit additives classified in the Joint FAO/WHO Expert Committee on Food Additives and the Flavour and Extract Manufacturers Association (24,25) as flavouring, regardless of amount levels used (that is, bans additives in concentration levels that are below consumers' perception) have been implemented in Canada, and adopted but not yet implemented in Brazil. Some European Union member states have banned specific classes of additives.

Support for flavour bans has also been studied. Studies from the United States have found > 60% support for bans on menthol and flavoured tobacco among youth and young adults across racial or ethnic groups, including those who use these products (26), and 58% support for a ban on flavoured tobacco among adults (27). A study of adults who smoke in Brazil also found majority support for a ban on the use of menthol in cigarettes (56%), and a ban on all additives in cigarettes and tobacco (62%), across all sociodemographic groups (28)

Implementation considerations specific to this FLM

As tobacco products can be produced with only very few or no additives, it is proposed to ban all additives, if needed with a few exceptions, such as preservatives. This will lead to a positive list of allowed additives, rather than a negative list of banned additives, facilitating implementation and enforcement. This would also preclude replacement by non-banned additives, for example, the shift to synthetic cooling agents when menthol was banned in the United States. Such a measure is forward looking and has only been implemented by few countries. Banning additives altogether would preclude the regulatory challenges that would arise by the need to prove that they help make tobacco products attractive, addictive, or toxic, which would be required by some jurisdictions if these additives were to be regulated separately.

Consideration of a comprehensive ban on additives in all tobacco products and flavour accessories will be important to ensure successful policy implementation. Implementation of a ban that covers all tobacco products would help to prevent shifts in tobacco product types used, as observed when the Netherlands and the United States banned flavours in cigarettes and not in small cigars (29,30). A study in the United States found that 11–46% of people who smoke reported that they would consider switching to other tobacco products, in response to a hypothetical menthol cigarette ban, including 15–30% to e-cigarettes (31). Moreover, the availability of flavour accessories in many countries may undermine the effectiveness of tobacco flavour and additive bans (32).

To ensure compliance, WHO FCTC Article 10 calls for regulations that require tobacco manufacturers to send ingredient information to the regulator. In addition, non-targeted laboratory methods for broad screening of the composition of tobacco products will be necessary to ensure compliance. The establishment of global or central laboratory capacity will also be necessary for enforcement, particularly in low- and middle-income countries.

Based on experiences from other countries that have banned menthol and other flavours in tobacco products, a complete ban on additives that have flavour and/or sensory properties may offer several advantages compared to a characterizing flavour ban. Characterizing flavour bans may be challenging to enforce. For example, they would require regulations to specify methods for determining the presence of a characterizing flavour. It may also be difficult to determine whether a compound was added to tobacco-leaf based products versus a by-product of manufacturing, and/or naturally present in tobacco leaves. For example, cigarettes may contain menthol, even if it is not intentionally added by manufacturers, as it can naturally occur in tobacco or be a contaminant of manufacturing processes (33,34).

Parties may also consider guiding principles for regulation of flavouring agents and other additives:

1) legislation needs to be comprehensive to minimize the potential for loopholes; 2) legislation needs to be flexible enough to adapt to developments and for changes to be made easily; and 3) to the extent possible, legislation should apply across all tobacco products (and nicotine and related products), to avoid consumer switching and thus undermining of the impact of the policy.

The tobacco industry and other critics of a flavour ban have suggested that such a policy would lead to an illicit market. However, studies have found no increase in illicit trade after the implementation of menthol cigarette bans in Canada (35,36), the Netherlands (37) and England (38).

Summary

This policy aims to ban all flavouring agents and other additives in all tobacco products, and it aligns with WHO FCTC Partial guidelines for the implementation of Articles 9 and 10 that call for measures to reduce the attractiveness, addictiveness and toxicity of tobacco products. Most additives have no beneficial effects on health. By contrast, additives such as flavouring agents do make tobacco products more appealing to new users or make it more difficult for established users to quit. Furthermore, additives can be toxic or can lead to toxicants created by pyrolysis.

A growing number of countries have implemented tobacco flavour bans. Studies show that cigarette flavour bans are effective for decreasing prevalence of use, especially among novice users. A small number of countries have banned specific additives such as cooling agents, or almost all additives, but research on the impact of such bans is not currently available. However, there is a strong conceptual foundation supporting the idea that a complete ban on flavourings and all other additives versus a ban on characterizing flavours in all tobacco products and accessories would optimize intended public health outcomes, prevent tobacco industry workarounds, and facilitate compliance and enforcement.

To check compliance, it is advised to oblige manufacturers to send ingredient information to the regulator and to use non-targeted laboratory methods for a broad screening of the composition of the products. Setting up worldwide laboratory capacity or central laboratories that can also help LMICs, can be considered. Banning all additives including flavouring agents removes the difficulties of enforcing flavour bans based on sensory assessment of characterizing flavours or labelling.

As tobacco products can mostly be prepared with only very few or no additives, it is proposed to ban all additives with a few exceptions. This will lead to a positive list of allowed additives, rather than negative lists of banned additives.

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(iii) Tobacco supply freeze on brands and reduction of variants

Abstract

Policy description and background. This policy aims both to freeze the quantity of tobacco products available in the market and to reduce the variety of products by banning – or, at a minimum, placing a moratorium on – the entry of new products (allowing only products already in the market to be sold). When combined with restrictions on existing brand variants (that allow only one presentation per brand), the approach will further reduce the number and variety of available products. Banning the entry of new tobacco products in the market would give countries the time to develop regulatory frameworks after evaluating the public health and environmental impacts of these products.

This FLM avoids the promotion of a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions through alignment with both Article 11 of the WHO FCTC, on measures on tobacco product packaging and labelling, and Article 13, through a comprehensive ban on advertising, promotion and sponsorship. The implementation of this FLM also aligns with the promotion of cessation of tobacco use and adequate treatment for tobacco dependence (Article 14). More broadly the FLM aligns with the aim to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke under Article 5.2.

Evidence of impact. There is evidence that a ban on new products and a reduction in brand variants can be implemented successfully. There is also evidence that the entry of existing products in new markets without regulatory frameworks, may lead to the emergence of new trends, such as the increase in waterpipe tobacco smoking among young people in the United States and Europe. As a result, waterpipe tobacco was banned from entering some markets, including Kenya, Pakistan and Tanzania; and snus is banned in Australia, the European Union (except for Sweden), New Zealand, Singapore and Sri Lanka. A 2023 systematic review of policies on smokeless tobacco products (including snus), covering countries where these products are banned, reported that in two of the three studies that evaluated the impact of bans on smokeless tobacco, there was a significant reduction in the sale and use of these products.

Uruguay is the only country to have implemented limitations on cigarette brand variants and successfully defended the policy against a legal challenge brought by a tobacco company. Research has demonstrated that replacing cigarette brand names with numbers may deter smoking initiation. Brazil also invoked this principle in 2009 when it restricted the entry of any products with an electronic element – including heated tobacco products – into the market, pending evidence of their safety and non-toxicity.

Benefits and strengths. A supply freeze would prevent the tobacco industry from continuing attempts to "reinvent" itself and launching new products — especially those that are particularly appealing to young people. A reduction in the types of variants from each brand would also reduce the brand appeal, and a freeze would preclude new products taking their place. These restrictions would have the potential to reduce youth experimentation, initiation and uptake, and could potentially encourage tobacco cessation among users versus switching to other tobacco products not yet available.

Implementation considerations. A tobacco supply freeze is a measure that governments can justify for the protection of public health. Regulations are necessary to limit both the number of brand variants and the number of brands that are allowed on the market. Implementation without a prolonged phase-in period would help to prevent the tobacco industry from flooding the market with new products ahead of entry into force. Enforcement would focus on measures to prevent illicit

trade and to ensure that sellers are informed about which products are allowed to be sold and what presentation (variant) of each product is allowed.

Conclusion. This policy is feasible, has been successfully implemented to varying degrees in other countries, has public support and, if implemented across all products, could have a significant positive impact on tobacco consumption and prevalence.

Description of the intervention

In this brief, a tobacco supply freeze on brands and reduction of variants is defined as a measure that prohibits the introduction of new products to the market, in combination with eliminating existing brand variants (that is, to only allow one presentation of a brand). This would thus reduce product supply (henceforth referred to as a supply freeze and reduction). "New products" are defined as those that would be new in a particular country's market, and not necessarily by how long a product has been in production. Banning new tobacco products and limiting the number of brand variants, or product presentations, could potentially reduce supply of tobacco products in the long-term. New products are often launched in test markets first, thus giving other countries the opportunity to place a moratorium or to ban these products from entering their markets a priori.

Tobacco product bans have been implemented by some countries. Snus, for example, is banned in the European Union (except for Sweden), Sri Lanka, Singapore, Australia and New Zealand. Water pipe is banned in Pakistan, Kenya and Tanzania. Uruguay is the only country that requires tobacco companies to sell a single variant per cigarette brand. Combined, these measures would create a supply freeze and reduction as variants would not be able to enter the market under the guise of new products.

In response to the implementation of WHO FCTC policies to curb the use of combustible tobacco products, the industry has attempted to overcome these restrictions by investing in a range of new tobacco and nicotine products. Evidence on the health and environmental impact of these new products is emerging (1-4).

This FLM would allow Parties to consider the appropriate regulatory framework for specific products before they enter the market, taking health and environmental impacts into account. This approach prioritizes the public health precautionary principle and allows for the regulatory process to take place proactively, while also disincentivizing increasing the range and variation of tobacco products in the market.

Brazil invoked this principle in 2009 when it restricted the entry of any products with an electronic element – including e-cigarettes and heated tobacco products – into the market, pending evidence of their safety and non-toxicity (5,6). A ban on new products, combined with a single brand presentation requirement – where only one variant per brand is allowed (for example, eliminating options such as Brand X in red, silver, and blue) – would reduce the number of products on the market and constrain the expansion and reach of marketing for existing brands. Such measures are well-aligned with the principles and obligations set out in WHO FCTC Articles 5.2, 11, 13 and 14.

Availability of information/research evidence on potential impact of FLM

This FLM measure would freeze and then reduce the supply of tobacco products in countries, by prohibiting new products to enter the market, and limiting existing products to a single brand variant. It would be applicable for both new industry-developed products as well as for existing products that are trying to enter a new market. It is aligned with the aim of the WHO FCTC to prevent or reduce nicotine addiction. A ban or moratorium in tobacco products, in accordance with a country's definition of tobacco products, would increase success of the measure and lead to a reduction in tobacco use prevalence. This FLM is could work alongside a sinking-lid strategy (7,8),

instead of lowering quotas of tobacco products supplied, as a sinking-lid strategy is designed to do, this FLM would freeze the market (that is, allowing only products already in the market to be sold), and would permit only one variety per brand to be sold.

Tobacco companies use colours, descriptors and other design features to extend a tobacco brand across multiple variants. This increases the reach for each brand, and the appeal to a broader potential consumer base. Uruguay is the only country that requires cigarette companies to adhere to a single presentation (one brand variant) per brand.

There is evidence that a ban on new products and a reduction on brand variants can be successfully implemented. The global increase in the use of non-combustible products, as well as water pipes among young people (9) remains a serious public health concern. Limiting the availability of and diversity of products available could potentially reduce experimentation and initiation of tobacco use among young people and could serve as additional motivation for Parties to prevent the entry of new products into their markets. Protection of young people is well aligned with the WHO FCTC (10), and with human rights to health (11).

It is important that a supply freeze focus on both existing products that are already marketed and sold in other countries (for example, water pipe), as well as new products that have little or no global presence. This will support the reduction of product availability, limit brand variants and prevent the introduction of new variants to the market under different brand names.

A supply freeze could also facilitate health communication with the public and counter misinformation and misperceptions, for example unfounded claims that waterpipe smoking is safer because the smoke passes through water (12). A supply freeze would also allow time to address the scientific and public knowledge gap on the health and environmental impact of new products (13).

A 2023 systematic review of policies on smokeless tobacco products (including snus), covering countries where these products are banned, reported that in two of the three studies that evaluated the impact of bans on smokeless tobacco, there was a significant reduction in the sale and use of these products (14).

Assessment of electronic cigarette use found that, after Brazil's ban, current use remained below 3.5% among young people (15) and adults (16), in comparison to higher rates of use in countries without a ban (17).

In 2016, Uruguay successfully defended its single brand presentation requirement after a six-year legal challenge brought by Philip Morris International under a bilateral investment treaty (18). The tribunal's decision emphasized the significance of Uruguay's obligations under the WHO FCTC as a key basis for its ruling (19).

A 2017 study found that 62% of cigarette brands in retail shops in Montevideo, Uruguay, were compliant with the single brand presentation requirement six years after the policy was implemented (20). The authors recommended that further restrictions (that is, cigarette package size) should be considered to more comprehensively standardize the availability of each brand in the market. Research has demonstrated that replacing cigarette brand names with numbers may deter smoking initiation (21,22).

Reach of the FLM: specific population groups versus broad general population

Implementing a supply freeze and reduction could reduce tobacco/nicotine use initiation, prevent addiction, and thereby decrease prevalence, especially among young people.

Young people appear to be particularly vulnerable to the introduction of new products. In several countries, including England, Ireland and Sweden, a decline in combustible cigarette use among young people was accompanied by an increase in other forms of nicotine product use, and a subsequent increase in combustible cigarette use (9,23–26).

Access to a wide range of tobacco products may hinder cessation efforts, encourage the use of multiple products and thus lead to increased nicotine intake, greater addiction and negative health outcomes (27). While there could be some concern for adult smokers who may want to switch to a product that would not be available in the market (23,24) and might be impeded to do so by this policy, these concerns could be countered by ongoing support for evidence-based cessation. Additionally, adult smokers in countries where such products are already available would continue to be able to access them, as the supply freeze would apply to new products only, not existing ones (28,29).

Potential of the FLM to disrupt systems that perpetuate and entrench tobacco use

There is high level of public awareness about the harms of tobacco products, and global tobacco use prevalence has declined since the WHO FCTC entered into force (30). Implementation of this FLM in combination with other measures, such as plain packaging, would decrease the tobacco industry's ability to introduce new brands in response to tobacco control policies, reducing the diversity of the tobacco product market.

As this FLM would limit the number of markets where the tobacco industry would be able to test and launch new products and new brand variants, it has the potential to disrupt systems that currently allow the tobacco industry to "reinvent" itself through new product ranges (31).

Strength of the FLM

This FLM has the potential to reduce experimentation with and initiation of use of new tobacco products among young people, by limiting the introduction of products that serve to maintain nicotine addiction in the face of declining combustible cigarette use (32).

A growing number of Parties have banned the use of flavours and other additives in tobacco products (33), and this FLM would go a step further by limiting all the various presentations, or variants, in any brand to one, as well as limiting entry of new flavours and new features in the market.

The level of impact will be determined by the comprehensiveness of the measure. Implementation of restrictions on brand variants restrictions that apply to all existing tobacco products in the market and not only to combustible cigarettes would have the greatest impact.

Population-level impact of the FLM

In addition to preventing experimentation and initiation, a supply freeze and reduction could potentially encourage people to quit tobacco use versus switching to other tobacco products not yet available. This could eventually lead to an overall reduction of tobacco/nicotine users.

Time frame of the FLM's impact after implementation

It is unclear how consumers will respond to such a measure. Brand consumers may migrate to the one existing brand, or migrate to another brand, depending on what remains on the market. Research evaluating the impact of menthol bans, for example, demonstrate that cessation was an

outcome, rather than migration to different menthol products (34). Similarly, research on policies to limit or ban availability of smokeless tobacco demonstrate a reduction in prevalence (14).

Awareness and profile of the FLM as a potentially promising intervention

A supply freeze has been discussed at several meetings of the COP, in the context of Parties that have banned one or more tobacco products from their market (35–38). The ban or restriction of sales of heated tobacco products (HTPs), water-pipe tobacco, and oral nicotine pouches in different countries globally shows that it is possible to ban the introduction of new products or restrict their use. There is growing awareness of this FLM in discussions of national definitions of the scope of regulatory authority among WHO FCTC Parties. When a complete ban of new products is not feasible, a moratorium for entry of new products would allow time for regulatory agencies to assess the public health and environmental impacts of these new products.

Uruguay's successful case to eliminate brand variants received wide attention but has not yet proved sufficient to generate the adoption of similar policies in other countries. Research has found an increase in cigarette brand variants that make references to quality (that is, premium), taste, colours and other descriptors that enhance cigarette brand appeal (39), after the implementation of tobacco plain packaging in Australia.

Implementation considerations specific to this FLM

The industry will likely make arguments that this FLM constitutes improper restrictions on the free commerce of goods. However, free trade and investment agreements often include provisions for the implementation of public health measures, provided they are justified and proportionate, and there are established legal precedents supporting restrictions on commerce for the protection of public health (40). A tobacco supply freeze is a measure that governments can justify for the protection of public health (41). Uruguay's legal precedent for a single brand presentation requirement may support Parties who are considering implementation of this policy in combination with a supply freeze.

It is important to note that while restrictions on tobacco brand variants will reduce product differentiation, they still allow tobacco companies to introduce new brands. In Uruguay, for example, the manufacturer of the leading Nevada cigarette brand responded to the single presentation requirement by replacing its "light" variant with a new "California" brand. Uruguay's experience highlights the need for regulations that limit both the number of brand variants as well as the number of brands that are allowed on the market.

Implementation of a supply freeze without a transition period would help to prevent the industry from flooding the market with new products before policy implementation. Successful implementation will require effective monitoring and regulatory capacity to identify non-compliant products, together with robust enforcement and penalties for those involved in the supply and sale of such illicit products.

Summary

Banning new tobacco products and limiting existing products to one presentation (or variant) would reduce uptake and use of these products, and encourage cessation, particularly among young people.

New products are often launched in test markets first, thus giving other countries the opportunity to place a moratorium or ban the entry of these products in their own market. It is important to realize that product ban per se is not a new concept.

There is evidence that the entry of existing products in new markets without regulatory frameworks, may lead to the emergence of new trends, such as the increase in waterpipe smoking among young people in the United States and Europe. As a result, water-pipe tobacco was banned from entering some markets, including Kenya and Tanzania. Banning the entry of new products in the market would give countries the time to develop regulatory frameworks after evaluating the public health and environmental impacts of these products.

Introducing a ban or moratorium on new products aligns with the WHO FCTC's mandate on reducing the demand to tobacco products by reducing availability in the market, encouraging quitting and protecting the environment and human rights to health.

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(iv) Ban on cigarette filters

Abstract

Policy description and background. This policy prohibits the sale, import, distribution and manufacture (where relevant) of cigarettes with filters, as well as filters that are sold separately from cigarettes. Around 90% of cigarettes on the market are filtered. Although filters are marketed by the tobacco industry as an effective method for reducing the harms of cigarette smoke, in reality they do very little to prevent the many toxicants in cigarette smoke from being inhaled and thus do not eliminate the harms of cigarette smoking. In fact, filters have been shown to lead smokers to engage in more intensive puffing, which leads to deeper deposit of the toxicants. Ultimately, this has contributed to increased rates of lung adenocarcinoma, a particularly deadly form of lung cancer. While the microfibres that comprise cigarette filters have been found in lung tissue of patients with lung cancer who smoke cigarettes, further research is needed to establish a causal effect. In addition to their negative impacts on public health, cigarette filters are harmful to the environment, as a major source of plastic pollution.

Removing any filters from cigarettes would have important effects in reducing the appeal and attractiveness of cigarettes, in line with Articles 9 and 10 and their Partial guidelines for implementation. Plastic filters in cigarettes pose additional environmental harms. In relation to Article 18, decision FCTC/COP10(14) recognizes "that plastic cigarette filters are unnecessary, avoidable and problematic, single-use plastics that are widely spread in the environment, killing microorganisms and marine life, as well as polluting oceans". In addition, it notes "the work of the Intergovernmental Negotiating Committee on Plastic Pollution, the issue of microplastic pollution caused by plastic cigarette filters, ongoing global efforts in the development of standards for hazardous waste management under environmental laws, and the fact that the WHO FCTC has been officially referenced during the United Nations plastics treaty negotiations".

Evidence of impact. To date, Santa Cruz County, in California (United States), has passed a filter ban that will be implemented in 2027 or when two other local jurisdictions pass similar ordinances, whichever is later. As there is no evidence of the impact of a filter ban at this time, the information presented in this report discusses the conceptual foundation for such a ban.

Benefits and strengths. Banning cigarette filters would: 1) eliminate the false perception that filtered cigarettes are safer than unfiltered cigarettes; 2) reduce plastic pollution; 3) reduce the economic costs of cigarette litter clean-up; and 4) reduce the environmental harm caused by toxic chemicals in discarded cigarette filters.

A comprehensive ban on cigarette filters — which have been identified by tobacco companies as features that improve brand popularity — would make smoking less attractive to people who smoke, and especially young people. Young people in particular perceive filtered cigarettes as less harmful, and this false perception would be removed. The harshness of the initial smoking experience may reduce its pleasurable effects, potentially discouraging young people from initiating smoking or progressing to regular smoking.

Because unfiltered cigarettes are perceived as offering a less satisfying sensory experience, their removal could potentially both decrease the likelihood of initiation or progression to regular smoking and increase the likelihood of quitting among those who smoke. However, there is no direct evidence of this. Banning cigarette filters would also prevent tobacco industry marketing that conveys misperceptions of safety or other desirable qualities of filtered cigarettes. Banning filters would also remove "flavour capsule" cigarettes from the market.

Implementation considerations. Strong regulatory and enforcement capacity will be important to ensure compliance. There will be resistance from the tobacco industry, which has relied on the

deception of filters to increase the appeal of cigarettes to those initiating smoking, particularly among young people and women, as well as to keep people who smoke from quitting. The industry may advocate use of biodegradable or plastic-free paper filters, which would do little to counter public misperceptions that these alternative filters reduce the harms of cigarette smoke, the resulting health consequences that sustain continued smoking and the environmental impact of toxins leaching from discarded cigarette butts. Implementation of a comprehensive ban on cigarette filters together with public education and producer pays regulations may accelerate health and environmental benefits. Santa Cruz County's filter ban, which was driven by environmental concerns, highlights the importance of building broad stakeholder support for this measure. Public education campaigns, cessation support, and surveillance to monitor changes in the market and consumer behaviour should also be considered to ensure effective implementation.

Conclusion. Banning cigarette filters could have positive health and environmental impacts, including reducing smoking prevalence and decreasing both the economic costs of cleaning up toxic cigarette butt litter and the environmental contamination from its toxic chemicals. Adopting this measure would reduce the demand for cigarettes and lower smoking uptake, thereby saving lives, and would promote environmental and socioeconomic objectives. To ensure successful implementation, a ban on cigarette filters, as part of comprehensive tobacco regulation aligned with the WHO FCTC, requires collaboration across sectors and coordination with global initiatives.

Description of the intervention

"Cigarette filters have been referred to as the deadliest fraud in the history of human civilization." (1)

Cigarette filters are components attached to the end of more than 90% of commercially sold cigarettes, claimed to reduce the amount of particulate matter that is inhaled by people who smoke, thereby reducing the perceived harshness of cigarette smoke (2). Cigarette filters are also sold separately for attachment to cigarettes (3). This FLM would prohibit the sale, import, distribution and manufacturing (where relevant) of cigarettes with filters, as well as all filters that are sold separately from cigarettes – referred to in this information brief as a ban on cigarette filters.

Although filters were introduced for cigarettes in the 1920s and 1930s, tobacco companies significantly increased their use in the 1950s as a so-called safer way to smoke, in response to scientific evidence that smoking causes lung cancer (4). Although filters are marketed by the tobacco industry as an effective method for reducing the harms of cigarette smoking, in reality they do very little to prevent the many toxicants in cigarettes from being inhaled. In fact, filters' design has been shown to lead smokers to engage in more intensive puffing, which leads to deeper deposition of the toxicants. Ultimately, this has contributed to increased rates of lung adenocarcinoma, a particularly deadly form of lung cancer (5,6).

In addition to their negative impacts on public health, cigarette filters are harmful to the environment. Cigarette filters are typically made of non-biodegradable cellulose acetate and are the most littered item globally (7). It is estimated that 1.58 to 3.59 trillion butts are discarded globally every year – see report *Regulatory options to prevent environmental harm and pollution across the tobacco product life cycle*, supplementary information to the document FCTC/COP/11/7) – amounting to 489 800 to 1 129 000 metric tonnes of waste. Discarded cigarette butts contribute plastic waste and leach toxicants from cigarette smoke into ecosystems, with an annual cost of US\$ 26 billion – including packaging waste, with LMICs bearing the greatest burden (6,8). Microplastics from filters have been found in lung tissues, posing additional health risks (9).

The WHO supports a ban on cigarette filters because they have no proven health benefits and are a major source of plastic pollution that is harmful to the environment (10).

Banning any cigarette filters aligns with the WHO FCTC guiding principles for the implementation of measures to reduce the attractiveness and incorrect perceptions of the safety of tobacco products, especially to tobacco-naïve young people and women. Plastic filters in cigarettes pose additional health and environmental harms. Decision FCTC/COP10(14) addresses the environmental harms of the tobacco products that are linked to the implementation of Article 18, "recognizing that plastic cigarette filters are unnecessary, avoidable and problematic single use plastics that are widely spread in the environment, killing microorganisms and marine life, as well as polluting oceans" (10). In addition, it notes "the work of the Intergovernmental Negotiating Committee on Plastic Pollution, the issue of microplastic pollution caused by plastic cigarette filters, ongoing global efforts in the development of standards for hazardous waste management under environmental laws, and the fact that the WHO FCTC has been officially referenced during the United Nations plastics treaty negotiations" (10). The WHO supports the immediate ban of plastics in nicotine and tobacco products, and where an immediate ban is not feasible, a gradual phase-out or stringent control of plastics present in tobacco products, electronic delivery systems, and packaging, recognizing them as problematic and avoidable plastics under the treaty (11). Given that the tobacco industry promotes their extended producer responsibility systems, it is important for Parties to protect tobacco-related environmental policies from the commercial and vested interests of the tobacco industry and those working to further its interests, as called for by WHO FCTC Article 5.3.

Banning cigarette filters would: 1) eliminate the false perception that filtered cigarettes are safer than unfiltered cigarettes; 2) reduce plastic pollution; and 3) reduce economic costs of cigarette litter clean up.

Availability of information/research evidence on potential impact of this FLM

Over 90% of cigarettes on the market are filtered (2). Filtered cigarettes are marketed as safer than unfiltered cigarettes, despite evidence of their harmful effects on health and the environment. Since efforts to change consumer behaviour have proven ineffective in reducing cigarette filter litter, banning filters could yield significant public health, socioeconomic and ecological benefits (12).

Health impacts

Cigarette filters were introduced and manipulated by tobacco manufacturers to give the impression of reduced harm, which increases smoking and reduces quitting (13-15). Consumers believe that filters make cigarettes safer (7). However, research shows that cigarette filters do not make cigarettes safer (4,5,13).

The incidence of squamous cell carcinoma of the lung declined with the decline in unfiltered cigarette use, while at the same time the incidence of adenocarcinoma increased and eventually surpassed it in countries, including the United States, Japan and Belgium. In women, it was observed that it was adenocarcinoma from the start, reflecting the high uptake of filtered cigarettes by women. It can be concluded that filters failed to protect against lung cancer and instead contributed to a shift in the predominant cancer type, from squamous cell carcinoma to adenocarcinoma (6,8).

The microfibers that comprise cigarette filters have been found in lung tissue of patients with lung cancer who smoked cigarettes, suggesting a potential health risk. However, these finding are not conclusive and further research is needed to establish a causal effect (16). This is important to keep in mind, as a filter, not filter ventilation, ban is needed.

Removing filters from cigarettes would have important effects in reducing the appeal and attractiveness of cigarettes, in line with the partial guidelines of Articles 9 and 10 (17). A 2023 study of adults who smoke found that unfiltered cigarettes are perceived as being harsher, worse tasting, less enjoyable, and less satisfying, as well as "more potent, aversive and negatively reinforcing". This suggests that banning filtered cigarettes may make them less appealing, which would have the

potential of reducing smoking (18). These points are also important to be considered when biodegradable filters are proposed by the industry, as such non-plastic filters would likely perpetuate the misperceptions that filters reduce the harms of cigarette smoke.

A filter ban would also prevent another cigarette design that has been known to increase appeal of cigarettes – flavour capsules. Flavour capsules are gelatine capsules filled with a flavouring liquid embedded in the filter, which is released when crushed. Flavour capsule cigarettes are particularly appealing to young people and women, as they are perceived as tasting better, smoother on the throat, more fun to use, and more attractive compared to non-capsule cigarettes. Their use is also disproportionally higher in LMICs (19).

The littering of cigarette filters is associated with areas of high frequency of socializing, greater diversity of people who do not know each other, and where smokers feel a sense of ownership, comfort and relaxation (20). Therefore, a filter ban could de-normalize smoking behaviour.

Environmental impacts

Cigarette filters are made of cellulose acetate, a non-biodegradable plastic. Based on 2020 cigarette sales data, it is estimated that 4.78 trillion cigarettes are smoked annually, leading to 1.58 to 3.59 trillion filters discarded into the environment (21); see also report Regulatory options to prevent environmental harm and pollution across the tobacco product life cycle (supplementary information to the document FCTC/COP/11/7)). These have a high toxic load and leach the toxins into the environment, impacting ecosystems, and posing a risk to human health (22). In Europe, cigarette filters make up 17% of all plastics and 21% of all single-use plastics found on beaches (4). Cases of small children ingesting cigarette filters, a third of which had transient nicotine toxicity, have been reported, placing them as an additional group who would be protected when a filter ban is put in place (16).

The cost of cleaning up discarded cigarette filters is generally incurred by taxpayers, rather than the tobacco industry. It is estimated that the global annual cost of plastic pollution from cigarette is US\$ 26 billion, with an estimated cost of US\$ 186 billion over a 10-year period. Highest costs will be borne by LMICs (8). Efforts to clean up cigarette litter cost taxpayers an estimated \$2.6 billion in China, > US\$760 million in India, > US\$ 200 million in Brazil and < US\$ 230million for Germany. These are the direct cleanup costs; however, the actual costs may be even greater when considering the potential reduction in ecosystem services (12). The relative costs of cigarette litter clean-up would be even greater in countries, such as Jordan, where tobacco product waste is estimated to account for about 42% of the all product waste (12). Nevertheless, clean-up efforts alone are inadequate to address the trillions of cigarette butts that are discarded annually.

Some jurisdictions have taken action to reduce the economic costs of cigarette butt litter. In November 2022, the mayor and City Council of Baltimore (United States) filed a lawsuit against six major tobacco companies to require them to provide compensation for the harms of cigarette litter, including "economic loss, including millions spent in clean up, decreased property values, and lost business revenue caused by smelly and unsightly litter; environmental degradation, including the poisoning of the city's water ways, beaches, fields, pets and wildlife; the diversion of city resources, such as government labour, time, and attention devoted to this problem; as well as the unmitigated harms caused by all the cigarette butt litter that deteriorates into microplastics full of toxic chemicals before it can be found and collected" (23).

In Spain, 2023 regulations require the tobacco industry to cover cost of road cleaning of cigarettes (estimated at between US\$ 13 to US\$ 22 per inhabitant per year)(24). The city of San Francisco (United States) established a Cigarette Litter Abatement Fee starting in 2009 by adding US\$ 0.20 to

every pack of cigarettes, placing the responsibility of clean up on the manufacturer. This fee has been raised over the years to reach US\$ 1.50 per pack as of 1 January 2024 (25).

Awareness and profile of this FLM as a potentially promising measure

On the basis of scientific evidence that cigarette filters are harmful to human health and the environment, the Belgian Superior Health Council proposed a ban on cigarette filters as single-use plastics (SUP) in 2023 (21).

In April 2023, the Dutch Secretary of State for Infrastructure and Water Management stated that "the government is seeking cooperation with other member states to put a ban on filters on the agenda for the next revision of the SUP Directive in 2026" (21).

The County of Santa Cruz (United States) passed legislation in October 2024 that prohibits the sale of filtered tobacco products, which will come into effect 1 January 2027, or when two other local jurisdictions pass similar prohibitions, whichever is later. This is part of the county's leading efforts in reducing plastic waste (26).

Recent policy developments have led to the adoption of extended producer responsibility (EPR) in several European countries. This policy aims to hold industries accountable for pollution, thereby implementing the principle of "polluter pays". While the approach has some advantages, it is insufficient to reduce plastic pollution because EPR primarily addresses pollution from a waste management standpoint, focusing on end-of-life products. However, research consistently shows that interventions earlier in the product life cycle are more effective. This concept aligns with the "waste hierarchy" established by the European Union (2008), which prioritizes waste prevention as the most desirable approach (12). Therefore, a complete ban on cigarette filters may be a more effective policy solution. Banning cigarette filters would have a positive effect on population health by both reducing smoking prevalence and protecting the environment. A 2025 study of the European Union Single-Use Plastics Directive and the United Nations Plastics Treaty negotiations also highlights the need for safeguards to prevent the industry from exploiting EPR programmes for tobacco waste to promote "corporate social responsibility" of the tobacco industry. The study proposes to rename tobacco EPR as "extended producer liability" to ensure that WHO FCTC health and environmental objectives are protected from industry interference. This distinction is essential: the tobacco industry would bear the financial liability, while the design and operation of EPR systems must, in accordance with Article 5.3, be entirely independent of industry involvement. In addition, it should be noted that any attempt by the industry to conduct corporate social responsibility marketing (for example, publicizing the fact that they were providing funding to clean tobacco waste, even if they were not managing clean-up activities) would run counter to Article 13 (27).

A comprehensive ban on cigarette filters would make smoking less attractive to people who smoke (18), especially for young people (28). Young people in particular perceive filtered cigarettes as less harmful (29), and this false perception would be removed instantly with a cigarette ban. The harshness of the initial smoking experience may reduce its pleasurable effects, potentially discouraging young people from initiating smoking or progressing to regular smoking. In a crossover randomized trial in which adults who smoke cigarettes were switched from filtered cigarettes to unfiltered cigarettes, those who smoked the unfiltered cigarettes perceived them to have greater nicotine effects, but less desirable sensory effects than filtered cigarettes, and they smoked fewer unfiltered cigarettes during the trial (18). Because unfiltered cigarettes are perceived as offering a less satisfying sensory experience, their removal could potentially both decrease the likelihood of initiation or progression to regular smoking and increase the likelihood of quitting among those who smoke. However, there is no direct evidence of this. Banning cigarette filters would also prevent

tobacco industry marketing that conveys misperceptions of safety or other desirable qualities of filtered cigarettes (28).

Banning filters would also remove "flavour capsules" which are inserted in cigarette filters from the market. Flavours have been associated with increased attractiveness, especially with tobacco naïve young people, and flavours are associated with reduced quit rates (19). Banning the sale of separate filters, used in roll-your-own cigarettes, would also decrease the attractiveness of these cigarettes, which are often used with separate filters.

There is strong evidence from lower levels of biological organization that cigarette filters pose a hazard to the environment and require tighter legislation (30) The average filter stays in the environment for over 10 years, leading to cumulative waste and increasing the leaching of toxins into ecosystems (12). Limited research has examined the damages caused to aquatic biota when cigarette butts are disposed of on water surface. However, there is evidence that even highly-diluted cigarette butt leachate (CBL) concentrations can induce behavioural changes in freshwater bivalves, and that CBL extrapolation to natural environments can damage the fitness of living organisms and affect the dynamics of their population (16). This is an important point to combat tobacco industry proposals to introduce biodegradable filters, as toxic leachates would still be present.

In addition to the health and environmental benefits, a cigarette filter ban would confer socioeconomic benefits by decreasing the clean-up costs that governments pay to clean up public spaces from cigarette filters (22), which even if properly disposed of, are still toxic waste that would need special ways of disposal (20); see also report Regulatory options to prevent environmental harm and pollution across the tobacco product life cycle (supplementary information to the document FCTC/COP/11/7)).

Implementation considerations specific to this FLM

The implementation of a ban on filters is in principle relatively simple, and monitoring and enforcement would also be simple, since compliance or violation is identified through simple visual inspection of cigarettes. Unlike other product regulations, no laboratory tests are necessary.

Tobacco industry interference, with legal and commercial objections, would be expected.(21) In response to a proposed filter ban, the tobacco industry may propose consumer-based solutions instead such as fines on littering, or labelling filters as plastic waste that needs to be disposed of properly. It is possible the tobacco industry may offer to assist with payment for clean-ups as a means of attempting to undermine the proposed ban. These have been described as "greenwashing" and fit within the industry efforts to present itself as socially responsible.

Interference from businesses that manufacture filters that will be affected by a filter ban (31) could also be expected, and the industry is already working on introducing biodegradable filters.(25)

It is noted that none of these likely alternative interventions proposed by industry will solve either the health effects of smoking nor will it reduce the environmental harms of filters due to both plastic waste and leaching toxins into the environment. In addition, a filter ban would only solve part of the problem, as emerging products come with increased waste, which led to ban of single use ecigarettes in the United Kingdom (which is scheduled to come into force June 2025) (32).

Important pre- and post-implementation considerations include emphasis on information campaigns to remove public misconceptions about filters, provide a clear explanation for the rationale of the ban, build public support and to ensure that the industry does not co-opt this policy measure for their reputational gain. It would also be critical to enforce regulations and monitor compliance regularly, as well as provide support to smokers to quit via approved cessation tools, with proven efficacy and safety. It would be key to maintain or strengthen surveillance systems to

monitor changes in the market and consumer behaviours. Not only will this strengthen the country's enforcement response, but it will also provide the necessary information to counter any industry claims and arguments.

Studies have generally found strong support for cigarette filter bans. For example, a Dutch consumer survey published in 2022, found that 63% of non-smokers and 35% of smokers were in favour of a filter ban. In addition, 12% of the respondents to the survey stated that filter -less cigarettes would be a direct reason to quit or reduce smoking (33), this is reflective of the increased attractiveness of cigarettes with filters. Additional studies on support for cigarette filter ban can be found in the report Regulatory options to prevent environmental harm and pollution across the tobacco product life cycle (supplementary information to the document FCTC/COP/11/7).

A 2022 study of adult smokers in Australia, Canada, England and the United States, found that almost 70% opposed banning cigarette filters, largely due to the widespread misconception that removing filters would make cigarettes more harmful. This incorrect belief was the strongest predictor of opposition to a filter ban (34), pointing out the need for educational efforts to rectify the belief among many that filters do not reduce the harms of cigarettes, and in fact actually increase their harms (35).

Case study

In October 2024, the Santa Cruz Board of Supervisors (United States) approved an ordinance that bans the sale of filtered cigarettes in unincorporated areas in the county. The ordinance was developed by the Board's Tobacco Waste Ad Hoc Subcommittee and supported by a broad coalition of environmental, health, educational and other groups and stakeholders.

This landmark measure builds on state-level efforts to protect the environment and human health by restricting plastics, and it was preceded by bans on various single-use plastics, such as bags, straws and stir sticks. Once the ban is implemented, it will restrict the sale of filtered cigarettes but does not prohibit the sale of other tobacco or nicotine products.

The ban will go into effect on 1 January 2027 or when two other local jurisdictions pass similar ordinances, whichever is later. The Tobacco Waste Ad Hoc Subcommittee has been coordinating with other local jurisdictions, two of which have followed the county by declaring tobacco waste a threat to the environment.

The Santa Cruz case reflects on the necessity of the cooperation between different stakeholders to advocate for a cigarette filter ban. It is also of benefit to address single use plastic ban and its impact on the environment and human health. Environmental topics are popular with, and often supported by, young people.

Summary

Cigarette filters were popularized in the 1950s in response to the growing evidence of the harms of cigarette smoke. They were marketed as a harm-reduction innovation, assuaging fears among those who smoke of diseases caused by smoking. However, filters are now widely recognized as a significant public health, environmental and economic threat. Made from non-biodegradable cellulose acetate, cigarette filters contribute to widespread plastic pollution and perpetuate the incorrect belief that filtered cigarettes are less harmful than unfiltered cigarettes. This measure proposes a complete ban on the sale, import, distribution, sale, and manufacturing (where relevant) of cigarettes with filters, including loose filters.

Health impacts

- False safety perception: Address the misconception that filters reduce harm, potentially reducing smoking initiation and promoting quitting, particularly among young people and women.
- 2. **Health risks**: Removing filters impacts cigarette combustion, reducing deeper inhalation and reducing risk of lung adenocarcinoma.
- 3. **Attractiveness**: Removing filters, including those with flavour capsules, reduces the appeal and palatability of smoking, particularly in LMICs, where they contribute to higher consumption.
- 4. **Evidence of risk**: Microfibers from filters have been found in the lungs of cancer patients, further highlighting their health hazards.

Environmental impacts

- Plastic pollution: Cigarette filters are the most littered plastic item worldwide, with 1.58 to 3.59 trillion filters discarded globally, accounting for 489 800 to 1 129 000 metric tonnes of waste.
- 2. **Toxic leachates:** Filters leach arsenic, nicotine, polycyclic aromatic hydrocarbons, heavy metals and other toxic components into the environment, harming marine and terrestrial ecosystems.
- 3. **Economic burden**: The annual clean-up cost of filter pollution exceeds US \$26 billion globally, with LMICs bearing the greatest burden

Policy alignment

- 1. **WHO FCTC**: A filter ban aligns with Articles 5.2, 5.3, 9, 10 and 18, addressing product attractiveness, environmental health and industry accountability.
- 2. **COP resolutions**: COP6 and COP10 recognized filters as "unnecessary, avoidable and problematic single-use plastics," and called for immediate bans.

3. Global support:

- a. Belgium proposed a general filter ban in 2023.
- b. Santa Cruz County in the United States is implementing a filter ban by 2027.

Socioeconomic and behavioural benefits

- Reduced smoking prevalence: Removing filters eliminates their perceived safety, making smoking less attractive, potentially reducing initiation and increasing quit attempts.
- 2. **Lower clean-up costs**: Governments can redirect significant resources currently spent on cleanup efforts to public health and social services.
- 3. **Environmental restoration**: A ban would significantly reduce the long-term environmental damage caused by plastic and toxic pollution.

Implementation feasibility

- 1. **Straightforward enforcement**: After a grace period, all filtered products would be illicit, simplifying enforcement.
- 2. **Industry resistance**: The tobacco industry may propose alternatives like biodegradable filters, which fail to address the underlying health and environmental issues.
- 3. **Complementary actions**: Combining the ban with public education can accelerate benefits.
- 4. **Including emerging products:** Plastic waste from emerging products is high, and several countries have imposed a ban on disposable, single-use e-cigarettes due to environmental concerns.

A ban on cigarette filters addresses multiple public health, environmental and economic challenges. It aligns with WHO FCTC strategies and international resolutions while offering measurable benefits.

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(d) Consumer

(i) Expansion of smoke-free venues in private/semi-private environments and reduction of exposure to second- and third-hand tobacco smoke

Abstract

Policy description and background. This policy focuses on expanding protection from exposure to tobacco smoke (Article 8 of the WHO FCTC) in public places and workplaces to private/semi-private places, for increased protection from second- and third-hand tobacco smoke. Relevant legislation, regulations, policies and standards have been enacted, both in environments with broad population reach – including multi-unit housing, rental dwellings and private cars – and in environments that reach subpopulations experiencing vulnerability, such as public/subsidized housing and housing for health and social services.

This FLM aligns with Article 4.2(a) of the WHO FCTC. It also aligns with Article 8, which requires Parties to adopt and implement effective measures to protect people from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places. The Guidelines for implementation of Article 8 note that this creates an obligation to provide universal protection by ensuring that all indoor public places, all indoor workplaces (including motor vehicles used as places of work – for example, taxis, ambulances and delivery vehicles), all public transport and possibly other (outdoor or quasi-outdoor) public places are free from exposure to second- and third-hand tobacco smoke. Further, the Guidelines explicitly state that careful consideration should be given to workplaces that are also individuals' homes or dwelling places – for example, prisons, mental health institutions and nursing homes. Including additional private/semi-private homes and vehicles under smoke-free protections would build on the Guidelines for implementation of Article 8.

Evidence of impact. Several examples of implementation exist, mostly in multi-unit housing and public/subsidized housing high-income countries. Most policies are generally voluntary and promoted either in individual homes or through housing operators. Some national- or federal-level regulatory implementations do exist but have not been comprehensively evaluated. The available evidence indicates that policies are associated with higher cessation rates, reduced consumption of smoked tobacco products, reduced exposure to tobacco smoke and lower incidence of breathing problems among residents, as well as lower levels of airborne nicotine and particulate matter in the buildings. Legislation requiring smoke-free private cars when children are present has been shown to reduce exposure to tobacco smoke among children.

Benefits and strengths. Smoke-free policies are the most effective method to reduce second- and third-hand tobacco smoke exposure in homes and cars. Concerns have been raised around reduced individual autonomy; however, smoke-free policies in homes and cars do not differ from other health and safety regulations for private spaces, such as compulsory smoke alarms in homes and seat-belt laws in cars.

Implementation considerations. Successful implementation requires effective enforcement, and unintended consequences in relation to bans on smoking in multi-unit housing can largely be avoided through: 1) planning and policy development tailored by property type; 2) clear and culturally relevant communication; 3) resident engagement; 4) cessation support; and 5) gradual implementation to allow transition time for residents who smoke. Economic benefits, such as decreased renovation and fire costs, appear to outweigh any implementation costs. Legislation requiring smoke-free private cars when children are present is already successfully implemented in several countries.

Conclusion. Expanding smoke-free environments – especially in multi-unit housing homes and cars – would be likely to reduce exposure to second- and third-hand tobacco smoke both in the general population and in vulnerable groups, contributing to prevention and cessation of tobacco use and improved health equity.

Description of the intervention

Article 8 of the WHO FCTC creates an obligation to provide universal protection by ensuring that all indoor public places, all indoor workplaces (including vehicles used as workplaces, for example, taxis, ambulances and delivery vehicles), all public transport and possibly other (outdoor or quasi-outdoor) public places – where legislation is appropriate – are free from exposure to second-hand tobacco smoke. Further, the guidelines for the implementation of Article 8 explicitly state that careful consideration should be given to workplaces that are also individuals' homes or dwelling places, for example, prisons, mental health institutions or nursing homes (1).

Including additional private/semi-private homes and vehicles under smoke-free protections, would be an extension to current Article 8 guidelines. Extending smoke-free protections to multi-unit housing (MUH) and rental dwellings would have a broad reach across the socioeconomic spectrum, whereas vulnerable populations would be reached especially through housing for health or social services ⁹ and public/subsidized housing. Reducing third-hand tobacco smoke exposure beyond solely implementing smoke-free legislation, and including smokeless tobacco under smokefree-free protections, are other possible approaches that fall under this FLM. Extending smoking bans is possible through tobacco control legislation, but also through existing legislation or other regulations, policies or standards especially for housing, rental leases, fire safety, environmental health, and occupational health and safety.

Availability of information/research evidence on the potential impact of FLM

The introduction of legislative smoking bans improves cardiovascular health outcomes and reduces mortality for smoking-related illnesses (2), increases voluntary home smoking restrictions (3), reduces children's exposure to tobacco smoke at home (4), reduces childhood hospitalizations for respiratory tract infections (5) and reduces stillbirths, low birth weight and neonatal mortality (6). While the majority of the WHO FCTC Parties have adopted a complete or partial smoking ban in most public places and workplaces (7), the protection in private/semi-private places may still be insufficient and contribute to considerable burden of disease. For example, among adults in 28 European Union (EU) countries in 2017, it was estimated that 526 000 disability adjusted life years (DALYs) and 24 000 deaths, mainly from chronic obstructive pulmonary disease and coronary heart disease, were attributable to exposure to tobacco smoke at home (8). Among children, the number of deaths was 335 and DALYs 35 633, with the largest burden due to low birth weight caused by exposure during pregnancy (9).

Smoking at home creates risks not only for residents, but occupational risks especially for care workers and home carers (10). Further, the toxic chemical residues from third-hand tobacco smoke persist in indoor environments for years (11). Smoking in cars amplifies exposure to both second- and third-hand tobacco smoke as it occurs in a very confined space (12). Strengthening protection in these settings not only prevents and reduces the associated health risks, but supports quitting and decreases cigarette consumption among people who smoke (13), and prevents smoking

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⁹ Examples of these include family day care (at home of the service provider), foster care, supported housing (people in need of support transferring to independent living, such as people recovering from drug abuse or mental health issues), and service housing (people who need constant help but not institutional care, such as the elderly and people with disabilities).

uptake by children and adolescents (14). Smoking at home is also a key risk factor in residential fires causing deaths, injuries and substantial property damage (15,16).

Of the different housing types, MUH in particular, also referred to as multi-family residential or multidwelling unit, lacks sufficient protection from exposure to tobacco smoke. This type of housing often consists of several separate living units within one building or separate buildings within one complex. Examples of these include apartment buildings, condominiums, townhouses and semi-detached houses. The units can generally be owned individually or in co-operatives or rented from individuals, corporates and not-for-profit or public owners. In MUHs, exposure can occur when smoke transfers between living units or from common indoor or outdoor areas through shared ventilation systems, construction defects, hallways, door spaces, ventilation windows and balconies. MUH resident and air monitoring studies consistently show that a considerable proportion of MUH residents are exposed to tobacco smoke incursions in their homes (17,18). Exposure to tobacco smoke has also been found to be higher among those living in rental dwellings as compared to owned dwellings (19). While risks for tobacco smoke incursions are highest in MUHs where living units are structurally connected or share common indoor or outdoor areas, third-hand tobacco smoke exposure remains an issue in detached houses when properties change occupants. Risks of third-hand tobacco smoke exposure are currently not well addressed in environmental, consumer and tenant protection, and real estate and rental disclosure policies and/or legislation (11).

Residents have limited tools to act on smoke exposure. These include either moral persuasion and mediation, which are often ineffective as they depend on people who smoke to change their smoking behaviours, or legal disputes which place a high evidence burden on complainants (20). A 2023 systematic review and meta-analysis of 99 studies reporting public support for smoke-free policies in different outdoor areas and (semi-)private places from almost 900 000 individuals across 33 countries found strong support for these policies, especially in places where children are present (21). In the pooled estimates, smoke-free cars with children was the most supported subcategory (86%), 76% supported indoor smoke-free multi-unit housing, 67% outdoor semi-private areas (for example, shared gardens), 59% indoor smoke-free private homes and 41% outdoor private areas (for example, private balconies). Support for smoke-free policies was lower among people who smoke, compared to those who do not smoke and those who have quit smoking.

There is strong evidence and public support to justify the extension of smoke-free legislation to private/semi-private places to improve protection from exposure to second- and third-hand tobacco smoke, prevent initiation and encourage cessation. In crowded livings conditions, particularly in areas with high degrees of extreme poverty, smoke-free policies will need to be part of broader public health efforts to improve air quality and living conditions. Including smokeless tobacco use in smoking bans, where relevant, would also enhance environmental protection and reduce tobacco waste, especially in countries such as India, where smokeless tobacco is a major source of tobacco waste (22).

Reach of the FLM

Housing has been identified as a major pathway through which health disparities emerge and sustain over time, and exposure to tobacco smoke directly affects housing conditions (23). Exposure to tobacco smoke at home is associated with lower socio-economic status across different country income groups and regions (24,25). Differences between ethnic/racial groups have also been found (19,26). Adults who receive housing assistance are an at-risk population for several adverse health outcomes associated with smoking and second-hand smoke (27). Exposure to tobacco smoke in MUH is high and more prominent among residents living in low-income housing and in buildings

with elderly, disabled people who smoke (17). The higher risk of residential fire incidents and associated injuries in social housing is partially attributed to smoking (28). Smoking in cars is also more common in higher deprivation areas (29).

Private homes remain a major source of exposure to tobacco smoke especially for women and children (30). Exposure to tobacco smoke at home among children co-occurs with higher adult smoking rates and more commonly in rural areas than in urban areas (31). Children of non-smoking families living in MUHs have higher cotinine levels than children who live in similar single-family homes (17,32). Children living in rental housing have higher exposure to tobacco smoke when compared to those in privately-owned housing (4). Public smoking bans have not been found to have any negative impact on social inequalities in children's exposure to tobacco smoke at home (33). Persistent and accumulated third-hand tobacco smoke affects the most vulnerable populations, including children, the elderly and immunocompromised persons, as well as lower-income and marginalized communities living in older, lower-quality and multi-unit housing (11).

MUH is commonly used in student housing, public and subsidized housing, or housing for health or social services, where residents are provided with a selected residence or subsidized rental costs in private-sector buildings. Yet, through urbanization, MUH is becoming a more common housing type globally (34), with a large variation in buildings and living units for residents across the socioeconomic spectrum. Increased working from home and COVID-19 stay-at-home orders have also shed new light on tobacco smoke exposure in MUHs (35,36). Further, increasing heatwaves may worsen tobacco smoke incursions in MUHs in urban settings, where dense population, higher buildings and infrastructure create urban heat and pollution islands (37,38). Tobacco smoke from adjacent ventilation windows, balconies or yards can enter inside when residents try to cool down their home. Strengthening protection from exposure to second- and third-hand tobacco smoke in all MUHs and in rental housing in general could have a broad reach, affecting not only vulnerable populations, but also people who pay market-rate rents or own apartments in MUHs.

Strength of the FLM

The majority of available evidence on the potential impact of smoke-free policies in MUHs is from the United States and suggests decreased current smoking, decreased smoking frequency, higher quit rates, reduced tobacco consumption and exposure, lower incidence of breathing problems, and lower airborne nicotine levels and particulate matter levels (17,39–42.) Successful implementation depends on effective enforcement and accessible cessation support (42). Cost analyses are limited but they suggest that the economic benefits – decreased renovation and smoking-attributable fire costs – outweigh any implementation costs (17). Studies documenting the transfer of tobacco smoke in MUHs, and highlighting the many factors that impact it, indicate that smoke-free building policies are the most effective method to fully reduce exposure to tobacco smoke (17).

Evaluation results over multiple years from smoke-free public housing policies in individual states in the United States show mixed results with enforcement problems, but also improved outcomes in air quality monitoring (43–46). A 2025 published evaluation of the federally mandated smoke-free policy in public housing in the United States showed that it was associated with small reductions in hospitalizations related to cardiovascular diseases among older adults in New York City (47). A 2024 review focusing on subsidized housing contexts in the United States and Canada suggests that smoke-free housing policies may increase cessation behaviours and reduce exposure to tobacco smoke in the short-term, but there is uncertainty about long-term adherence to these policies (48). Some inconsistent findings were observed, potentially due to residents misunderstanding the rules, or switching from smoking on balconies to inside homes. Residents were more likely to quit if

cessation services were available (48). Evidence of impact on long-term health outcomes is still lacking, with two studies with mixed findings (48).

Despite rigorous family and carer smoking control intervention research to reduce children's exposure to tobacco smoke, beneficial intervention effects have only been found in a minority of studies, and it is difficult to identify the specific effective elements in these interventions (49). These interventions have adopted various methods, including personalized counselling, which requires financial and human resources. A 2015 meta-analysis of the impact of non-regulatory interventions on home air quality showed only a limited degree of decreased home tobacco smoke air pollution (air nicotine and/or particulate matter) (50). On the other hand, a meta-analysis found an overall effect of decreased exposure to tobacco smoke in the children's homes after the introduction of public smoking bans (RR = 0.72; 95% CI = 0.62-0.83) (51). A 2021 meta-analysis of the impact of smoke-free car policies showed a reduction in tobacco smoke exposure in cars (risk ratio 0·69, 95% CI 0·55-0·87) (52).

More evaluation studies of smoke-free housing policy implementation are needed. Besides MUHs and public/subsidized housing, research is limited to voluntary measures to introduce smoke-free homes. In some reviews of smoke-free policies, homes are intentionally excluded (53), even though different national, regional or local level regulations in connection to housing policies or standards exist that allow for the introduction of smoking bans. Based on the available evidence, it is likely that introducing smoking bans to home settings through appropriate legislation/regulation is a cost-effective way to achieve reduction in exposure to tobacco smoke, and to encourage reduced consumption and quitting among people who smoke.

Population-level impact of the FLM

System-level interventions and policies that change the environmental context for individual behaviour to make healthy options the default choice - regardless of education, income, service provision or other societal factors – are generally the most effective public health actions (54). As alternatives to smoke-free housing policies, it is possible to consider programmes that build on persuasion and encouragement to facilitate voluntary restrictions (55). Examples of these could be recommendations to housing operators, campaigns to residents or family and carer programmes. Currently, there is no evidence to suggest that these approaches alone will achieve sufficient reduction in exposure to tobacco smoke in home settings (55). Recommendations and voluntary measures do not seem sufficient to achieve the desired population-level impact. For example, the United States Department of Housing and Urban Development first recommended public health authorities adopt smoke-free polices in 2009, reiterated its guidance in 2012, but no major movement in increasing smoke-free public housing was observed until the federal policy took effect in 2018 (55). Considering that smoke-free housing and vehicle policies have the potential to reach and affect both vulnerable population groups (for example, affordable housing residents, supported/serviced housing residents and staff, children and pregnant women) and general population (for example, MUH overall, rental dwelling), the population impact is likely to be high.

Time frame of the FLM's impact after implementation

Depending on the intended outcomes, strength of policy enforcement and existing supportive measures such as smoking bans in public places, smoke-free housing and vehicle policies could have short-term impacts, particularly in changing smoking behaviours and improving health outcomes (for example, respiratory health of children). While these policies often have a transition time before

the implementation starts (for example, six months), reduction in airborne nicotine and PM2.5 in buildings can be observed and measured as soon as the first month after implementation, but often within the first year (48,56.) Regular monitoring is important as it may also provide information of potential compliance issues indicated by even increased levels of tobacco smoke (56).

Potential of the FLM to disrupt systems that perpetuate and entrench tobacco use

Evidence shows that legislative bans on smoking in public places may encourage citizens to establish voluntary restrictions at home through their influence on social norms (3). Changing community norms regarding exposing others to tobacco smoke, particularly children, followed by restrictions on smoking in public places have also been identified as key factors in encouraging voluntary home smoking bans (57). Extending smoking bans in private/semi-private places is likely to strengthen these norms and contribute to the de-normalization of smoking.

Awareness and profile of the FLM as a potentially promising intervention

There are both proposals and existing implementations of these measures in some countries, with varying levels of public support. The examples are presented in alphabetical order, by country/city name.

Homes in general

- In Japan, the large investment bank Nomura has introduced smoking bans during working hours even while working from home, alongside subsidizing the cost of smoking cessation treatment and support, and other anti-smoking measures. Both smoking prevalence among employees as well as the proportion of employees feeling uncomfortable or sick at work due to smoking have decreased substantially (58,59).
- In Thailand, the Act on Promotion of the Family Institute Development and Protection (effective August 2019), considers smoking at home as a form of domestic violence due to its harmful effects on health. Under this Act, if it can be proven that the health problems of family members stem from second- or third-hand tobacco smoke at home, the case may be tried in the Criminal Court or the Central Juvenile and Family Court (60,61).

Multi-unit housing (MUH)

• In Australia, the National Tobacco Strategy 2023–2030 includes in its priority area actions the following: "Monitor the issue of smoking and smoke-drift at residential premises and strengthen policy and regulatory approaches to increase the number of smoke-free homes, including in social housing and multi-unit housing." (62) New South Wales and Victoria have model by-laws which specifically address smoking in multi-unit housing. In New South Wales, Strata Schemes Management Regulation 2016 (New South Wales) includes a "tier" of by-laws regarding smoking from which an owners' corporation can choose. Where an owners' corporation has not selected between the tiers, the default tier will apply prohibiting smoking on common property, but not in private living areas. However, under the default by-law, an owner or occupier has an obligation to ensure that smoke from private living areas do not penetrate common property or any other private space. In Victoria, since 2021, the model rules in the Owners Corporations Regulations 2018 (Victoria) have included a specific rule addressing smoking, which requires a lot owner or occupier in a multi-level development to "ensure that smoke

caused by the smoking of tobacco or any other substance...on the lot does not penetrate to the common property or any other lot" (61).

- In Bangladesh cities, exposure to tobacco smoke in MUH is common, and there is strong support for a smoke-free housing. Overall, 94.8% of the respondents wanted smoke-free housing. Among those, 44.9% preferred a smoke-free building policy, 28.3% preferred a smoke-free common area policy and 20.2% favoured a smoke-free unit policy (63,64).
- The 2016 Finnish Tobacco Act prohibits smoking in shared indoor areas of housing corporations. Moreover, housing corporations may request that the municipality impose a smoking ban in areas under the control of residents. It is also possible for stricter requirements to be imposed in situations where smoke spreads from one residence to another via the building structure. Half the general population (51%) supports such measures (66% of people who have never smoked and 11–24% of people who smoke). Extending the current regulations has been proposed in 2023 by a ministerial working group (65,66) (see the case study below).
- In Lithuania, since 2021, smoking in balconies, terraces and loggias of multi-apartment buildings that belong to individual owners, provided at least one of the residents of the building concerned objects to smoking, has been prohibited. The law stipulates that building/apartment owners or any other persons who use the building/apartment must ensure that tobacco smoke enters neither the premises of another owner, that is, another building or apartment, nor the premises of the same apartment (67). A 2025 proposal to amend the law would require smoking to be prohibited in these spaces if at least half of residents object (68).
- In Norway, a smoking ban in shared areas inside and outside of apartment buildings has undergone public consultation. The tobacco control strategy states that the Government will consider introducing measures where the municipalities may ban smoking in private apartments if neighbours are negatively affected (69).
- In the Republic of Korea, multi-family housing has been designated as non-smoking since 2016, pursuant to the amendment to the National Health Promotion Act (69).
- Across the United States, Canada, and the United Kingdom in 2013–2015, only 27.8% of MUH smokers reported that smoking was completely prohibited in their building. Across all three countries, 36.1% of smokers in MUH reported they preferred a complete smoking ban in all building areas (70).
- In the United States, as of 2024, 84 municipalities have enacted a law at the city or county level that prohibits smoking in private units of rental multi-unit housing properties. Of these municipalities, 77 have laws that prohibit smoking in 100% of private units of both rental and owner-occupied multi-unit housing properties. The vast majority of the laws apply to properties with two or more units (71).
- Based on two reviews of data from the United States, smoke-free MUH policies are supported by most MUH residents. Full within-unit smoke-free policy is supported by a majority of non-smokers, less so among smokers, but the majority of smokers do support smoke-free indoor common areas. Most studies have been conducted in states with

- historically progressive tobacco control efforts, including California, Oregon, New York and Minnesota (17,72).
- In Israel, 74% of the population lives in MUH (73), with 39% to 45% of the population reporting tobacco smoke incursion (TSI) into their home residences (73,74). Those in the lowest income group are most severely affected (74). In Israel, there is very high public support for protection of neighbours from TSI: 83.7% of Israelis, including 64.9% of those who smoke, support legal protection (75). Because of the need for legal protection to protect people from TSI, particularly those of low equity, in 2021, an administrative case High Court of Justice case 1416/21 was submitted to the Israeli Supreme Court on behalf of the nongovernmental organization Clean Air and six individuals (76). The case was primarily against the Minister for the Environment, but secondarily against the Minister of Health and the Minister for Internal Security, for not enforcing existing environmental laws that could be used to protect people from TSI. There have been three hearings to date, but a final ruling has not been issued as of 14 April 2025.

Rental dwellings in general

- In Finland, a 2024 ministerial working group proposal for the revision of the Act on Residential Leases underwent public consultation. Under the proposed revision, a smoking ban would be imposed for all new and existing residential leases by default, and smoking could only be allowed with the landlord's permission if the landlord can issue such a permit without prejudice to any other law, order issued by an authority or an order in the articles of association of a housing company (see related case study below).
- Studies in Minnesota, United States (77,78), show that around half of renters have experienced tobacco smoke entering their apartments, or smelled tobacco smoke in their apartment. Most of these reported being bothered by the smoke, with over a third so much so that they were thinking of moving. While living in smoke-free buildings was uncommon, most non-smokers preferred living in a smoke-free building.

Public/subsidized housing

- In Canada, smoke-free policies have been studied among two affordable housing providers: Waterloo Regional Housing, which has required new leases to be non-smoking and exempted existing leases, and Yukon Housing Corporation, which has required all leases (existing and new) to be non-smoking. Based on qualitative data, both types of smoke-free policies have helped tenants to reduce and quit smoking. However, exempting existing tenants from the policy has created challenges for monitoring compliance and enforcing the policy, and smoking by some new tenants in the exempted units undermined the policy and maintained smoking behaviour (79).
- In Finland, several public housing authorities in large cities have implemented smokefree housing policies (see case study below).
- In New Zealand, the Christchurch City Council has created smoke-free policies in its subsidized MUH complexes. The policy was generally accepted and complied with by tenants and supported by tenancy advisers. Overall, 87% of the 788 tenants (people who do not smoke and people who smoke) who responded to the tenants' survey indicated that they supported the policy (80). Additionally, the Wellington City Council has

established a smoke-free policy for new and refurbished Council housing and the communal areas of Council housing complexes (81).

- In 2018, a large natural experiment took place, when the United States Department of Housing and Urban Development (HUD) required public housing authorities (PHA) to implement a smoke-free housing policy, affecting an estimated 2 million people living in public housing owned by 3300 PHAs (82). In Columbia, a study of resident support across three time points over four years found that support varied over time among people who smoke (5.3%, 30.7% and 22.5%), and less so among people who do not smoke (48.2%, 52.2%, and 40.0%) (83).
- The above HUD requirement does not extend to Section 8 housing, a programme that
 provides subsidies for private rental housing to low-income residents, supporting over
 2 million households in 2019. In a nationally representative survey of adults, the 71%
 supported prohibiting indoor smoking everywhere inside buildings that have Section 8
 housing units (84).
- Based on a review in subsidized housing in the United States and Canada, people who
 did not smoke tended to support policies for health reasons while many of those who
 smoked opposed policies due to perceived unfairness. Overall, resident support for
 smoke-free housing policies was high (50–89%) (48).

Housing for educational, health and social services¹⁰

- In Australia, New South Wales, the Family Day Care and Home Based Child Care Services
 Regulation 1996 states that the carer must provide a smoke free environment while
 children under care are in the carer's home (85).
- The Finnish Tobacco Act prohibits smoking and smokeless tobacco use in indoor and outdoor facilities of day-care centres or educational institutions providing pre- or basic education, vocational training or upper secondary education, including student apartments. In family day care provided at home, smoking is prohibited indoors during the provision of the day care (see case study below).
- In the San Diego (United States), a pilot study examined the introduction of a smoke-free policy in permanent supportive housing for formerly homeless individuals (86). The policy led to a 60% reduction in indoor smoking, and a 13% reduction in the proportion of residents who reported current smoking. Resident support for the policy increased after the implementation (87).

Private vehicles

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• In 2020,¹¹ 17% of WHO FCTC Parties reported a complete smoking ban and 21% a partial ban in private vehicles (7). Based on the WHO FCTC implementation data (69) and Smokefree Partnership data from 2022 (88), smoking is prohibited in private vehicles where a child is present in: Tasmania and in the Australian Capital Territory, Australia

¹⁰ As stated in the implementation guidelines for the Article 8, workplaces that are also individuals' homes or dwelling places, for example, prisons, mental health institutions or nursing homes, should provide protection from exposure to tobacco smoke. Therefore, the examples in this section focus on other than institutional care.

¹¹ Due to technical issue, 2023 data on this measure is not available.

(children under 16 years of age), Austria (under 18 years of age), Belgium, Canada, in a number of jurisdictions (children under 16 years of age), Cyprus, Finland (under 15 years of age), France, Georgia, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Slovakia, Slovenia (under 18 years of age), the United Kingdom and Türkiye. In Norway, the measure has undergone public consultation. Further, Ireland and Italy also have a smoking ban if a pregnant woman is present in the car. In the United States, smoking in private cars when children are present is prohibited in several states (89).

• In 2024, the European Union published a proposal for a Council Recommendation on Smoke- and Aerosol-Free Environments, replacing Council Recommendation 2009/C 296/02 (90). While most of the focus in the updated recommendation is to extend smoke- and aerosol-free environments to public outdoor premises, it also contains a recommendation to consider the inclusion of private cars where children, minors or vulnerable people are present.

Implementation considerations specific to the FLM

Potential challenges/barriers to adoption of FLM

A systematic review based on qualitative studies from the United Kingdom, Australia, the United States, Canada and China analysed the barriers, motivators and enablers for voluntary smoke-free home rules (57.) Findings showed mixed degrees of restrictions on smoking within the home, from no restriction to a total ban, with many participants restricting smoking to specific rooms, or restricting smoking in the presence of children, and exceptions to rules were frequently reported. The review highlighted the complexity faced by many households in having a smoke-free home through the practical, social, cultural and personal issues that need to be addressed and balanced by households. These related in different approaches to knowledge, awareness and risk perception, agency and personal skills/attributes, wider community norms and personal moral responsibilities, social relationships and influence of others, perceived benefits, preferences and priorities, addiction and habit, and practicalities. Another systematic review on smoke-free homes focused on Indigenous populations of Australia, New Zealand, Canada and the United States (91). In this review, knowledge of the harms associated with exposure to tobacco smoke fuelled parents' motivation to protect their children by establishing smoke-free homes. Supporting factors to establish such a home policy were individuals who approached implementation with confidence, coupled with clear communication about smoke-free home rules.

Studies of MUH operators, based on a review in the United States context, suggest that the transfer of tobacco smoke is often not recognized as an issue, many operators have incomplete information about the legal and economic ramifications of implementing smoke-free building policies and misperceptions about resident preferences, as well as the challenges of increased vacancy and tenant turnover (17.) Yet, it appears that most MUH operators who have implemented smoke-free building policies have not experienced difficulties with policy enforcement, and they have mostly used methods that require little investment of money or staff time, such as written warning letters (17). Another three-state case study based in the United States emphasized that engaging a wide variety of traditional and nontraditional partners is critical to gather buy-in, and champions increased visibility and public support (92.) Successful implementation depends on the existence and compliance with smoking bans in public places, and social norms that support protection from tobacco smoke.

Potential negative consequences or risks of the FLM

Some potential unintended effects of smoke-free housing policies include higher turnover of some populations living in subsidized housing, property damage and resident misunderstanding of policy leading to increased indoor smoking (48). This may increase exposure to tobacco smoke among children. Further, people who smoke may consider such a housing policy intrusive, unfair and affecting their "right" to smoke in their own home, especially if the policy is introduced after the residents have established tenancy (48,72). Different policies in new and existing leases in public housing units have been found to challenge the policy enforcement (79), which may create tension among residents. Extending smoke-free regulations in housing and vehicles is likely to have only minor potential negative consequences which are largely avoidable.

People who smoke generally form a minority of residents and as smoking decreases this is increasingly the case. The majority who do not smoke have a right to clean air, which is reiterated in the human rights treaties (93). Ensuring protection from exposure to tobacco smoke is especially important for those who have limited housing options and are currently disproportionately exposed to tobacco smoke. Successful implementation of smoke-free housing and car policies includes avoiding unintended consequences through careful planning and policy development tailored by property type, clear and culturally relevant communication, resident engagement, gradual implementation when necessary to allow transition time for existing residents who smoke, and provision of cessation support. Implementation toolkits that address specific circumstances in smoke-free housing policies are also available (94,95).

From an ethical perspective, public health benefits of prevented harms outweigh concerns about reduced individual autonomy (55). Further, restrictions to protect children from exposure to tobacco smoke in private spaces are similar to others that are already deemed acceptable with the aim to protect children, such as seatbelt and car seat laws (89). Legal analyses in the United States context have not flagged any issues preventing the implementation of smoke-free building policies, but rather the contrary – these are likely to protect owners and operators from liability related to exposure to tobacco smoke (17). Smoke-free policies do not differ from other health and safety regulations for private spaces. For example, smoke alarms are mandatory in private homes in several countries.

Case study

Advancing smoke-free housing and vehicles through national legislation in Finland

In Finland, smoking bans in public places, workplaces and restaurants have been introduced gradually between 1995 and 2006 under amendments to the Tobacco Act. In 2010, as part of a larger revision of the Act, the smoking ban was extended to shared and public indoor areas of housing corporations. In Finland, a housing corporation or company – a legal entity that owns one or more residential buildings, where the ownership is divided by shares that give the right to specific apartment – is a common form of multi-unit housing, involving public and private owners and rental dwelling. ¹² In a population of 5.5 million people, there are approximately 90 000 housing corporations. Nearly half of Finnish households live in blocks of flats (96).

In the 2016 Tobacco Act revision, housing corporations were further granted the right to prohibit smoking in shared outdoor areas under their control near the entrances and air inlets of the building,

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¹² Definition in the Tobacco Act: Housing corporation means a limited liability company within the scope of application of the Limited Liability Housing Companies Act (1599/2009), a corporation and foundation within the scope of application of the Right-of Occupancy Housing Act (650/1990), a housing cooperative, a rental building as referred to in section 2 of the Act on Joint Management of Rental Buildings (649/1990) and other rental building stock owned by corporations.

in children's play areas, and on shared balconies. Further, the housing corporations were granted the right to request the municipality impose a ban that forbids smoking on the balconies of individual apartments in a building belonging to the housing corporation, in the outdoor areas to which the apartments have access, and inside apartments. The occupants need to be consulted before submitting the application. The municipality shall impose a smoking ban if, due to structural or other conditions, tobacco smoke may, other than occasionally, spread from the area in question to another balcony, to an outdoor area belonging to another apartment, or inside another apartment. Smoking may be prohibited inside an apartment only if the spreading of smoke cannot be reasonably prevented by repairing or altering the structures and the occupant of the apartment has been, prior to the ban, given an opportunity to take measures to prevent the smoke from spreading. In the same 2016 Tobacco Act revision, smoking in private vehicles with anyone under the age of 15 present in the vehicle was also prohibited.

The total number of applications related to smoking bans in housing corporations processed in municipalities increased from 113 in 2020 to 174 in 2021 (65). In 2022, the Ministry of Social Affairs and Health assigned a multisectoral working group to develop proposals for further legislative amendments, including improving smoke-free environments in housing corporations. The working group report in 2023 (66) noted that the process related to applying for a smoking ban is perceived as burdensome, difficult and slow by housing corporations and municipalities alike. The working group proposed simplifying the process so that in a housing corporation, a majority vote would be sufficient to impose a smoking ban in residential apartments, on balconies and in similar outdoor spaces. The working group considered the fundamental legal challenges of the proposal: in practice, a majority would decide on a matter of health, private life and domestic peace on behalf of a minority. However, the working group emphasized that the proposal meets the requirements of necessity, proportionality and precision. It can be considered necessary to protect the health of people who do not smoke, just as the health of workers in smoke-free workplaces has been protected. The proposal promotes the right of children to grow in a safe and healthy environment, which supports the United Nations Convention on the Rights of the Child ratified by Finland.

The working group report also noted that different forms of housing and different resident groups are currently in an unequal position in terms of smoking bans, and it proposed a smoking ban on all new residential leases. In 2024, another working group nominated by the Ministry of Justice (97), proposed a smoking ban be imposed on both new and existing residential leases by default through a revision of the Act on Residential Leases (98). The proposal would mean a change to the current state in which smoking has to be separately prohibited in the tenancy agreement or by agreement between the parties to the tenancy. However, the proposal would not restrict the parties' freedom to contract: the landlord could still allow smoking if there is no other barrier. Considering that over a third of all Finnish households live in rented dwellings, and for households of persons aged under 30 this proportion is 82% (99), changing the national legislation would gradually impact a large population as the contracts are renewed over time.

Currently, several public housing companies are already including smoking bans in their rental policies. For example, Heka, wholly owned by the capital city of Helsinki, has about 54 500 regular rental apartments, and approximately 3000 special housing apartments that are rented to the City of Helsinki Social Services and Health Care Division, which in turn rents them to older people, persons with disabilities, and substance abuse and mental health rehabilitees. Heka has different smoking bans concerning apartments and properties depending on factors such as the year of construction and the start date of the lease agreement. All of Heka's new buildings and renovated properties whose construction or renovation started after May 2016 are completely non-smoking.

In these, the smoking ban is a condition of the lease agreement. Smoking is prohibited in all indoor and outdoor common spaces of all their buildings.

In the Finnish Tobacco Act, the scope of the bans regarding smoking and tobacco smoke have been defined to also apply to the consumption of herbal products for smoking and the use of electronic cigarettes. The Act also prohibits both smoking and smokeless tobacco use in indoor and outdoor facilities of day-care centres or educational institutions providing pre- or basic education, vocational training or upper secondary education, including student apartments. In family day care provided at home, smoking is prohibited indoors during the provision of care.

Smoke-free housing is also promoted as part of the "Safely at All Ages: Programme for the Prevention of Home and Leisure Injuries 2021–2030", under the measures to improve fire safety in home environments (100). The programme specifically aims to decrease the number of fires caused by smoking, as well as the numbers of fire deaths and injuries. Efforts will be made to reduce smoking and substance use as well as residential fires and fire injuries resulting from their combined effects, in working age populations and the elderly. The target groups include both people who smoke, as well as providers of social services for high-risk groups, and substance abuse workers. The programme states that alongside smoking risk management and reduction, smoking cessation will also be promoted.

Summary

Article 8 of the WHO FCTC obligates Parties to adopt effective measures to protect people from exposure to tobacco smoke in indoor workplaces, indoor public places, public transport, and "as appropriate" in "other public places". The Guidelines for implementation of Article 8 notes that this creates an obligation to provide universal protection from exposure to tobacco smoke in public places. Such protections do not adequately capture private/semi-private environments, especially at home. Exposure to tobacco smoke in private/semi-private settings disproportionately affects vulnerable population groups such as children, pregnant women and people with limited housing opportunities. Housing conditions are a major contributor to health inequities.

Increasing smoke-free homes and vehicles through appropriate legislation or regulation is well justified considering the evidence on improved health outcomes, prevention of uptake of smoking, and reduced consumption and increased quitting among people who smoke. There are several examples of implementation of smoke-free housing policies mostly in Western, high-income countries, but they are primarily based on promoting voluntary policies in individual homes or for housing operators. A few national- or federal-level regulatory implementations do exist, but they have not been comprehensively evaluated. Smoke-free private cars where children are present is required under national or regional legislation in several jurisdictions, and results in reduced exposure to tobacco smoke among children.

Barriers to smoke-free policy adoption are largely manageable and avoidable if lessons from past successful implementation by different types of housing operators in various jurisdictions are applied. Adoption and implementation of these policies is likely to benefit public health in several ways in the long term and also produce short-term benefits to property owners from reduced renovation and fire costs. Extending smoke-free environments in homes and vehicles is an important measure to also reduce exposure to third-hand tobacco smoke. Resources to communicate information about the new policies and cessation support in a culturally appropriate way are needed to support policy implementation, especially during the early adoption phase.

Overall, there is underused potential to introduce smoke-free policies through legislation or other regulations, policies or standards, especially for housing, rental leases, fire safety, environmental health, and occupational health and safety legislation. There is generally high support for these policies, especially among people who do not smoke who form the majority of residents. From an ethical perspective, the public health benefits of prevented harms outweigh concerns about reduced individual autonomy among people who smoke, and restrictions to protect children in private spaces can be likened to other laws that aim to protect children, such as seatbelt and car-seat laws. Smoke-free policies are comparable to other health and safety regulations in private spaces, such as compulsory smoke alarms. While these policies are likely to improve protection from exposure to tobacco smoke, especially among vulnerable population groups, urbanization and the global trend towards living in multi-unit housing also increases the population reach of these measures.

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