PART 2
THE PROCESS OF PUBLIC HEALTH LAW REFORM
Introduction

The processes involved in reforming or introducing new public health laws are critical to the legitimacy and success of law reform efforts. “Process”, in this report, refers to the practical steps that governments and other stakeholders take to advance the goal of law reform, within the political context of each country. In addition to discussing these practical steps, this report points to principles of good governance that the process of law reform ought to reflect. The law reform process provides the opportunity for lawmakers to consult with stakeholder groups and others who will be affected by the law and to build public support for the changes that are required. This can improve the implementation of the law and compliance with legal requirements.

Part 2 of this report begins by explaining the context of public health law reform (Chapter 2). Although the law reform process will vary greatly between countries, Chapter 2 distinguishes between the following three activities:

- Health legislation review: this is the formal process of reviewing public health laws, either generally or in a specific area, and assessing the need for reform.

- Implementing recommendations from a legislative review: this is the process of designing and drafting public health laws. It also includes the political process of passing legislation through parliament, as well as arrangements for the implementation and enforcement of laws.

- Designing the review process: ensuring good governance throughout the process of reviewing, drafting and amending public health laws.

One of the first questions a government will consider is whether the goals that it wishes to achieve require a legislative or regulatory response, or whether other forms of governance (e.g. self-regulation or co-regulation) are more appropriate (see Section 2.3). This question may also arise when a government is considering how best to implement the recommendations from a health legislation review.

In many cases, the decision to review existing public health laws or to introduce new laws will be made for quite specific purposes. As a result, the scope of the legislative review process may be narrowly defined. At the same time, the purpose of this report is to encourage governments to consider the flexible role that law can play in national efforts to realize the right to health for all members of the population. This report therefore takes a broad perspective on the process of public health law reform. Section 3.1 considers some common reasons why public health laws may need to be revised, and encourages governments to consider the benefits of updating and improving their public health laws generally.

Depending on its scope, the process of reviewing public health laws may provide the opportunity to identify priorities for legislative reform, based on evidence of the burden of disease in each country and the major health issues that each country is facing. Despite the differences between them, many
low- and middle-income countries face remarkably similar health challenges. These include the need for legal frameworks to respond effectively to HIV, to pandemics of contagious disease, to the major risk factors for the rising burden of noncommunicable disease (including tobacco use, harmful use of alcohol, poor diet and obesity), and to the large burden of preventable injuries. These priority areas are reviewed in Section 3.2.

Although law reform is primarily the responsibility of the government, civil society organizations can make an important contribution by educating the community about the need for reform, and by mobilizing political support for law reform within government (Section 3.3). In some countries, political and legislative mechanisms facilitate the direct participation of the community in the development of health policy. These mechanisms, as well as public interest litigation, can act as triggers or catalysts for the reform of public health laws, as discussed in Section 3.4.

After it has made a formal commitment to implement recommendations from the legislative review process, government will face the challenge of translating those recommendations into effective public health legislation. The process of designing and drafting new laws will benefit from a good understanding of the range of legal strategies that are available to governments to improve public health and to implement policy recommendations. Chapter 4 reviews some of the components or characteristics of effective public health laws. Governments that have chosen to amend their public health laws should ensure that the law provides a clear mandate for public health actions and sets out the powers and responsibilities of public health officials clearly. Other issues for consideration include the need for coherence between public health laws and laws administered by other ministries, and the need for human rights safeguards (such as protection from discrimination) to be built into public health laws.

The process of formally reviewing public health laws, drafting new ones and gaining parliamentary or executive approval for new laws, is complex and will often be subject to political pressures. Lawmakers will need to comply with parliamentary (or other law-making) rules and procedures. Chapter 5 emphasizes the importance of good governance throughout the law reform process. This includes resisting efforts to corrupt the law-making process, and implementing the principles of accountability, transparency and respect for the rule of law.

In some cases, the public health goals that a government is seeking to achieve will require a collaborative approach between the health ministry and other ministries. This may lead to formal consideration of how best to facilitate and coordinate an intersectoral approach to addressing public health priorities. Globally, there is growing awareness of the importance of coordinated, intersectoral action to improve public health and to reduce health inequalities. Chapter 6 considers how law and governance reforms can support and improve the process of collaboration between ministries, and with other stakeholders that are participating in intersectoral health initiatives.
Chapter 2: The context of public health law reform activities

**SUMMARY POINTS**

- Laws that protect the health of the population may be organized and administered quite differently in different countries, depending on historical and constitutional factors, and the specific health challenges each country has faced in the past. The concept of public health law is not limited to laws regulating the provision of health care services, but extends to the legal powers necessary for the State to discharge its obligation to realize the right to health for all members of the population.

- The scope of any formal review process of public health legislation may vary widely according to the political and legal context and priorities of each country.

- The capacity and willingness of governments to amend or replace public health laws, based on the recommendations of a formal legislative review, may be affected by the political ideology of the government concerned, the political feasibility of reform proposals, competing legislative priorities and available resources.

- When implementing law reform recommendations, governments should plan to monitor and evaluate their impact. This will involve identifying indicators that are suitable for tracking the impact of the law on relevant practices and health outcomes.

- Governments may need to set national priorities and to implement public health law reform recommendations in a stepwise manner, dedicating resources to a smaller number of cost-effective reforms that will deliver the greatest overall health benefits, and working towards implementation of a broader set of reforms as resources allow.

- Countries may use a variety of different forms of regulation to regulate health risks and other health matters. These include legislation, subsidiary regulations, decrees and executive orders, as well as guidelines and codes of conduct. Governments may adopt forms of co-regulation that formally include the participation of industry or professional bodies and/or civil society organizations. Governments may also defer to customary law as a valid source of law, or declare it to be the governing source of law in certain contexts.

- In considering whether public health law reform is appropriate, and whether self-regulatory codes and guidelines, or co-regulatory schemes, are failing to achieve public health goals, independent monitoring and evaluation are critical.

**2.1 What are public health laws?**

The Constitution of WHO makes it clear that health is not only about the absence of disease or infirmity, but is a complete state of physical, mental and social well-being. Similarly, the concept of public health law, as understood in this report, is not restricted to laws that regulate the provision of health care services, but includes the legal powers that are necessary for the State to discharge its obligation to realize the right to health for all members of the population.
Laws that protect the health of the population may be organized and administered quite differently in different countries, depending on historical and constitutional factors, and the specific health challenges each country has faced in the past. These may include laws that regulate food safety, tobacco control, environmental sanitation, registration of pharmaceuticals, the registration of health practitioners, sexually transmissible infections, the management of communicable diseases, quarantine, public health emergencies, collection and management of health data, the powers and functions of public health officers, and the performance of public health functions by local and regional governments.

Typically, the health ministry will administer laws that affect the provision of health care services and address a range of other health risks. Outside the health ministry, other ministries will administer laws that may also have a significant influence on health risks and health outcomes. Examples include laws relating to pollution and environmental contamination, consumer protection, criminal justice, local government, transport, housing and agriculture. Although the health ministry will usually lead initiatives to reform public health legislation, collaboration between ministries and agencies will be essential where the issue under consideration does not lie within the sole operational domain of the health ministry. For example, the reform of laws that aim to prevent violence against women will necessarily require the involvement of the justice ministry, while any initiative that relates to the taxation of tobacco or alcohol will normally involve the finance ministry. Efforts to reduce the health disparities that arise from social disadvantage may involve ministries with responsibilities for employment, public housing, transport and social security.

Where more than one ministry or agency is involved, the process of legislative review necessarily becomes more complex. Chapter 6 identifies practical steps for initiating intersectoral initiatives to improve public health, and presents several case studies of governance reforms that have supported government-wide efforts in this area.

2.2 Conceptualizing the process of health legislation review

(a) Impetus for a review

The opportunity to review public health laws may arise in many different ways, with many variations between countries. The review process may evolve in response to specific concerns about the failure of current laws or policies, or from broader discussions about how to improve policies, modernize laws or adapt to new challenges. The impetus for a review may come from government itself, from stakeholder groups outside government, or from development partners. International factors may also have an influence, such as the need to discharge obligations owed under international law (e.g. the WHO Framework Convention on Tobacco Control\(^5\) or the International Health Regulations (2005)\(^5\)), or to implement recommendations and action plans, such as WHO’s Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020.\(^5\)
(b) Scope of the review process

Assuming that government has formally decided to conduct a review of existing public health laws, the scope of that review may vary widely. It may range from reviewing the adequacy of a particular section within a statute or code to revising or introducing an entirely new public health act. Even more ambitiously, the review process may include consideration of laws and matters administered by ministries outside the health ministry. An intersectoral or cross-ministerial review process may be necessary in order to respond effectively to persistent health challenges; for example, in order to improve food security, to reduce health inequalities, to improve maternal and child health, and to reduce the risk factors for noncommunicable diseases (see Chapter 6).

The scope of the review will often have an influence on the agency or person chosen to undertake the review and the formal processes involved. A review may be carried out by independent consultants at the request of the health ministry, by health ministry officials, by a parliamentary standing committee, by a specially-formed commission or review committee, or by a specialist law reform body such as a law reform commission. The person or committee that undertakes the review may report back to the health ministry, or report directly to those who have political influence, such as the health minister, a group of senior government ministers, or even the prime minister or president. The question of who undertakes the health legislation review, and to whom they report, may have an important impact on how seriously the recommendations of the review are taken, and whether they remain on the political agenda.

The issues considered during a health legislation review will also vary widely, according to the terms of reference of the review. For example, the review may include a consideration of: the specific problems that have arisen with the administration of current laws; the opinions of the key stakeholder groups (including political parties, business and professional groups, faith-based organizations, civil society organizations and development partners); the legislative and constitutional powers of the government to reform the law in a particular area; recent international developments; and the extent to which law reform is occurring in other countries and jurisdictions.

(c) Implementing recommendations

It is helpful to distinguish between the recommendations made during a formal review of public health laws, and any subsequent decision by government to amend or replace existing laws. The capacity and willingness of a government to implement the recommendations of a review may be affected by the political ideology of the government concerned, the political feasibility of the reform proposals, competing legislative priorities and available resources.

The design and drafting of new public health laws raises a wide range of matters for consideration. Law reformers will need to consider the most appropriate legislative mechanism for implementing the recommended changes, and specify who will administer the new law and what legal powers they will require to do so effectively. They should also consider the compatibility of the law with human rights principles and the potential role of regional, city and local governments in making the new law work. Legislative drafters should consider whether those who will administer the new law have the
capacity to understand its requirements, as well as the process of transition from existing laws to new laws.

When implementing law reform recommendations, governments should plan to monitor and evaluate their impact. This will involve identifying indicators that are suitable for tracking the impact of the law on relevant practices and health outcomes. For example, monitoring the impact of tobacco control laws may require both baseline and follow-up surveys to determine smoking prevalence. Governments may also monitor the impact of mandatory helmet laws in terms of infringement notices and road accident fatalities. In many countries, the resources of governments to engage in public health law reform are limited. Governments will therefore need to set national priorities and proceed in a stepwise manner, dedicating resources to a smaller set of cost-effective reforms that will have the greatest overall health benefits, and working towards implementation of a broader set of reforms as resources allow.

This report includes many case studies and examples of legislation from around the world. These are not “model laws”, and in many cases simply reflect the local circumstances of each country. However, by sharing the experience of other countries, the report aims to give public health authorities a greater understanding of the options for reform, and a determination to use legal powers effectively to realize the right to health.

2.3 Why legislate?

In many countries, a variety of forms of regulation are used by governments to regulate health risks and to create healthier environments. These range from legislation, subsidiary statutory instruments, decrees and executive orders to “soft law” instruments such as guidelines and self-regulatory codes of conduct. In some countries, governments may also refer to customary law as a valid source of law, or declare it to be the governing source of law in certain contexts. For example, Fiji’s Public Health Act states that the Act does not apply to villages (with the exception of those provisions governing infectious diseases), although the Minister of Health retains residual power to extend the application of any provision of the Act to villages by executive order. As a result, customary law and forms of social organization remain the operative source of authority for managing “minor public health risks, sanitation and general village neatness”. As with other sources of law, governments should ensure that customary law upholds universal human rights and does not legitimate discrimination.

In addition to statutory regulation, and voluntary forms of regulation, governments may adopt forms of co-regulation that draw on the participation of industry, professional or civil society organizations (Box 2.1). For example, government may give an industry-administered code or self-regulatory process official status within a statutory scheme. Alternatively, it may enhance the status of an industry code in other ways, such as through the participation of a government representative on its governing board. As Box 2.1 illustrates, in some countries, important matters of health policy – such as the regulation of food advertising to children, or regulation of electronic cigarettes – may be regulated by industry-based bodies within statutory schemes that lie outside the responsibility of the health ministry. Governments should consider carefully whether it is appropriate to delegate responsibility for important health issues to industry-based, non-health bodies.
Box 2.1: Advertising regulation in the United Kingdom: an example of co-regulation

In the United Kingdom, both non-broadcast and broadcast advertising are governed by a co-regulatory system. The Committee of Advertising Practice (CAP) is responsible for writing and updating the United Kingdom Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing, while the Broadcast Committee of Advertising Practice (BCAP) writes and updates the United Kingdom Code for Broadcast Advertising. The membership of both Committees is made up of advertising associations, media owners and other industry groups. Although CAP and BCAP are responsible for the standards that govern the content of advertising in the United Kingdom, an independent body, the Advertising Standards Authority (ASA) administers the codes by acting on complaints and taking action against misleading, harmful or offensive advertisements. The ASA Council hears complaints and decides if advertisements have breached the advertising codes (two thirds of its members are independent of industry). The United Kingdom Office of Communications (Ofcom) remains the statutory regulator for the communications industries, signs off on major changes to the Codes and has ultimate responsibility for enforcing compliance with the Codes. The co-regulatory advertising scheme of the United Kingdom has addressed concerns relating to the advertising of unhealthy products in a number of ways. In 2007, Ofcom banned the advertising of foods high in salt, sugar and fat (based on a nutrient profile developed by the Food Standards Agency) in television programmes commissioned for or directed at audiences below the age of 16. The ASA’s Council has also upheld a number of complaints against advertisers for making misleading and deceptive claims about the health effects of electronic cigarettes (e-cigarettes). In 2014, the CAP and BCAP published new rules for the marketing of e-cigarettes. These rules were intended to operate during the two year period until the United Kingdom became required to implement the requirements of the revised European Union Tobacco Products Directive (2014) into United Kingdom law. The Directive limits the advertising of e-cigarettes, and extends the same legal restrictions to electronic cigarettes as already apply to other tobacco products.

The use of statutory regulation and softer, non-mandatory standards is not mutually exclusive. Governments frequently adopt a mix of regulatory instruments to address different aspects of a health challenge. For example, the government of Mexico has responded to rapidly rising rates of obesity with a variety of regulatory and non-regulatory strategies. These include:

- commissioning voluntary evidence-based guidelines on beverage consumption;
- a “National Agreement for Healthy Nutrition” that committed the Mexican Government, the food industry and other stakeholders to work together to achieve 10 objectives;
- statutory regulations to remove foods and beverages with high levels of sugar and saturated fat from schools and to improve access to clean water and healthy foods;
- a voluntary, front-of-pack scheme to identify the healthiest products in each food category; and
- a tax of around 10% on sugar-sweetened beverages, and 8% tax on high-calorie foods.
The use of statutory instruments does not always mean that the government is adopting a coercive or mandatory approach. For example, legislation can establish institutions that carry out public health functions, as in the case of Tonga’s Health Promotion Foundation Act 2007. In general, however, the benefit of statutory regulation is that it enables governments to impose technical standards and requirements that are mandatory, rather than voluntary or discretionary. Statutory regulation is therefore suited to contexts where the protection of public health requires widespread (and ideally, uniform) compliance with common, minimum standards (e.g. sanitary requirements, control of infectious diseases, food safety, tobacco control), or where guidelines and other voluntary commitments impose only weak and ineffectual standards.

Although industries that wish to avoid legislative regulation may point to the existence of a self-regulatory code as evidence that industry is taking health concerns seriously, statutory regulation also has the benefit of creating a level playing field. It prevents businesses from suffering the market disadvantages that might otherwise arise if they were left to decide whether or not to adopt standards voluntarily. In each case, the central issue is whether the incentives that drive business conduct are adequately aligned with the actions and outcomes that are required in order for governments to progressively realize the right to health. In some cases, as with the tobacco industry, the drivers of business conduct are diametrically opposed to public health goals.

Governments may be reluctant to impose additional requirements on businesses or individuals where there is evidence that voluntary standards or self-regulation are working effectively. Co-regulation may also benefit the public interest by maintaining an open dialogue with those who are subject to regulation, by giving government access to the knowledge and expertise of private sector organizations about how to achieve shared goals, and by encouraging a collaborative approach. While the monitoring and enforcement of legislative standards may impose substantial costs on government, the costs of self-regulation may be shared with or transferred onto industry. In evaluating the relative benefits of legislative and non-legislative options, governments must remember their obligation to seek to achieve the right to health for their population (see Section 1.1).

Independent monitoring and evaluation are critical when evaluating the performance of self-regulatory codes, guidelines or co-regulatory schemes in achieving public health goals. Where credible evidence demonstrates that industry standards are inadequate, governments will need to consider the most appropriate and feasible regulatory response. While that may include the introduction of new legislation, the form of that legislation may vary depending on the context. For example, a government may require the registration of an industry code and make such registration conditional on the code meeting specified criteria. These minimum criteria may close off the major loopholes and escape clauses in the voluntary code that undermine the health goals that the government is seeking to achieve. In addition, the government may specify measurable targets and indicators for evaluating the success or performance of industry self-regulation. The government may also mandate regular monitoring, with results reported to parliament, or to an appropriate regulatory agency, thereby enhancing transparency and public accountability. Where an industry code fails to achieve these benchmarks, the case for direct statutory controls will be more compelling.
REFERENCES


9 Public Health Act [Cap 111] s. 140 (http://www.paclii.org/fj/legis/consol_act_OK/pha126/).


17 The Tobacco and Related Products Regulations 2016 implemented the Tobacco Products Directive 2014/40/EU within the United Kingdom.

18 Article 20(S) of the revised Tobacco Products Directive (2014) prohibits the advertising of electronic cigarettes in the press, radio, television and the internet, although this prohibition does not apply to other

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1 All references were accessed on 1 May 2016.


22 Health Promotion Foundation Act 2007 (Kingdom of Tonga) (http://crownlaw.gov.to/cms/en/).