

I. Introduction

The epidemic of tobacco use is one of the greatest threats to global health today. About one-third of the world's adults use tobacco. Half of them will die from it. To take one vivid example, China is home to some 350 million smokers. Some 175 million of them are likely to die prematurely from tobacco use. This epidemic poses more daunting challenges than traditional health problems, because it involves a powerful addiction, deeply established social customs and beliefs, as well as a global industry with a history of undermining public health efforts. Fortunately, we know what works—a comprehensive legislative approach. Legislation can significantly reduce tobacco use by young people, help smokers quit and protect non-smokers from exposure to tobacco smoke. The historic WHO Framework Convention on Tobacco Control (WHO FCTC), which entered into force on 27 February 2005, will provide new impetus for the implementation of effective laws. This guide offers a starting point for health officials, nongovernmental advocates and others interested in developing this legislation.

II. Legislation and the tobacco epidemic

Legislation is at the heart of effective tobacco control. It expresses society's deeply held values, institutionalizes a country's commitment, creates a focus of activity, and controls private conduct in ways that informal measures cannot. Enacting strong legislation involves difficult challenges, however. These often include limited public understanding of the problem, as well as the need to develop national "capacity"—the infrastructure and resources for a critical mass of support. Perhaps the greatest barrier to success is the extraordinary opposition of the tobacco industry and its allies. Understanding their most common strategies and arguments will equip supporters to overcome this opposition. Success usually requires firm political will, sustained through adversity, however. This legislative guidebook is intended as a tool for overcoming these barriers. It is meant as an introductory guide—an orientation for health officials, advocates and others with no background in legislation and policy-making. It combines two perspectives: a theoretical perspective, to give readers a logical frame of reference for what must be done, and a practical, hands-on perspective to help them get started. The goal is not to answer every question, but to help the reader understand the questions to ask, and to ensure that, even if the legislative process remains unpredictable, it need not be intimidating.

III. An introductory guide to terms and concepts

To make informed decisions about legislation, it is necessary to understand the basic forms laws can take and some of the features that distinguish different governments and legal systems. Statutes, the form of law most often used to regulate tobacco use, are laws created by legislative bodies, at the national or subnational level. National legislation has advantages and disadvantages. These vary among countries, depending on the distribution of power among different levels of government and the form of electoral representation. Subnational legislation has been used successfully in some countries, though it has weaknesses as well as strengths. Issues of "pre-emption," in which a higher level of government blocks subordinate governments from creating laws in a designated

subject area, have been a source of frequent controversy and litigation. Administrative regulations are another common form of law, especially in areas requiring technical expertise. The scope of an agency's legal authority and the procedural steps for adopting rules will affect the attractiveness of this approach. Constitutional law limits the power of legislative bodies and administrative agencies. Through the process of "judicial review," courts apply these constitutional limits, decide private disputes and interpret legislation in ways that can determine the fate of tobacco control programmes. All of these considerations will influence the choice of a strategy for legislation.

This chapter also elaborates on some aspects of treaty law as it relates to the development of the WHO FCTC. The role of international law in tobacco control requires an understanding of key concepts and the nature of this diverse area of law. The WHO FCTC has been developed through an international legal process. The treaty will also be implemented by State Parties at the national level through their national legal processes. Furthermore, the law of the European Community on treaty implementation is briefly introduced in this Chapter.

IV. Foundation for success: capacity-building

A country's institutional "capacity" to support tobacco control efforts—in the form of human and financial resources, technical expertise and political will—is the essential foundation for success. This foundation should be in place before legislation is proposed. One of the keys to success is to develop champions—leaders with experience, knowledge and a passionate commitment to the issue. A national "focal point," or designated authority with lead responsibility for the issue, is critical, as is the active involvement of civil society. The base of support should be widened by reaching out to involve an ever-broadening circle of supporters. Another important aspect of capacity-building is the ability to generate reliable information about the political environment, the medical and economic impact of tobacco use, public opinions and beliefs, and the activities of the tobacco industry. Capacity-building requires coordinated efforts to educate the public, a process that requires a coordinated communications strategy. Ultimately, capacity-building is about changing the culture of the society, from one that accepts tobacco use as "normal," to one that rejects it as deadly, addictive and harmful to society.

V. Approaching legislation: strategic choices

Before developing legislation, proponents of tobacco control need to make a series of fundamental decisions; this chapter discusses the considerations involved in these critical choices. First, proponents must assess their readiness for the effort. Second, they must consider whether to seek comprehensive legislation at once, or to use an incremental approach, adding components over time. They must weigh the benefits of proceeding at the national level against the option of subnational legislation. Administrative regulations should also be considered as an alternative. Importantly, advocates should think carefully about whether they will advocate the best possible legislation or propose a weaker law that may seem more feasible, and should reach agreement in advance on any areas where compromises are acceptable. If comprehensive legislation is not possible, advocates must also decide what elements of a comprehensive law to pursue first.

VI. The elements of comprehensive legislation

In formulating legislation, advocates should be guided by the fundamental values of their society and by the abundant evidence regarding the most effective strategies reflected in the WHO FCTC. Resolutions of the WHO's World Health Assembly and studies by the World Bank have provided an insight into the most effective elements of a comprehensive tobacco control strategy. This chapter discusses the elements of a comprehensive law, and the key choices involved in formulating policies in each area.

- *Institutions and mechanisms.* Legislation should create, empower and fund an authority to implement and direct the legislation.
- *Public education.* Large public education campaigns are important parts of changing public attitudes and beliefs.
- *Advertising, promotion and sponsorship.* A comprehensive ban on tobacco advertising, promotion and sponsorship is a centrepiece of an effective tobacco control programme.
- *Taxes.* Tax increases have been proven to be one of the most effective means of reducing tobacco consumption, especially among young people.
- *Second-hand smoke.* Eliminating smoking in workplaces and public places protects non-smokers from the hazards of exposure to smoke, discourages smoking initiation and promotes cessation.
- *Labelling and packaging.* Large, clear health warnings and informational messages, using rotating messages developed by national authorities, should be required on tobacco packaging, and tobacco products should not be promoted with misleading terms.
- *Product regulation.* Regulatory authority should be given to a specialized agency, to address such issues as ingredient disclosure, permissibility of harmful constituents, additive safety, and tar and nicotine yields.
- *Tobacco sales.* Legislation should prohibit the sale of tobacco to minors.
- *Smuggling.* To combat illicit trade, comprehensive legislation should include measures such as requirements for package markings or creation of a regime for tracking and tracing products through the distribution chain.
- *Cessation.* Comprehensive tobacco control must include issues relating to smoking cessation in order to support smokers and consumers of tobacco products to quit
- *Other issues.* Comprehensive legislation may also include provisions to address smoking cessation, create school-based programmes, modify agricultural policies or address issues of legal liability.

VII. The drafting process

Drafting, the process of creating actual text for legislation, is a specialized discipline, and must be approached carefully. It is important not to confuse the roles of the draftsman and the advocate, and to create a partnership of public health and law, to ensure that the proposal is both legally correct and an effective health measure, involving a large circle of participants to build consensus and support. Drafting should be guided by principles of

clarity, simplicity, consistency, familiarity and flexibility. Model legislation and assistance from experts, both local and international, can ease the drafting process.

VIII. Passing legislation

Successful legislative advocacy usually requires a multi-faceted campaign, guided by a coordinated advocacy plan. Recruiting effective legislative sponsors, and working effectively with them and other lawmakers, are critical. Campaigns must mobilize the base of existing support for tobacco control, expand that base, and reach out to engage the general public. Milestones of the legislative process, including the introduction of the proposal, public hearings and debate over amendments, all offer opportunities for publicizing the debate and generating support. The many communications activities of a complex campaign should be coordinated within an overall communications strategy. When a law is enacted, the battle does not end. Legislation is a never-ending process: advocates should prepare for ongoing efforts to strengthen the law and guard against sabotage.

IX. Challenges and obstacles

Opposition to tobacco control legislation is unusually ferocious because of the role of the tobacco industry. Once-secret tobacco company documents offer insights into the ways this industry mobilizes every resource at its disposal when threatened. The industry's web of influence runs through the fabric of society, and enables it to fight tobacco control in both overt and covert ways. Much of this is done through surrogates, including third-party allies, front groups and "independent" sources secretly paid by tobacco companies. Through all these channels, tobacco companies put forth several recurring arguments, minimizing the importance of the tobacco epidemic, insisting that tobacco use is a matter of personal freedom, denying that legislative measures will work, and suggesting that tobacco control will cause economic injury.

X. Making it work: implementing the legislation

To ensure that the enactment of legislation is not a false victory, proponents must not neglect the process of implementation and enforcement. The start-up period is especially important for winning public compliance. The selection of the right enforcement authority, the right mix of penalties, and the right enforcement procedures, is critical to effective enforcement. Another vital aspect of implementation is to ensure adequate mechanisms for monitoring compliance. Ultimately, though, the best law is one that so shapes social norms that it becomes self-enforcing.

XI. Evaluation

Evaluation is the vital process that enables policy-makers to know whether legislation is achieving its purposes. The evaluation process should be guided by a detailed plan prepared in advance, and should include both "process evaluation" and "outcome evaluation." Process evaluation gauges how well a programme has been implemented, by

assessing the activities involved in implementing the programme, as well as the programme's short-term effects—often by answering a series of increasingly more focused questions. Outcome evaluation measures the law's impact on results that indicate success. Recognized “essential indicators” of success—mortality rates, tobacco consumption, prevalence of use and policies—offer one approach for evaluating the outcome of tobacco control laws. Selection of outcome indicators, measurement tools and strategies, and data interpretation all involve complex technical issues. Evaluation is not successful unless the results are disseminated widely and put to effective use.

XII. Lessons in legislation: case studies from eleven countries

Many countries have enacted tobacco control legislation, and each has faced stiff opposition. There is no single formula for success, and each campaign brings its own surprises. Still, lessons can be drawn from others' experiences, which illustrate the forms opposition can take and the ways it has been overcome. This chapter describes briefly the paths taken in eleven countries:

- Brazil, where strong, new legislation, firm regulations and a coordinated approach to national, state and local activity have made the country a global leader.
- Canada, which has persistently overcome obstacles to set global standards for best practices in warning labels and other areas.
- Egypt, where an advertising ban has been enacted after having been sabotaged and defeated by multinational tobacco companies in the 1990s.
- India, which has adopted a comprehensive tobacco control legislation that serves as a good example for countries working to develop their own tobacco control legislation.
- Ireland, which has adopted a comprehensive smoke free workplace legislation that has been shown to be a major success since the law entered into force in March 2004.
- Norway, where a groundbreaking 1973 law provides a flexible framework for comprehensive legislation that still sets global standards.
- The Philippines, where health authorities and the national Senate support strong comprehensive legislation, but the House of Representatives has blocked proposals for nearly a decade.
- Poland, with comprehensive legislation the World Health Organization (WHO) calls “an example to the rest of the world.”
- South Africa, which has transformed in less than a decade from a country with little interest in tobacco control to the home of some of the world's strongest comprehensive measures.
- Thailand, where attempts by multinational tobacco companies to force their way into the Thai market accelerated development of some of the world's strongest and most innovative legislation.
- The United States of America, where effective tobacco control comes from the subnational level, in a jumble of legislation at the state and municipal levels.

These stories suggest several lessons: the importance of strong support from public health officials; the need for active involvement of nongovernmental organizations (NGOs); the need for flexibility in legislation; the need to prepare for the likely opposition; and the importance of considering the implications of trade issues for legislation.

XIII. International law and its implications

Chapter XIII aims to explore the significance of international law for national tobacco control measures. This chapter can provide only a summary description of this complex area of international concern; it is not comprehensive and does not purport to survey all existing international law with potential applicability to tobacco control. It examines the obligations established under relevant existing international agreements and their potential impact on the authority and responsibility of States to develop and implement national tobacco control policies. At the global level, such international commitments include international trade obligations established under the auspices of the World Trade Organization (WTO); international human rights obligations established pursuant to the human rights covenants of the United Nations; and obligations established under the auspices of the World Customs Organization (WCO). The chapter reviews legal obligations relevant to tobacco control established under the auspices of treaties of various regional organizations, focusing in particular on the European Union (EU). Finally, it considers the potential legal significance of the WHO FCTC, the relationship between the WHO FCTC and other existing international legal obligations and the process by which state parties to the proposed convention can implement the treaty into domestic law and policy.

XIV. Conclusion

Awareness of the tobacco epidemic has accelerated rapidly in recent years, and the case for legislation is now well established. There is no turning back. The WHO FCTC will spur the adoption of new laws and set a global standard for action. Responsibility for moving forward now shifts back to the world's governments. If this guide can make that process slightly easier, it will have served its purpose.