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Foreword

By Dr Soumya Swaminathan, Deputy Director-General for Programmes, World Health Organization

The goal of the World Health Organization (WHO) is to advance the health and well-being of people all over the world. Working through offices in more than 150 countries, WHO staff work side by side with governments and other partners to combat communicable and non-communicable diseases, to reduce injuries and health inequalities, to achieve universal health coverage and to create healthy and sustainable futures for all. Our work includes strengthening health systems and addressing the social, economic and environmental determinants of health – including the legal and regulatory frameworks that determine vulnerability to accidents and disease, and access to medications, treatment and rehabilitation.

This publication is timely and illustrates how the strengthening of public health laws is essential to fulfilling WHO’s global health mandate. Examples include the control of infectious diseases with pandemic potential, such as Zika and Ebola, the prevention and control of non-communicable diseases through tobacco control, the regulation of marketing of food and non-alcoholic beverages to children, and legal frameworks for road safety including motor cycle helmets, seat belts and drink-driving laws.

Drawing on experience from high-, middle- and low-income countries, this publication demonstrates that enabling legal frameworks for health are not only a result of economic development but are an essential component of and contributor to such development.

Advancing health requires commitment and action from all sectors of government. Well-designed laws and governance processes can support this process; for example, through setting targets that are shared across the different sectors of government, and through inter-sectoral taskforces and committees to identify the actions that non-health ministries – such as finance, agriculture, consumer affairs, trade, environment and communications – can make towards the achievement of national health goals.

When various actors work hand in hand to promote public’s health, accountability is crucial. Strong legal frameworks are needed to clarify the rules for action and the roles and responsibilities of various actors. For example, the law can establish transparent processes for tendering and for contracts with government, require members of parliament and government officials to declare and manage conflicts of interest effectively, and establish independent institutions to investigate allegations of corruption fairly.

This year, as WHO celebrates its seventieth birthday, the world faces immense health challenges – many familiar and some emerging. The WHO report Advancing the right to health: the vital role of law(2017), and this summary guide, demonstrate the depth and breadth of law’s role in protecting and promoting the right to health. With these tools WHO, our Member States, and the global public health community will be better prepared to deliver on the goal of universal health coverage, while ensuring that no one is left behind.

Soumya Swaminathan
Preface

The WHO Constitution states that “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being … dependent upon the fullest co-operation of individuals and States”. Progressively realizing the right to health is a legal obligation enshrined in the International Covenant on Economic, Social and Cultural Rights; in other international treaties; and in constitutions and statutes in many countries. The law is a powerful tool for safeguarding and promoting the public’s health and safety, and all sovereign states have the power, and the duty, to advance the right to health. The most effective legal tools for achieving this end are the many laws and regulations that have a demonstrable impact on the health and safety of populations. Public health laws should be evidence based, fairly and effectively implemented, and for the good of the population.

Communicable and noncommunicable diseases

Control of communicable (infectious) diseases is perhaps the most powerful illustration of the law’s vital role in public health, from responses to long-standing diseases through to modern pandemics. Recent outbreaks of Ebola virus and Zika virus diseases emphasize the need for all countries to urgently implement the International Health Regulations (2005) to combat modern pandemics and novel infections.

The law also plays a vital role in the prevention and control of noncommunicable diseases (NCDs). Cancer, cardiovascular disease, diabetes and respiratory disease are now responsible for the greatest global burden of disease and early death, mostly in low- and middle-income countries. Innovative governments have shown that public health laws can make a substantial difference to health outcomes in this area; for example, smoking rates have dropped sharply in countries that have implemented the WHO Framework Convention on Tobacco Control.

Tools shown to be successful in tobacco control can be applied to other risk factors for NCDs, such as harmful consumption of alcohol and unhealthy foods and drinks, and physical inactivity. The law can transform economic, informational and built environments to reduce morbidity and premature mortality caused by NCDs. Legal avenues can be used to provide incentives for healthy behaviours, educate and empower consumers to make healthier choices, and improve the built environment.

Injuries

Injuries contribute significantly to health burdens in low- and middle-income countries. Often, injuries are referred to as “accidents”, suggesting they are not preventable. However, laws and regulations can significantly reduce injuries and help make them preventable; for example, road and traffic regulations can reduce injury rates. Similarly, injuries occurring in homes can be prevented if building and workplace practices are better regulated. Intentional injuries (assaults, murder and suicide) are also preventable; for example, by improving laws on gun control, preventing intimate partner assaults, and reducing access to the means for suicide.

Universal health coverage

Universal health coverage (UHC) is a vital policy to advance the right to health. Building robust health systems starts with planning and sustainable financing for clinics, hospitals and staff. The law also plays a role in UHC, establishing governing institutions, and ensuring universal access to health services, equity, and quality at an affordable cost.

Multisectoral engagement

National and global legal regimes extend beyond the health sector. “All-of-government” national strategies are needed, with leadership at the highest level and active engagement between ministries and levels of government. This is also true at the global level. For example, strategies are needed for trade and intellectual property to ensure access to essential medicines or vaccines; and for agriculture, to reduce antimicrobial resistance.
Stigma and discrimination

Equitable and fair treatment is key to human rights and the right to health. The greatest health burdens usually fall on the most vulnerable, marginalized and impoverished individuals; also, in many societies, these people are routinely denied equal access to opportunities and services. The purpose of the law is to protect them against discrimination and improve their access to services.

Law as an obstacle to health

The law can sometimes prevent progress in health and human rights. For example, during major disease outbreaks, many countries restrict travel and trade or enforce quarantine, against WHO recommendations. Some countries have laws that punish people for their sexual orientation or gender identity, or that impede public health policies for reduction of harm from drug use. It may therefore be necessary to dismantle some laws to advance the right to health.

Good governance

The rule of law also requires the “good governance” that ensures fair and efficient operation of public institutions and social structures, which in turn requires a legal infrastructure that can implement legal rules. Good governance encompasses all the norms, processes and institutions of a just society that passes and enforces laws for the common good.

We hope our examination of what countries can do to protect the health and dignity of all peoples will contribute to greater understanding and better use of the law in advancing the right to health.

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Abbreviations

AAAQ availability, accessibility, acceptability and quality
CESCR Committee on Economic, Social and Cultural Rights
COP Conference of the Parties
CVD cardiovascular disease
FCTC Framework Convention on Tobacco Control
ICESCR International Covenant on Economic, Social and Cultural Rights
IDLO International Development Law Organization
IHR International health regulations (2005)
NCD noncommunicable disease
NGO nongovernmental organization
PIP Pandemic Influenza Preparedness
SDG Sustainable Development Goal
SSB sugar-sweetened beverage
TB tuberculosis
TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights
UHC universal health coverage
UN United Nations
UNICEF United Nations Children’s Fund
USA United States of America
WHO World Health Organization
WTO World Trade Organization

In this Summary Guide, cross-references to pages, sections or boxes contained in the full report are shown in bolded text, within curly brackets {}.

The full report - Advancing the right to health: the vital role of law - can be downloaded from the WHO website at:

http://apps.who.int/iris/bitstream/handle/10665/252815/9789241511384-eng.pdf;jsessionid=CE19AF3161C3448A9BF316DEE236DDAB?sequence=1
Introduction

In 2017, WHO published *Advancing the right to health: the vital role of law* (1). The aim was to raise awareness about the role that the reform of public health law can play in advancing the right to health and in creating the conditions for people to live healthy lives. This update and summary guide summarizes and expands on that report.

Purpose and audience

This update and summary guide aims to illustrate the power and flexibility of law as a tool for addressing health risks and creating the conditions in which all people can live healthy lives. The audience for this guide includes:

- senior officials working within ministries of health;
- officials in other ministries within government who can influence public health through their actions and policies, and through the laws they administer (e.g. officials in agriculture, communications, consumer affairs, education, energy, environment, finance, foreign affairs, housing, infrastructure, justice, social security, trade and transport);
- members of the legislative, executive and judicial branches of government (including parliamentarians, ministers, judicial officers and their advisers); and
- other stakeholders, such as members of health organizations, philanthropic organizations, the media, industry,
- academia, employer and labour organizations, and civil society organizations.

References to the full report *Advancing the right to health: the vital role of law*

This update and summary guide summarizes, updates and expands on the full report (1). It contains links to relevant parts of the full report where further details can be found; these cross references are shown in italics, in bolded blue text, within braces. This guide also contains a list of references at the end; in the text, each reference is identified as a number, in italics, within parentheses.

Summarizing the report

The full report aims to encourage and assist governments to reform their public health laws in order to improve population health. In doing so, the report:

- highlights important issues that may arise during the process of public health law reform (Part 1);
- discusses the process of public health law reform; that is, the practical steps involved in advancing the political goal of law reform, and the kinds of issues and obstacles that may be encountered along the way (Part 2); and
- identifies priorities for public health law reform; that is, core areas where regulation is essential for governments to discharge their basic public health functions, ranging from clean water and sanitation to tobacco control and nutrition (Part 3).

This update and summary guide generally reflects the structure of the full report, although some headings have been modified. Where relevant, it includes diagrams, text boxes and other visual aids in order to present detailed material from the report in a concise format; and case studies and examples from developing and developed countries to highlight the power and potential of law as a tool for action.
Updating and expanding on the report

This update and summary guide draws attention to several topics that were beyond the scope of the full report. It includes subsections on the Sustainable Development Goals (SDGs) (1.3), the Nagoya Protocol (11.1(d)) and alcohol control (12.3). It integrates new health data and refers to new developments, including a list of highly cost-effective legal measures for reducing risk factors for NCDs, drawn from the updated Appendix 3 of the WHO NCD Global Action Plan, and the new Independent Oversight and Advisory Committee for health emergencies (11.1(c)). It also references selected new decisions, such as the unsuccessful claim by a tobacco company against Uruguay’s tobacco control laws (2), and the decision of the Constitutional Court of Colombia confirming the right to receive information about the health effects of sugary drinks (3).
Part I: Advancing the right to health through law reform

Chapter 1: Public health regulation and the right to health

The human right to health provides an overarching and exacting standard to guide the actions of governments as they strengthen their health systems by reforming their public health laws. Section 1.1 explains how the interpretation of the right to health under the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides an impetus for States to improve their public health laws in order to meet their legal obligations. Section 1.2 explains how the goal of universal health coverage (UHC) is closely aligned with the right to health, and how right-to-health concepts assist in evaluating progress towards UHC. Section 1.3 introduces the SDGs and explains how the reform of public health laws may assist countries to meet the aspirations set out in the health-related SDG targets.

1.1 Justifications for public health regulation

There are many different justifications for public health regulation. These include:

- reducing externalities (e.g. by protecting non-smokers from second-hand smoke or improving vaccination rates);
- protecting the enjoyment of public goods (e.g. by improving air quality or vector control);
- providing consumers with information about harmful goods (e.g. through health warnings on tobacco and alcohol products);
- providing consumers with information to help them make healthier choices (e.g. through front-of-pack nutritional labelling); and
- reducing the health inequalities that have emerged and persisted during the process of economic and social development.

The full report approaches public health law reform through two fundamental human rights concepts:

- the rule of law – this is the principle that law-making processes should be transparent, laws should be enforced fairly, courts and tribunals should be independent, and the administration of law and its substantive content should be consistent with international human rights standards (Box 1.1); and
- the right to health – the right of everyone to enjoy the highest attainable standard of physical and mental health (Box 1.2); this right extends beyond health care to the underlying determinants of health, such as sanitation and potable water.

The right to health is well-established in international treaties such as the ICESCR and the Convention on the Rights of the Child, and in major regional human rights agreements in Africa, Europe and the Americas. On a national level, many countries have recognized the right to health in their constitution. For example, the Constitution of Brazil designates and protects health as a social right (Section 1.1).

According to the United Nations (UN) Committee on Economic, Social and Cultural Rights (CESCR), States have obligations to respect, protect and fulfil the right to health, as shown in (Fig. 1.1).
The right to health requires States Parties to:

- respect the right to health: by not directly or indirectly interfering with the enjoyment of the right;
- protect the right to health: by taking actions necessary to prevent third parties from interfering with the right; and
- fulfil the right to health: by taking actions to facilitate, provide and promote the conditions in which the right can be fully realized.

(a) Obligations of immediate effect under the right to health

Although resource constraints may mean that countries will need to take steps to progressively realize the right to health over time, certain obligations are of immediate effect. For example, there is an immediate obligation to ensure that access to health services and other underlying determinants of health is not undermined by discrimination on grounds such as race, colour, sex, religion, national or social origin, physical or mental disability and political status, as set out in the ICESCR. Countries also have an immediate obligation to take deliberate, concrete and targeted steps towards the full realization of the right to health.

(b) Core obligations arising under the right to health

The CESCR has identified several core obligations that may be seen as priorities for action as States progress towards the full realization of the right to health; for example, ensuring (4):

- safe and nutritionally adequate food; basic shelter, housing and sanitation; and safe and potable water;
- provision of essential medicines (as defined by WHO);
- equitable distribution of health facilities, goods and services; and
- the adoption and implementation of a national plan of action for health.

In addition, there are a number of obligations of comparable priority. These include the obligation to ensure:

- reproductive, prenatal and postnatal maternal and child health care;
- immunization for priority diseases;
- the prevention, treatment and control of epidemic and endemic diseases;
- education about major health challenges facing the community; and
- appropriate training for health personnel, including education on health and human rights.

(c) The right to health and health systems

The obligation to respect, protect and fulfil the right to health requires States to invest in the components or building blocks of an effective health system (Fig. 1.2).
1.2 Concepts and principles for guiding and evaluating law reform efforts

The right to health and the goal of UHC provide important concepts and principles that can be used to both evaluate the adequacy of existing laws and determine the scope of necessary reforms.

(a) The goal of universal health coverage

UHC has emerged as a unifying concept and goal for governments as they seek to strengthen their health systems and to discharge their obligations under the right to health (6: pp 2–6). UHC is achieved when all people receive the quality health services that they need without discrimination or financial hardship (see Chapter 7). UHC is typically presented as a cube (the “UHC cube”), with the three dimensions or axes representing the population, health services and health costs (Fig. 1.3).

The UHC cube is designed to encourage countries to expand the provision of priority health services, to extend the coverage of those services to more people and to reduce out-of-pocket payments. Four guiding concepts – availability, accessibility, acceptability and quality (the “AAAQ framework”) – discussed below, provide a framework for evaluating the actions taken by governments to expand UHC.

(b) Availability

Availability is the concept that health-care facilities, goods and services, and public health services, facilities and programmes should be available in sufficient quantity. It is linked to the services axis because improving availability means investing more in the resources that are needed to increase the range, volume and capacity of services to the population. South Africa’s National Health Act is an example of legislation that established a national health system with the goal of increasing availability in an equitable manner (Box 1.5).
(c) Accessibility

Accessibility is the concept that health-care facilities, goods and services, and public health services, facilities and programmes should be accessible to the entire population. This concept is linked to the population and cost axes of the UHC cube. To improve accessibility, States should ensure:

- **non-discrimination** – by implementing and enforcing non-discrimination laws;
- **physical accessibility** – by providing adequate infrastructure and services for marginalized or vulnerable groups;
- **economic accessibility** – by funding mechanisms that reduce out-of-pocket payments imposed at the time the service is delivered; and
- **information accessibility** – by supporting the right to seek, receive and express information about health issues.

The Constitution of the Islamic Republic of Iran provides an example of using the law to improve economic access to health-care services (Box 1.6).

(d) Acceptability

The concept of acceptability is that health-care facilities, goods and services should be delivered in ways that are culturally appropriate, sensitive to gender and to different age groups, and consistent with ethical obligations. It is linked to the population axis of the UHC cube because it directs attention to factors that may undermine demand for health services by those who need them. For example, legislation that criminalizes the possession of needles and syringes can undermine efforts to reduce HIV transmission in injecting drug users.

(e) Quality

Quality in health care is the concept of care that is safe, effective, people centred and built on the foundations of a motivated and well-trained health workforce, quality drugs and medical products, and appropriate infrastructure. It requires a skilled health workforce, and processes for assuring the supply of approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

1.3 The Sustainable Development Goals

The SDGs, which were adopted by the UN General Assembly in 2015, are a globally agreed framework for advancing the development and prosperity of all countries over the period 2015–2030. The 17 goals and 169 targets address the three dimensions of sustainable development: economic, social and environmental. They include goals for ending poverty, reducing inequalities, promoting just and inclusive societies, achieving gender equality and achieving sustainable management of natural resources.

SDG 3 is to “Ensure healthy lives and promote well-being for all at all ages”. The targets that sit under this and other health-related SDGs cover the spectrum of health challenges. This report highlights a range of areas where the reform of public health laws will help countries to discharge their obligations under the right to health, while also contributing towards achievement of the health-related SDG targets.
Part II:  
The process of public health law reform

Chapter 2: The context of public health law reform activities

This chapter discusses the scope of public health laws and their administration (Section 2.1); the process for reviewing these laws – drivers, scope and implementation (Section 2.2); and the different forms of regulation that countries may use to regulate health risks (Section 2.3).

2.1 What are public health laws?

The WHO Constitution 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. Thus, public health law includes both regulation of health-care services and the legal powers that are necessary in other areas for the State to discharge its obligation to realize the right to health for all members of the population.

How countries organize and administer laws to protect the health of their populations will reflect the specific health challenges they face. Public health laws may cover diverse areas ranging from tobacco control and food safety, to management of communicable diseases, regulation of pharmaceuticals, and the powers of public health officers.

Typically, the ministry of health administers laws that affect the provision of health care and address health risks. However, other ministries often administer laws that may also affect health risks and health outcomes. Where more than one ministry is involved, the process of governing public health and reforming public health laws becomes more complex.

2.2 Conceptualizing the process of health legislation review

(a) Impetus for a review

Political willingness to review public health laws may develop in response to specific concerns about 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 or from development partners. International factors may also have an influence; for example, the need to discharge a country’s obligations under international agreements or to implement recommendations and action plans.

(b) Scope of the review process

A formal review of existing public health laws can vary from assessing the adequacy of a particular section within a statute or code, to revising or introducing an entirely new public health act. An intersectoral or cross-ministerial review may be necessary to respond to health challenges that are influenced by policies overseen by nonhealth ministries; for example, in areas such as food security and efforts to respond to risk factors for noncommunicable diseases (NCDs).

The scope of the review will influence who conducts it – independent consultants, officials from the health ministry and other relevant ministries, specially formed committees or specialist law reform bodies. The person or agency chosen to undertake the review, and the formal processes involved can influence how seriously the recommendations are considered by government, and whether the issues remain on the political agenda.
(c) Implementing recommendations

The capacity and willingness of a government to implement the recommendations from a formal review of public health laws may be affected by the political ideology of the government, the political feasibility of reform proposals, competing legislative priorities and the availability of resources. The design and drafting of new public health laws involves consideration of issues such as:

- the most appropriate legislative mechanism for implementing the recommended changes;
- the specific legal powers and responsibilities arising under the new law; and
- the compatibility of the law with human rights principles.

Governments should plan to monitor and evaluate the impact of changes to public health laws, by selecting indicators for tracking the impact of the law on relevant practices and, where appropriate, intermediate or longer term health outcomes. Governments may need to set national priorities and implement public health law reform recommendations in a stepwise manner, starting with reforms that will deliver the greatest overall health benefits.

The full report provides many case studies and examples of legislation from different countries, to give public health authorities a greater understanding of the options for reform, and encourage them to use legal powers to realize the right to health.

2.3 Why legislate?

Forms of regulation that can be used to regulate health risks and other health matters include legislation, subsidiary regulations, decrees and executive orders, guidelines and codes of conduct. Governments may also defer to customary law, or declare it to be the governing source of law in certain contexts, an example being the application of customary law within villages in Fiji (Section 2.3).

Another option is to adopt forms of co-regulation that formally include the participation of industry, professional bodies or civil society organizations, as was done with co-regulation of advertising in the United Kingdom (Box 2.1). Governments often use a mix of legislation and non-mandatory standards to address different aspects of health challenges, as seen in Mexico’s efforts to address obesity, which included a tax on sugar-sweetened beverages and a voluntary front-of-pack nutrition labelling scheme (Section 2.3).

Statutory or legislative regulation is particularly suited to situations where the protection of public health requires widespread compliance with common, minimum standards (e.g. control of infectious diseases and tobacco control). Such regulation is also suited to establishing institutions that conduct public health functions, an example of which is Tonga’s Health Promotion Foundation Act 2007 (Section 2.3).

Independent monitoring and evaluation is critical for determining whether self-regulatory codes and guidelines or co-regulatory schemes are achieving public health goals and are therefore a suitable form of regulation.
Chapter 3: Assessing the case for the reform of public health laws

This chapter considers some of the reasons that may justify a review of public health laws (Section 3.1), the process of setting priorities for reform of such laws (Section 3.2), the various bodies who may initiate the reform process (Section 3.3) and the types of factors that may trigger reform (Section 3.4).

3.1 Common reasons for reviewing and updating public health laws

Countries may review their public health laws for a variety of reasons; for example:

- current laws may be outdated, have multiple layers or be inconsistent (as summarized in Fig. 3.1);
- major health hazards and current challenges may require new legislative frameworks;
- governments may lack the powers they need to discharge their public health responsibilities effectively; and
- current laws may fail to appropriately balance the rights and interests of individuals with public health and with other public interests.

3.2 Identifying priorities for public health law reform

The major health challenges that a country is facing may not always be high on the political agenda, especially where the impact of the health threat falls disproportionately on poor or marginalized populations. This section describes some of the major risks to health that require urgent attention in many countries. Effective prevention and control of these diseases requires strong legal frameworks.
(a) Communicable diseases

Pandemics of contagious diseases, such as pandemic influenza (Box 3.2), pose a powerful threat to global health security. They have the potential to overwhelm health systems, and threaten economic stability and growth. (8)

- **Infectious diseases with pandemic potential** – Under the International health regulations (IHR) (2005) (9), Member States are required to notify WHO if there is a potential “public health emergency of international concern”. Law is critical in establishing the institutional structures and formal processes through which governments respond to outbreaks of contagious diseases, and in setting limits for the exercise of coercive power over citizens and businesses, to mitigate the risk of disease spread (see Chapters 9–11).

- **HIV-related diseases** – HIV infection and HIV-related diseases are a critical global and national challenge (Box 3.3); in 2016, nearly 37 million people were living with HIV and 1 million people died from AIDS-related diseases. Certain laws can help to prevent and control the spread of HIV, whereas others create obstacles to effective treatment and prevention (e.g. laws that explicitly criminalize the transmission of HIV). However, laws prohibiting discrimination against people living with HIV are often not enforced.

- **Tuberculosis (TB)** – TB remains a persistent threat to global health, with an estimated 10.4 million people falling ill from the disease in 2015. Adequate legal powers are needed to encourage treatment adherence by those with TB, in a manner that is consistent with human rights and dignity.

(b) Noncommunicable diseases

NCDs – principally cardiovascular disease (CVD), cancer, respiratory diseases and diabetes – are responsible for about 70% of global mortality, and this situation is expected to get worse, as shown by the following:

- **Obesity** – In 2015, more than 107 million children, and 603 million adults were obese, putting them at higher risk of heart disease, cancer and diabetes (10). The number of adults with diabetes is projected to increase from 382 million in 2013 to 592 million in 2035.

- **CVD** – CVD is the leading cause of death worldwide, causing more than 17 million deaths each year (almost 75% of these in low- and middle-income countries). This number is projected to increase to more than 22 million deaths per year by 2030.

- **Cancers** – In 2015, cancers were responsible for more than 8 million deaths, and by 2030 are expected to cause more than 12 million deaths per year. Leading modifiable risk factors include tobacco use, lack of physical exercise, obesity, harmful use of alcohol, air pollution, infections and ultraviolet exposure.

NCDs have a disproportionate effect on low- and middle-income countries, which account for almost 75% of deaths from CVD and 70% of tobacco-related deaths; rates of increase of child overweight and obesity are also 30% higher in these countries (Box 3.4). In addition, many low- and middle-income countries now face a double burden of communicable diseases and NCDs. Law has an important role to play in responding to the burden of NCDs, as discussed in Chapters 6, 12, 13 and 16.

(c) Injuries

Although neglected in many countries, injuries caused nearly 5 million deaths in 2016 (11). Priority areas for governments include enforcing laws requiring motorcycle helmets, and mandatory seat belts and child restraints in vehicles. Important interventions to reduce violence and intentional injuries include strengthening the control of alcohol and firearms laws.

3.3 Who can initiate public health law reform?

As discussed in Section 2.2, although the health ministry will often take the lead in public health law reform, consultation with other ministries may be critical to ensuring effective implementation and enforcement. For example, the drafting and implementation of Papua New Guinea’s Provincial Health Authorities Act benefited from intensive consultations between the Health Ministry and Treasury, and led to new Treasury guidelines governing the payment of funds to newly created provincial health authorities (Box 3.5). The prime minister, president, cabinet or a law reform commission may also be crucial in providing leadership and support for public health law reform.
Beyond government, consultation with health professionals, the private sector, civil society, academia and others may improve proposals for reform of public health laws. For example, civil society was directly involved in Brazil’s constitutional amendments affecting health (Section 3.4). Although stakeholder input can benefit the law reform process, governments should ensure that lobbyists and sectional interests do not undermine the public health goals that the reform is intended to achieve.

### 3.4 What factors can act as triggers for public health law reform?

**a) Triggers for public health law reform within government**

Among the events that may trigger the reform of public health laws are disease outbreaks, sunset clauses in legislation and obligations under international law such as the IHR (2005), the WHO Framework Convention on Tobacco Control (FCTC) and strategy documents such as the WHO Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013–2020 (the WHO NCD Global Action Plan 2013–2020).

**b) Community participation as a trigger for public health law reform and policy-making**

In some countries, formal mechanisms for ensuring community participation in the processes of law-making and law reform may enable civil society organizations to put health issues on the government’s agenda. For example, Thailand has formalized community participation in the formation of health policy through its National Health Assembly (Section 3.4).

**c) Litigation and public health law reform**

In countries where constitutional provisions recognize a right to health or health-care services, litigation may compel governments to protect these rights through legislation, and to take reasonable measures to secure the enjoyment of the right, within the limits of available resources. About two thirds of countries have such provisions. One example is South Africa, where civil society organizations litigated restrictions on access to nevirapine, an HIV medicine, under the Bill of Rights, which recognizes a right to access health-care services (Box 3.6).

In some countries, right-to-health litigation has triggered a broader reform of coverage of health-care services, and adjustment of health budgets. For example, Colombia initiated a sweeping reform of its health system – including changes in the coverage of health-care services – following a finding by the Constitutional Court that systemic problems within the public health system constituted failure to fulfil the right to health (Section 3.4).

Even in countries where there is no express constitutional protection of the right to health, other constitutional rights may provide indirect protection. Thus, in India, a court ordered that citizens should be protected from exposure to second-hand smoke through the constitutional right to life and to personal liberty (Box 3.7). Similarly, in Uganda, the High Court ruled that public smoking violated a number of constitutional rights, including the right to life, and the right to a healthy and clean environment (Section 3.4).
Chapter 4: Building blocks for effective public health laws

Law reform is a process that will reflect the legal history, legal and constitutional structure, and the political context of each country. This chapter considers what such reform seeks to achieve and who undertakes it (Sections 4.1 and 4.2), and some building blocks for good public health laws that may help in designing legislation and implementing recommendations from a review of public health laws (Sections 4.3–4.6).

4.1 Legislative goals, mandates and principles

The public health functions of governments cover a wide range of activities (Table 4.1). Governments need to consider how these functions can be best supported by legislation.

Table 4.1. Core public health functions of government

<table>
<thead>
<tr>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance and monitoring</td>
</tr>
<tr>
<td>Public health protection and assurance, including discharge of regulatory functions and statutory responsibilities</td>
</tr>
<tr>
<td>Health promotion</td>
</tr>
<tr>
<td>Financing of public health interventions</td>
</tr>
<tr>
<td>Training and capacity-building</td>
</tr>
<tr>
<td>Research and evaluation</td>
</tr>
</tbody>
</table>

Public health legislation should clearly set out the mandate, powers and responsibilities of the government and of public health officials. The aim is to ensure that the officials have the powers they need while governments remain accountable for discharging their statutory duties and functions. For example, public health legislation in Victoria, Australia, encompasses a mandate for population-wide health protection, promoting healthy environments and reducing health inequalities (Section 4.1).

4.2 Powers and responsibilities of the health ministry, and coordination with other agencies

Public health legislation should explicitly state the functions and responsibilities of the relevant minister, as well as those of regional, local and city councils. Countries that have devolved public health functions to regional and local levels should ensure that this does not compromise the capacity of the national government to ensure the availability, accessibility, acceptability and quality of public health services. Coordination is critical when dealing with public health emergencies and discharging other public health functions. In emergencies, coordination is needed both between different levels of government, and between agencies with specialized responsibilities (e.g. in customs, border control, and reporting of notifiable and quarantinable diseases). A national focal point will be required to coordinate the flow of information between WHO and relevant parts of the national government.

4.3 Legal tools and strategies for discharging public health responsibilities

Public health laws address a wide range of matters and may draw on a range of underlying strategies (Table 4.2):

- public health infrastructure and governance structures;
- economic policies;
- alteration of the informational environment;
- regulation of businesses, professionals and individuals;
- environmental policies; and
- health inequalities.
Although governments are the key actors in protecting public health, national constitutions and legal systems may also permit individuals to vindicate private rights through the courts, and to make complaints (e.g. through consumer protection agencies).

4.4 Building flexibility into public health laws

New health risks and hazards continue to emerge; also, the leading causes of death and disability within countries are changing. Public health laws and statutory powers need to be sufficiently flexible to permit governments to respond swiftly and effectively in each situation (Box 4.2).

Communicable and noncommunicable diseases

For practicality, communicable diseases are usually regulated through generic provisions in public health laws. These laws impose reporting requirements for lists or categories of diseases, set out in regulations or executive orders that can be easily updated. Laws may also provide for the designation of a serious, highly transmissible disease as a “quarantinable disease”, triggering additional powers. A similar strategy may be used with NCDs (Box 4.2).

Regulating “public health risk activities” and “public health risk procedures”

Flexible legislation can give authorities the power to designate activities or procedures that may result in harm or disease transmission as “public health risk activities”. Such designation allows authorities to impose licensing conditions, and to issue infringement or prohibition notices if a business fails to comply with those conditions. Thus, in Australia, the Australian Capital Territory has used this mechanism to regulate water utilities (Box 4.2).

4.5 Integrating human rights protections into public health law

States have an obligation to frame public health laws in ways that are consistent with their human rights obligations, including civil and political rights, the right to health, and other social and economic rights.

The right to health, as recognized in international law, provides a foundation for health development. Viewing the process of reforming public health laws through the lens of the right to health helps States to consider the broad social determinants of health, and the health impacts of policies and laws across different sectors.

Women, adolescents and children may experience health inequalities caused by discrimination based on their sex and age. The Convention on the Elimination of All Forms of Discrimination Against Women addresses discrimination in access to health-care services. The Convention on the Rights of the Child also highlights the vulnerability of children, and recognizes children’s rights to non-discrimination and to health. Several countries have recognized the rights of children in their national constitutions; for example, Brazil’s Constitution recommends that the State allocate a percentage of its public health-care funds to mother and child assistance (Box 4.3).

Public health legislation can and should protect individuals from discrimination and ensure fair access to health services. For example, under New Zealand’s Human Rights Act, the country’s Human Rights Commission hears complaints of discrimination in areas such as employment, and the provision of goods and services (including health-care services) (Section 4.5).

In some countries, individuals and groups can appeal directly to the courts to vindicate their constitutional rights, including women’s rights to non-discrimination. For example, Colombia’s Constitution provides for the protection of specific groups, including women and newborn children (Section 4.6).

4.6 Creating coherence between public health laws and other laws

Governments should seek to ensure coherence between public health laws and other laws (in particular, criminal laws). For example, criminal penalties for the transmission of HIV may have unintended effects, discouraging women from being tested or from having their babies tested, for fear of prosecution.
“Governance” refers to both the capacity of a government to develop and implement policies, and the ways in which power is exercised for the purposes of managing a country’s economic and social resources. “Good governance” refers to governance processes that reflect the values and principles that will contribute most effectively to economic and social development, including the progressive realization of the right to health. This chapter explains the importance of governance in public health law reform (Section 5.1), discusses how governance can help to address corruption (Section 5.2) and outlines the principles of good governance (Section 5.3).

5.1 Public health law reform, good governance and human rights

Good governance is essential to a successful law reform process. It can protect the process from inappropriate influence by those pursuing their own interests (e.g. lobbying by manufacturers of harmful products), and from other attempts to weaken the content of laws, or to undermine their implementation and enforcement.

Public health law reform connects the principles of good governance and human rights (e.g. ensuring the participation of those who are affected by public health laws is both a principle of good governance and a well-recognized dimension of the right to health). Similarly, if the principle of fairness is honoured in the law reform process, this will help to ensure that law does not legitimate the discriminatory treatment or exclusion of individuals or vulnerable groups (violating the right to health). Good governance is necessary for countries to respect, protect and fulfil the right to health.

5.2 Good governance and corruption

As with other forms of corruption in the health sector, corruption in the development and implementation of public health laws threatens progress towards national health goals. Civil society organizations and an independent media are important when powerful industries or other vested interests seek to weaken legislation or to corrupt public officials charged with enforcing legislation.

Legislation from sectors outside health may provide lessons on how good governance can address corruption. For example, legislation can establish principles governing public–private partnerships, such as requiring transparency in the processes for establishing partnerships, setting up mechanisms to manage conflicts of interest, and requiring such partnerships to contribute to national health goals and reduce health inequities. Such legislation should also have procedures for oversight and evaluation. An example is Uganda’s Public–Private Partnership Act (2015), which establishes a legislative framework for good governance of public–private partnerships.

5.3 Principles of good governance

To maximize the success and legitimacy of the public health law reform process, States should integrate the following six principles of good governance into the law reform process:

- **Stewardship** – those managing the reform of public health laws must put aside personal interests, and work to maximize the health interests and to realize the right to health of all of the people they serve (Section 5.3);
- **Transparency** – as far as possible, the process of developing, implementing and enforcing law should be open and visible to the public (Section 5.3);
- **Participation** – those directly affected by the law should be consulted in the law-making process, unless they have a vested economic interest in weakening or undermining effective public health laws (Section 5.3);
- **fairness** – States have international human rights obligations to eliminate discrimination and ensure equality of opportunity for people to enjoy the highest attainable level of health (*Section 5.3*);
- **accountability** – legislation should set out the responsibilities and functions of public health officials, clarifying who is accountable for enforcing the law and for exercising powers to protect the public’s health (*Section 5.3*); and
- **the rule of law** – all persons, officials and institutions are accountable under laws that are publicly accessible, equally enforced, independently adjudicated and consistent with international human rights standards (*Section 5.3*).
Chapter 6: Coordinated, intersectoral action to improve public health

The factors that influence health outcomes are complex; they extend well beyond the provision of healthcare services, and are often outside the authority of the health ministry (e.g. physical, economic, social and political environments affect the health of individuals and populations). Hence, the obligation to progressively realize the right to health must be shared across the whole of government.

Intersectoral health challenges such as climate change, humanitarian crises and infectious disease outbreaks require coordinated action between ministries, different levels of government and stakeholders outside government. Intersectoral legal and regulatory reforms can:

- provide a clear mandate for actions by relevant agencies and authorities;
- establish new governance structures and processes for advancing shared goals; and
- establish an accountability framework that clearly sets out the responsibilities of participants.

This chapter describes the purpose and scale of such reforms (Section 6.1), outlines practical steps for initiating the process (Section 6.2), and uses case studies to illustrate how governance reforms can support intersectoral action on health (Section 6.3).

6.1 The purpose and scale of intersectoral reforms to improve public health

The structures and processes that countries use to formalize intersectoral and intergovernmental collaboration will depend on existing institutions, traditions and constitutional arrangements, and on the specific priorities that are being pursued. Governments may choose to address different health priorities by investing in processes and structures of varying scale and focus (e.g. with the initiatives framed largely in terms of the health benefits they aim to achieve, or designed to achieve several related economic and social objectives). Table 6.1 highlights the evolution of understanding about the importance and value of intersectoral action on health.

6.2 Practical steps for initiating intersectoral action

Intersectoral action can be initiated across national, regional, city or local levels. High-level political commitment is vital, and may help to reduce resistance from ministries whose goals may conflict with public health. A successful partnership across sectoral boundaries requires the active participation and goodwill of all partners. A government’s political commitment may be strengthened by formalizing the partnership (e.g. in a declaration or memorandum of understanding setting out shared goals and each partner’s responsibilities). For example, in Brazil, government and civil society organizations signed a declaration on prevention and control of NCDs that commits the parties to take preventive actions at all government levels, while ensuring integrated action between sectors and broad community participation (Section 6.2).

Declarations and statements of intent are not substitutes for action by governments. WHO has identified various practical steps that may assist health ministries as they seek to work with other ministries to realize the benefits of an intersectoral approach (Section 6.2).
### Table 6.1. Intersectoral action in health: the evolution of an idea

<table>
<thead>
<tr>
<th><strong>Alma Ata Declaration (1978)</strong> (Section 6.1)</th>
<th><strong>Ottawa Charter for Health Promotion (1986)</strong> (Box 6.1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intersectoral action was recognized as a key to improving primary health care, through coordinated action across a range of sectors, including animal husbandry, food, industry, education, public works and communications.</td>
<td>Intersectoral action is fundamental to reducing inequalities in health status within the population. Health should be “on the agenda of policy-makers in all sectors and at all levels, directing them to be aware of the health consequences of their actions and to accept their responsibilities for health”.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WHO Commission on the Social Determinants of Health (2008)</strong> (Box 6.2)</th>
<th><strong>Adelaide Statement on Health in All Policies (2010)</strong> (Box 6.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disparities in health between rich and poor countries, and between rich and poor people within the same country, are fundamentally linked to disparities in power and income, goods and services. In turn, these factors lead to disparities in living and working conditions; the quality of the surrounding natural environment; and access to health-care services, education and leisure. “[The] unequal distribution of health-damaging experiences is not in any sense a ‘natural’ phenomenon but is the result of a toxic combination of poor social policies and programmes, unfair economic arrangements and bad politics” (13).</td>
<td>Governments can design successful approaches to intersectoral action on health by setting shared goals across government sectors, creating a clear mandate for intersectoral action, creating systematic processes for interactions across ministries and sectors, and ensuring transparency and accountability. Successful tools and instruments for these approaches include interministerial committees, integrated budgeting, health impact assessments and legislative frameworks.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>World Conference on the Social Determinants of Health (2011)</strong> (Section 6.1)</th>
<th><strong>6.3 Case studies of governance reforms supporting intersectoral action on health</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intersectoral engagement and action on health needs to be institutionalized and integrated at all levels, from UN agencies to local communities, and requires “a long-lasting sustainable process rather than a single event or programme” (14).</td>
<td>Case studies in the full report highlight ways in which intersectoral structures and processes have been used to advance health in different areas.</td>
</tr>
</tbody>
</table>

#### (a) Disease prevention and health promotion

In Mexico, a National Council for the Prevention and Control of Chronic, Noncommunicable Diseases was established by presidential decree. The Council links the health ministry with other sectors such as finance, agriculture, education and trade (Section 6.3). In the United States of America (USA), the National Prevention, Health Promotion and Public Health Council was established by the executive order of the President. Comprising the heads of 20 federal government agencies, the Council is supported by an advisory group of experts appointed by the President (Section 6.3).

#### (b) Promoting health equity and reducing health inequalities

In the United Kingdom in the early 2000s, the government adopted a series of national health targets to reduce inequalities in infant mortality and life expectancy at birth, and to reduce the gap between the most deprived local area authorities and the population as a whole. As part of the strategy, local government authorities were invited to review local challenges in collaboration with other stakeholders, and to agree on outcome-focused targets for local performance. These targets covered a range of areas in addition to national health inequality, and those authorities that met their targets received a reward grant (Section 6.3).

#### (c) Improving food and nutritional security in Brazil

Brazil introduced comprehensive intersectoral governance reforms to reduce hunger and improve nutritional security through the Fome Zero (Zero Hunger) initiative. Reforms included establishment of the National Council of Food and Nutrition Security (CONSEA), with delegates drawn from ministries associated with food and nutritional security, nongovernmental organizations (NGOs), social movements, and professional and religious organizations. CONSEA’s role includes convening the National Conference on Food and Nutrition Security every 4 years, which proposes and prioritizes policies and guidelines that form the foundation of the National System for Food and Nutrition Security (Section 6.3).
Part III: Priorities for public health law reform

Chapter 7: Achieving universal access to quality health services

Universal health coverage (UHC) has emerged as a unifying concept and goal for governments as they seek to strengthen their health systems and meet their obligations under the right to health. UHC is the goal of ensuring that all members of the population have access to promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality to be effective, without being exposed to financial hardship. UHC has been included as a specific target in SDG 3. In this chapter, Section 7.1 discusses the concept and scope of UHC, and Section 7.2 outlines the various legislative frameworks that are needed to support UHC.

7.1 The concept and scope of universal health coverage

Making progress towards UHC requires governments to strengthen those building blocks of the health system that make it possible to deliver services of high quality (shown in Fig. 1.2, in Chapter 1). Health systems are complex, and it is necessary to make progress with each of the building blocks to make progress on the overall goal of UHC (Table 7.1).

In different ways, each building block is directed towards making progress along the three axes of the UHC cube (shown in Fig. 1.3, in Chapter 1). UHC requires governments to expand the range and volume of priority health services (services axis), expand the number of people covered by a funding mechanism created from pooled funds (population axis) and reduce the proportion of health costs that impose direct costs on individuals and families (cost axis).

7.2 Legislative frameworks supporting the provision of health services

Legal frameworks are an essential part of an effective health system. Although laws and regulatory structures are not always visible, they are critical for clarifying roles, powers and responsibilities. Countries will take different pathways towards UHC, and priorities for law reform are likely to emerge incrementally as countries identify particular problems with the performance of their health systems and seek to remedy them. However, there are common regulatory issues that governments will need to consider, as discussed in the rest of this section.

(a) Membership, coverage and entitlements

Governments scaling up health insurance systems may wish to formally recognize the right of members of the population to access a defined set of benefits or services. While the government does not need to be the sole provider of all health services, it does need to pursue the intermediate objectives that will advance progress towards UHC. Governments may strengthen the implementation of this right (and the quality of the health services provided) by creating a formal complaints scheme for those who are not treated in accordance with their entitlements under the scheme. Such schemes should include complaints based on discrimination.
(b) Financing of health services

In establishing financing systems for health services, governments should avoid two main risks:

- the risk of catastrophic expenditure (leading to impoverishment), caused by the need for large out-of-pocket payments for medical services when a person falls ill; and
- the risk that even modest user fees may dampen demand and create barriers to access for the poorest members of the population.

To mitigate these risks, governments can raise funds for expanded coverage through compulsory pre-payment mechanisms (e.g. taxation or compulsory insurance contributions) and can exempt from contributions those who cannot afford to contribute at any level. For example, under Rwanda’s community-based health insurance scheme, the government currently pays premiums for the 25% of the population classified as vulnerable (Section 7.2).

Legal regulation of the financing of health services includes the regulation of revenue collection, the funding pools that are used to pay for health services, and the purchasing of health services provided to covered populations. WHO has recommended that governments consider new ways of increasing their revenues; for example, by imposing or increasing excise taxes on tobacco and alcoholic beverages, sugary drinks, airline tickets or currency transactions.

Governments may regulate funding pools to ensure capital adequacy and impose controls over the investment of funds. They may also impose requirements to report to the central government, and governance requirements on the health insurance entities that administer insurance schemes based on pooled funds. Private health insurance schemes often coexist with public schemes that governments use to scale up coverage. In the case of private insurers, governments typically regulate various matters such as registration and prudential requirements, competition, advertising and premiums. Governments may also consider performance-based financing as a way of improving the volume or quality of services provided (Box 7.1).

(c) Health services and health service providers

The services axis of the UHC cube requires governments to achieve greater population coverage by expanding the range and the capacity or volume of services provided in the benefits package. WHO advises governments moving towards UHC to emphasize primary care, taking into consideration existing health inequalities. Robust primary-health-care systems are associated with reduced morbidity and premature mortality, and lower costs.

The health workforce is crucial in scaling up the coverage of health services. Legislative frameworks not only regulate the purchasing of services and the remuneration of health-care providers, they also have important gateway functions (e.g. licensing health-care providers to practise their profession within the jurisdiction, and accrediting health service providers under the health insurance scheme). Governments may also establish quality agencies to support the improvement of quality standards and governance processes.

Formal recognition of new professional categories and roles may be required as countries scale up the training and education of the health workforce and adapt to the changing burden of disease. For example, Tonga now has nurses who specialize in the prevention, detection and management of NCDs (Section 7.2).

By imposing licensing requirements on the practice of medicine and other health professions, governments can protect the public from unskilled and poorly skilled individuals who claim the right to provide medical services. Some countries have national councils that oversee registration, continuing professional education and professional conduct of health professions; an example is South Africa’s legal requirements for the practice of medicine (Box 7.3). Legislation can also create various offences for inappropriate medical practice, such as using unapproved medicines, carrying out experimental treatment without consent, and soliciting money and gifts from patients. For example, China has laws that regulate registration of medical practitioners (Section 7.2).

Governments may require accredited health-care providers to contribute to compensation schemes for individuals who are injured through medical negligence or substandard care, or who are victims of criminal offences committed by health professionals. Licensing requirements for health professionals should be sufficiently flexible to permit the delivery of emergency health services by authorized personnel (including foreign health professionals.
contracted to international agencies or accredited NGOs) following a natural disaster or public health emergency. Governments may also impose licensing requirements on health-care institutions; for example, in Argentina an NGO provides voluntary accreditation to public and private hospitals \(\text{(Section 7.2)}\).

\(\text{(d) Governing institutions}\)

As countries scale up towards UHC, they need to establish governing institutions as part of the law reform process. Examples of such institutions are a national health insurance authority and a medicines regulation authority (the functions of which are sometimes merged within a single institution).

A national health insurance authority charged with improving population coverage may, for example, register members; collect health insurance contributions; manage pooled funds; accredit, contract and reimburse health service providers; and comply with government reporting requirements. A medicines regulation authority may assess and authorize the entry of medicines into the country (drug registration); monitor safety and effectiveness; regulate domestic manufacturing, importation and distribution of drugs; and regulate pharmaceutical advertising. To undertake these functions, regulatory authorities commonly perform more specific functions set out in legislation \(\text{(Box 7.4)}\). The full report contains a case study of how legislation governing Ghana’s national health insurance scheme has helped that country advance towards UHC \(\text{(Section 7.3)}\).
Chapter 8: Clean water, sanitation and vector control

Safe, clean drinking-water and sanitation facilities (covered in Section 8.1) are essential to the enjoyment of life and all human rights, including the right to health. This is reflected in SDG 6, which includes several targets for improvements in water and sanitation. Water and sanitation laws are also fundamental components of a modern public health system. Vector control measures (covered in Section 8.2) are also critical for reducing the transmission of disease and for the realization of the right to health. SDG 3 contains specific indicators relating to reducing vector-related diseases. Climate change is expected to affect both sanitation and hygiene and vector control. It is likely to increase the risk of contaminated water and waterborne diseases (through increased droughts and rainfall), and to have direct and indirect impacts on vector-borne diseases, including changes in the distribution of vector-habitable areas (15).

8.1 Sanitation and hygiene

(a) Clean water supplies

Public health laws for clean water should address how water is managed. Water management laws may impose general duties on local governments and town councils to provide, protect and conserve sources of clean drinking-water. These laws will require supporting powers; for example, the power to enter and acquire land, purchase water rights, construct reservoirs and water storage tanks, test water supplies, and enter into contracts for the supply of water. In settings with financial and water-resource constraints, governments may use laws to encourage point-of-use water treatment and safe storage. An example is Belize, where domestic laws regulate the quality of drinking-water (Box 8.3).

To protect against human rights violations by third parties, water management and sanitation laws should include duties on landowners and those occupying premises to ensure adequate drainage of waste and flood water, to dispose of domestic waste appropriately, and to not pollute or contaminate sources of drinking-water and water catchment areas.

Imposing user fees may help to conserve scarce water supplies. However, the privatization of water provision services raises human rights concerns, and should be accompanied by a closely monitored strategy to safeguard access by those who are most disadvantaged. Governments may legislate to prohibit the disconnection of water services to private dwellings, or to allow user fees only for water use that exceeds basic needs. For example, in the United Kingdom, domestic laws prohibit the disconnection of water supplies and the use of limiting devices for non-payment of charges (Section 2.3).

To plan for future needs, public health laws should authorize governments to collect and analyse data on water resources, take samples, monitor quality, and install and remove monitoring equipment. This is the case in Australia’s Northern Territory, where domestic laws authorize the monitoring and investigation of water supplies (Box 8.4).
(b) Sanitation facilities

Laws regulating the provision and maintenance of sanitation systems are critical to public health, and minimizing faecal–oral transmission of disease. The WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation has published guidance on the range of facilities that provide a basic level of health protection (16).

Public health laws may set out the kinds of premises that must have water supplies and functioning sanitation facilities connected to a sewerage system or septic tank. They may also authorize health and sanitation inspectors to direct an owner or occupier of premises to:

- install sanitary facilities;
- dispose of sewerage and contaminated waste; and
- take such actions as are necessary to prevent a wastewater system from causing a risk to public health.

Thus, Australia’s Northern Territory has domestic laws that empower public health officers to give directions in relation to wastewater systems (Box 8.5).

Public health laws may require local and city governments to install public toilets, washing facilities and associated septic tanks or sewerage systems in public areas where members of the public travel and congregate (e.g. train and bus stations, sporting facilities and petrol stations). Toilets and washing facilities require regular maintenance and cleaning to ensure they do not fall into disrepair, and they must be secure, so that members of the public, particularly women, feel safe while using them.

Sanitation reforms need to take gender into account. Women and girls should have access to clean water and sanitation facilities that protect their health, safety and privacy. For example, in Belize, the Public Health Act provides for sanitation facilities for both sexes (Box 8.6). Laws should empower health inspectors to test water quality, and to control or regulate any activities that are likely to contaminate public water supplies (including disposal of waste and refuse). Subject to constitutional considerations, governments should ensure that the health ministry retains oversight and ultimate responsibility for the provision of clean drinking-water.

8.2 Vector control

This section of the full report focuses on mosquito and rodent control, although vectors such as cockroaches, sandflies and tsetse flies may also pose a health threat in some regions.

(a) Malaria and other mosquito-borne diseases

Vector-borne diseases, such as malaria, are preventable. Nevertheless, in 2015 malaria caused more than 435,000 deaths, mostly among African children (Box 8.7). WHO’s global strategy for malaria encourages countries to move towards malaria-free status by implementing a strategy based on three pillars (17):

- universal access to measures for the prevention, diagnosis and treatment of malaria;
- strengthening epidemiological surveillance of malaria and banning over-the-counter antimalarial medicines; and
- upgrading surveillance within all national and subnational malaria strategies, and investing in health information systems.

To support national strategies based on these pillars, public health laws should mandate vector surveillance and authorize public health authorities to take whatever actions are necessary to implement evidence-based control strategies. Two key malaria control interventions in high-burden areas are providing long-lasting insecticide-treated mosquito nets, and indoor residual spraying. To ensure effective malaria treatments, governments should prohibit the marketing, sale and use of oral, artemisinin-based monotherapies, and promote the use of artemisinin-based combination therapy.
For mosquito-borne diseases generally, public health laws should provide a clear mandate for the development of national strategies, and for locally led surveillance, monitoring and enforcement of regulatory requirements. Strategies include ensuring that water-storage containers are covered and cleaned regularly, large waste items that can collect water are disposed of and hollow building materials are avoided. The safe use of pesticides should be incorporated into national public health laws or regulations.

(b) Rodent control

Rodents can transmit disease, particularly in urban or overcrowded areas. Rodent control measures include improving environmental sanitation procedures; securing the storage of food, grain and animal feed; and removing household rubbish and waste.

Public health laws can support vector control by creating statutory offences for causing or permitting a nuisance that applies to owners or occupiers of premises. Typically, public health laws authorize local authorities to enter and inspect premises, and to take actions themselves to abate a nuisance when an owner or occupier fails to do so. Jamaica’s Public Health (Nuisance) Regulations 1995 are an example of using regulations for vector control (Box 8.9).
Chapter 9: Monitoring, surveillance, and investigation of health threats

Monitoring, surveillance and investigation of threats to public health are vital capabilities for an effective, well-functioning health system. The IHR (2005) require countries to maintain an integrated, national system for public health surveillance and response, and set out the core capabilities countries are expected to achieve. Public health laws support effective surveillance systems by identifying the diseases and conditions that must be reported to authorities, and by designating the persons responsible for reporting. This chapter describes different types of surveillance (Sections 9.1–9.4) and discusses the development of national surveillance capabilities (Section 9.5).

9.1 Clinical and laboratory-based surveillance

The systematic monitoring of serious infectious diseases and other conditions is typically achieved through notifiable diseases legislation based on clinical observation and laboratory confirmation. Clinical surveillance can provide early warning of disease outbreaks that require rapid response. It involves health-care providers diagnosing diseases based on signs and symptoms, with or without laboratory-based tests. Public health laws typically establish lists of “notifiable diseases” and other conditions – including risk factors for NCDs – that health-care providers, hospitals and (sometimes) laboratories are required to report to local, regional or national public health authorities. For example, New York City in the USA has expanded reporting obligations for notifiable diseases to include a risk factor for diabetes (Box 9.1).

Clinical and laboratory-based surveillance systems also provide the basis for the systematic collection of vital statistics including births, deaths and causes of death. Public health laws may require the reporting of data to particular hospitals or research centres that lead national surveillance and research efforts, or that host specific disease registers. Clinical and laboratory-based surveillance systems are passive systems; hence, efforts to improve access to health-care services and achieve UHC will help to improve clinical surveillance capacities.

In some low-resource settings, clinical or laboratory-based surveillance may not be feasible. In such settings, public health laws may impose reporting requirements for suspected cases of epidemic diseases on a wider range of people, including non-medical personal. Suspected cases identified in this way must be treated with respect and protected from discrimination, with diagnosis confirmed by qualified health workers at the earliest opportunity. An example is Zimbabwe’s domestic laws that require medical and non-medical personnel to report possible epidemic diseases (Box 9.2).

A significant degree of stigma may attach to some diseases, such as HIV, sexually transmitted infections and diabetes. Notifiable diseases legislation should require the protection of personal information, and clearly define any exceptions. Concerns about discrimination and breach of privacy may be addressed by requiring certain diseases to be reported on an anonymous or de-identified basis.

9.2 Sentinel surveillance

Sentinel surveillance aims to provide early warning of disease outbreaks, rates of specified infectious diseases or other health conditions. Although these are passive systems, carefully chosen sentinel sites may provide early warning of disease outbreaks of national and international significance.

9.3 Community-based surveillance

Community-based surveillance uses non-medical personnel to identify potential outbreaks. Laws or strategies involving community-based surveillance need to strike an appropriate balance between sensitivity (identifying all important events) and sustainability (maintaining the reporting and response capability without undermining other public health functions). Public health laws should ensure that teams responding to community reports have the appropriate powers to respond and implement health measures.
9.4 Comprehensive surveillance systems

Public health laws establishing surveillance systems may use a combination of surveillance strategies to overcome the limitations of each strategy and to provide a clearer picture of the health burden, as seen with Argentina’s different strategies for tracking and investigating notifiable events (Box 9.3). The IHR (2005) require countries to meet “core capacity requirements” for surveillance and response at local, intermediate and national levels, as set out in Annex 1 of the IHR (Box 9.4).

9.5 Developing integrated national capabilities for surveillance and response

Countries may use legislation or regulations to establish or improve a comprehensive public health surveillance and response system. In federal systems, tools for achieving an integrated system include intergovernmental agreements, federal grants and conditional funding agreements. These tools are particularly useful where public health surveillance is coordinated at the regional (state or provincial) level.

The cases of disease or harm captured by effective surveillance systems may reflect a variety of public health hazards. Legislation covering public health risks (e.g. infectious diseases, food safety, chemical accidents and animal health issues affecting human health) may be administered by different ministries and at different levels of government. Hence, countries may find it useful to establish an intersectoral committee to consider whether existing legislation, regulations and other instruments are adequate to ensure a rapid and effective public health response, and to fulfil the obligations set out in the IHR (2005). For example, Columbia’s public health surveillance system was established via a presidential decree that sets out the functions of responsible agencies (Box 9.5).
Chapter 10: Controlling the spread of infectious diseases

Minimizing the transmission of infectious diseases is a core function of public health law. Law can contribute to the prevention of infectious diseases in various ways; for example, by improving access to vaccinations and condoms, and by facilitating screening, counselling and education of those at risk of infection. Law also has a reactive role, supporting access to treatment, and authorizing public health authorities to limit contact with infectious individuals and to exercise emergency powers in response to disease outbreaks. This chapter discusses how ethical principles can be included in such legislation (Section 10.1), and how public health law can be used to prevent or reduce the spread of infectious diseases (Sections 10.2–10.4).

10.1 Building ethical principles into infectious disease legislation

Laws governing the control and prevention of infectious diseases may involve limitations on human rights such as freedom of movement, control over one’s body, privacy and property rights. Public health ethics requires the exercise of such powers to be based on the five ethical principles shown in (Fig. 10.1).

Fig. 10.1. Building ethical principles into infectious disease legislation affecting personal rights and freedoms

10.2 Preventing the transmission of infectious diseases

(a) Immunization

Immunization is a successful and cost-effective public health strategy that, every year, saves millions of lives and prevents serious disability from vaccine-preventable diseases such as diphtheria, rubella, mumps, measles, human papillomavirus, polio and hepatitis B. Governments can support vaccination coverage by ensuring that vaccinations are free or affordable, by ensuring that all children are vaccinated (with limited exceptions for medical or religious reasons), and by documenting vaccination rates and their impact on health outcomes. For example, in Belize, the Public Health Act sets out the requirements for child vaccination (Box 10.1).
(b) Screening

Screening individuals to determine whether they have been infected with or exposed to an infectious disease is a core public health strategy. Early treatment has important public health benefits; for example, people receiving treatment for TB and HIV infection are less likely to transmit the infection to others. Routine, voluntary HIV testing facilitates early access to prevention, care and treatment services.

Health laws can improve the success of voluntary screening programmes by including counselling requirements, ensuring the confidentiality of test results, and protecting individuals diagnosed with particular diseases from discrimination. The law should protect the confidentiality of a person’s HIV status, authorizing disclosure to third parties only in limited circumstances where a third party is at significant risk of HIV transmission and where other statutory preconditions are met. In East Africa, regional laws incorporate human rights principles into HIV prevention and management policies (Box 10.2). They also cover permissible disclosure of HIV test results, post-test counselling and disclosure of HIV status (Box 10.3).

(c) Criminal laws and mandatory disclosure laws

Governments should carefully consider the appropriate role of criminal law when amending laws to prevent the transmission of infectious and communicable diseases. For example, criminal penalties for transmission of HIV may create disincentives for individuals to come forward for HIV testing and treatment, or may provide the pretext for harassment of and violence against vulnerable groups (18). Encouraging personal responsibility and self-protection is critical, especially in countries where rates of HIV infection are high.

10.3 Compulsory treatment orders

Public health laws should authorize compulsory treatment only in circumstances where an individual is unable or unwilling to consent to treatment, and where the person’s behaviour creates a significant risk of transmission of a serious disease. Compulsory treatment orders should restrict individual liberty only to the extent necessary to effectively reduce risks to public health. An example is South African legislation that sets out permissible circumstances for compulsory treatment (Section 10.4).

10.4 Limiting contact with infectious persons

Public health laws may authorize the isolation of individuals and groups who may have been exposed to an infectious disease. Compulsory orders should be used as a last resort and should be minimally restrictive (see Fig. 10.1 above). Laws may also authorize the closure of businesses and premises, and the confiscation of property. Where this causes more than trivial economic loss, public health laws should provide for fair compensation. The exercise of public health powers must be based on public health considerations, and must be without discrimination on grounds of race, gender, tribal background or other inappropriate criteria. Also, laws should include procedural safeguards, such as giving individuals who are subject to a quarantine or isolation order the right to seek review by a court within a reasonable time. Model public health legislation drafted in the USA provides an example of quarantine and isolation laws that incorporate human rights protections (Box 10.4).
Chapter 11: Public health emergencies

Disaster management is a core function of public health law. Public health emergencies can arise from various causes, such as outbreaks of contagious, life-threatening disease; natural disasters; chemical contamination of the environment; and the release of radiation. In emergencies, large numbers of people may require medical attention, health-care systems may be over-stretched and public order may be threatened. National laws and emergency plans must take account of international obligations for the management of public health emergencies, including the IHR (2005). This chapter discusses management of emergencies at international and national levels (Sections 11.1 and 11.2, respectively), the workforce involved (Section 11.3), control of areas that may pose a risk to health (Section 11.4) and maintenance of health-care services during an emergency (Section 11.5).

11.1 International management of public health emergencies

(a) The International health regulations (2005)

The purpose of the IHR (2005) (9) is to prevent and manage the public health risks arising from the international spread of disease while avoiding “unnecessary interference with international traffic and trade”. WHO provides resources to help countries to use national legislation to implement and prioritize their obligations under the IHR (Box 11.1). Priority areas for implementation of the IHR include:

- **national IHR focal points** – countries are required to establish a national IHR focal point that is accessible at all time with communications with WHO;
- **reporting obligations** – each country must develop the capacity to assess health risks within its territory, and must notify WHO of all events that may constitute a public health emergency of international concern (Box 11.2);
- **surveillance and response capabilities** – countries must strengthen and maintain their surveillance and response capabilities at local, intermediate and national levels, and locations (designated airports, ports and ground crossings);
- **temporary recommendations** – the WHO Director General may make non-binding, temporary recommendations to countries in whose territory a public health emergency of international concern has arisen;
- **human rights protections** – the IHR require countries to exercise their health powers in a non-discriminatory way, with full respect for dignity, human rights and fundamental freedoms (Box 11.3).

(b) Pandemic Influenza Preparedness Framework

The Pandemic Influenza Preparedness (PIP) Framework provides guidance on the rapid sharing of influenza viruses with human pandemic potential. The PIP Framework is part of the WHO-coordinated Global Influenza Surveillance and Response System. It includes a benefit-sharing system that gives commercial entities access to PIP biological materials in exchange for providing assistance to developing countries (e.g. donating pandemic influenza vaccines and antiviral drugs) and capacity-building (Box 11.4).

(c) Strengthening WHO’s emergency response capacity

National governments bear the primary responsibility for developing their domestic health systems and establishing an effective health emergency workforce. To support national efforts, WHO is expanding its partnerships with other UN agencies, funds and programmes; it is also improving international coordination of responses, as leader of the Inter-Agency Standing Committee’s Global Health Cluster of international humanitarian health organizations. For example, WHO is developing a process for deploying a global health emergency workforce, and a contingency fund to support the organization’s emergency response capacity (19). WHO’s health emergencies programme is now overseen by the Independent Oversight and Advisory Committee.1

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1 http://www.who.int/about/who_reform/emergency-capacities/oversight-committee/en/
(d) Nagoya Protocol: Access to pathogens and benefit-sharing

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) is a supplementary agreement to the Convention on Biological Diversity (20). Under this protocol, the user of a genetic resource must obtain “prior informed consent” from the provider of the resource on “mutually agreed terms” (e.g. an agreement to share the benefits arising from the use of the resource). In cases where a specialized instrument exists and is consistent with the objectives of the Nagoya Protocol, Parties to that instrument are not required to enter into individual negotiations for access and benefit-sharing for the relevant genetic resource. In 2017, the WHO PIP Framework Review Group concluded that the PIP Framework is a multilateral access and benefit-sharing instrument that is consistent with the objectives of the Nagoya Protocol (21). However, the framework has not yet been recognized as a specialized instrument for the Nagoya Protocol.

In implementing the Nagoya Protocol domestically, governments should ensure coordination between ministries (health, environment and other ministries, as relevant), to ensure that implementation is consistent. The European Union has adopted binding regulations that provide for access and benefit-sharing for genetic resources and traditional knowledge over which States exercise sovereign rights and which fall outside the procedures established by the PIP Framework (and by other specialized instruments for benefit-sharing that are consistent with the Nagoya Protocol) (22).

11.2 National public health emergencies

National authorities should develop a national emergency plan that sets out a clear chain of command and takes into account all relevant levels of government. The legal authority and roles of key officials during an emergency should be defined in legislation, including the authority to take such actions as are reasonably required to deal with a serious risk to public health. Public health laws should also establish clear triggers for the application of emergency powers, with clear time limits. Disaster management laws should enable individuals to seek an independent review of decisions that restrict their fundamental rights.

11.3 Emergency health workforce

To ensure an adequate health workforce during an emergency, public health laws may grant temporary practice licences to health professionals who are inactive, retired or licensed in other jurisdictions. For example, the USA has model legislation for maintaining the health workforce during a public health emergency (Box 11.5).

11.4 Control of premises, facilities and supplies

A public health emergency may create dangerous or contaminated areas that present a risk to health. Public health laws may authorize authorities to compel the evacuation and closure of any premises or public area, and include the power to enter premises and private property to dispose of infectious waste or contaminated material. In some circumstances, public health laws authorize government authorities to take control of premises, facilities and supplies (including health facilities and medical supplies), provided that reasonable compensation is paid. National emergency plans should establish a national stockpile of essential medicines, vaccines and medical supplies to meet emergency needs. For example, model legislation in the USA authorizes the emergency use of facilities and pharmaceuticals (Box 11.6).

11.5 Health-care services during a public health emergency

To effectively deal with a public health emergency, public health laws should authorize officials to:

- take such actions as are reasonably necessary to investigate the causes, sources and means of transmission of disease agents;
- authorize diagnostic testing and compulsory medical treatment; and
- make orders for isolation or quarantine.
Any laws that directly restrict the freedom of individuals during a disaster or public health emergency should comply with the human rights protections set out in the IHR (2005) (Box 11.3), with the UN’s Siracusa Principles (Box 11.7), and with any domestic human rights regime that protects fundamental rights.

During an emergency, women and adolescent girls, in particular, may be at increased risk of sexual violence and in urgent need of emergency contraception, emergency obstetric care or treatment for sexually transmissible infections (23-25).
Chapter 12: Enabling environments to support healthy and safe behaviours

NCDs kill more than 41 million people every year (26), with more than three quarters of these deaths occurring in low- and middle-income countries. Injuries and violence account for a further 5 million deaths. The most prominent NCDs (CVD, cancer, diabetes and chronic respiratory diseases) are linked to a cluster of behavioural risk factors such as tobacco use, harmful use of alcohol, unhealthy diets and lack of physical activity.

Where they have the information and resources to do so, individuals share responsibility for the choices they make about their health and lifestyle. However, States have an overriding responsibility to seek to realize the right to health of the populations they represent. Public health laws can significantly reduce the occurrence of injuries and the preventable component of NCDs by supporting individuals and populations to make healthier choices and engage in safe behaviours, and by creating safer environments. This chapter considers how laws can enable behaviours that reduce risks for NCDs (Section 12.1), discourage behaviours that contribute to injuries (Section 12.2) and control the harmful use of alcohol (Section 12.3).

12.1 Enabling behaviours that reduce risks for NCDs

(a) Global targets for reducing mortality from NCDs

Members of the World Health Assembly have committed to reducing premature mortality from NCDs and to a set of supporting targets covering key risk factors, as shown in (Fig. 12.1).

Fig. 12.1. WHO’s comprehensive global monitoring framework, including nine voluntary global targets for prevention and control of NCDs (27)

Overall target:
- By 2025, a 25% relative reduction from 2010 levels in mortality from CVD, cancer, diabetes and chronic respiratory diseases in persons aged 30–70 years.

Eight supporting targets:
- 10% relative reduction in harmful use of alcohol;
- 10% relative reduction in prevalence of physical inactivity;
- 30% relative reduction in mean average population salt intake;
- 30% relative reduction in prevalence of tobacco use (persons aged 15+ years);
- 25% relative reduction in raised blood pressure;
- 0% increase in diabetes and obesity;
- 50% coverage for drug therapy and counselling for those at risk for CVD; and
- 80% coverage of affordable technologies and essential medicines for treating NCDs in both public and private facilities.

The SDGs also include a specific target for NCDs.

Goal 3: Ensure healthy lives and promote well-being for all at all ages

SDG 3, Target 4: By 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well being
(b) Implementing “best buys” for NCDs

The WHO NCD Global Action Plan 2013–2020 identifies a suite of policy options to assist countries in meeting global targets. This menu of policy options (in Appendix 3 of the Action Plan) was updated and endorsed by the World Health Assembly in 2017 (27). Several of these options are “best buys” (i.e. highly cost effective and affordable in low- and middle-income countries). Many of these policies for reducing risk factors for NCDs will require legal and regulatory controls for effective implementation (Table 12.1).

Some of the legally oriented best buys are shown in Box 12.1. Efforts to strengthen health systems will also enable countries to provide additional best buys for CVD, diabetes and cancer. These include drug therapy for those with diabetes mellitus and for those at moderate to high risk of having a heart attack or stroke, vaccination against human papillomavirus in girls, and implementation of strategies for cervical cancer screening.

<table>
<thead>
<tr>
<th>Box 12.1</th>
<th>Highly cost effective and affordable legal measures to reduce risk factors for NCDs</th>
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<tbody>
<tr>
<td><strong>Tobacco:</strong></td>
<td></td>
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<tr>
<td>■ Increase excise taxes and prices on tobacco products.</td>
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<tr>
<td>■ Implement plain tobacco packaging and large graphic health warnings on all tobacco packages.</td>
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<tr>
<td>■ Enact and enforce comprehensive bans on tobacco advertising, promotion and sponsorship.</td>
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<tr>
<td>■ Eliminate exposure to second-hand tobacco smoke in all indoor workplaces, public places and public transport.</td>
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<tr>
<td><strong>Alcohol:</strong></td>
<td></td>
</tr>
<tr>
<td>■ Increase excise taxes on alcoholic beverages.</td>
<td></td>
</tr>
<tr>
<td>■ Enact and enforce:</td>
<td></td>
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<tr>
<td>- bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media); and</td>
<td></td>
</tr>
<tr>
<td>- restrictions on the physical availability of retailed alcohol (via reduced hours of sale).</td>
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<tr>
<td><strong>Diet:</strong></td>
<td></td>
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<tr>
<td>■ reduce salt intake by:</td>
<td></td>
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<tr>
<td>- reformulating food products to contain less salt, and by setting target levels for the amount of salt in foods and meals;</td>
<td></td>
</tr>
<tr>
<td>- establishing a supportive environment for reduced-salt options to be provided in public institutions including hospitals, schools, workplaces and nursing homes; and</td>
<td></td>
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<tr>
<td>- implementing front-of-pack labelling.</td>
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<tr>
<td><strong>Cancer:</strong></td>
<td></td>
</tr>
<tr>
<td>■ Vaccination against human papillomavirus (two doses) for girls aged 9–13 years.</td>
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</tbody>
</table>

To ensure that these measures are implemented, with adequate budgets for monitoring and enforcement, high-level leadership is required from presidents, prime ministers, health ministers and other senior cabinet ministers. The involvement of nonhealth ministries is also vital, since many of the most important interventions to address risk factors for NCDs will be implemented outside the health sector.

(c) Engaging with the private sector

When implementing effective measures to prevent and control NCDs, governments can expect resistance from manufacturers and retailers of tobacco, alcohol and unhealthy foods, and their allies. The tobacco and alcohol industries should have no role in the formation of tobacco and alcohol control laws and policies (28, 29).

Some countries have used voluntary partnerships between government, retailers, public health stakeholders and food manufacturers to reformulate food products and to reduce levels of salt, saturated fat and sugar over time. However, where such partnerships are ineffective in achieving national targets, governments may consider strengthening their level of oversight of the industry, and implementing a co-regulatory approach. Several countries have implemented mandatory standards for salt levels in particular categories of food; others have introduced substantial taxes on sugary drinks (Section 16.2 16.3 16.6 16.7).
(d) Supporting health promotion

Governments have a responsibility to disseminate accurate information about health risks to their populations and to promote healthy lifestyles. Independent health promotion agencies, established by legislation, are one way to provide national leadership in health promotion. For example, in 2007, Tonga passed legislation to establish an independent national health promotion body that works with communities, NGOs and government departments to promote healthy lifestyle changes throughout the country (Section 12.1).

Access to health information also forms an important element of the right to health’s AAAQ framework. For example, the Constitutional Court of Colombia has affirmed that freedom of information, as protected in the Constitution, encompasses the right to receive facts, ideas and opinions through the media, including information about the health effects of sugary drinks (3).

12.2 Discouraging behaviour that contributes to injuries

Injuries claim nearly 5 million lives each year, but are a neglected global health priority. Nearly 90% of fatal injuries occur in low- and middle-income countries (11). More than one quarter of these deaths are caused by road traffic injuries. A target for road traffic accidents was included in SDG 3.

| Goal 3: Ensure healthy lives and promote well-being for all at all ages |
| SDG 3, Target 6: By 2020, halve the number of global deaths and injuries from road traffic accidents |

Countries should develop national strategies for preventing road traffic injuries, including designating a single agency with responsibilities for collaborating across ministries, the community and transport companies. Legislation can be important in reducing road traffic injuries; for example, by setting and enforcing speed limits on roads, regulating the licence system, implementing drink-driving countermeasures (e.g. random breath testing) and making it an offence to drive while intoxicated. Other legal measures include a graduated licence system for new and inexperienced drivers; offences for using hand-held devices while driving; and requirements for seat belts to be used by all occupants of motor vehicles, and for helmets to be worn on motorcycles and bicycles. For example, in Viet Nam, the introduction and enforcement of a national motorcycle helmet law increased helmet use up to 99%, avoiding many deaths and injuries from motor vehicle accidents (Box 12.2).

12.3 Controlling the harmful use of alcohol

WHO estimates that the harmful use of alcohol causes 3.3 million deaths every year (30). Harmful use of alcohol is a causal factor in over 200 disease and injury conditions, including liver cirrhosis, CVD, certain cancers, injuries from violence, road traffic injuries, alcohol dependence and fetal alcohol syndrome. Harmful levels of drinking may also affect the course of HIV/AIDS, and the incidence of communicable diseases such as TB (30). These health outcomes are determined largely by the volume of alcohol consumed on a particular occasion and the pattern of drinking over time.

WHO has identified various national policy options and interventions for countries to consider, several of which (as noted in Section 12.1) are highly cost effective and affordable in low- and middle-income countries (31).

Law is an important tool for regulating the commercial and public availability of alcohol. Examples include licensing retail sales, or regulating the location and number of retail premises authorized to sell alcohol; establishing a minimum age for the purchasing and consumption of alcohol; making illicit alcohol production an offence; and regulating the sale of alcohol to intoxicated persons. Increasing the price of alcoholic beverages is a particularly effective way to reduce the harmful use of alcohol; for example, by increasing taxation on alcoholic beverages and adjusting the rate of taxation regularly to account for changes in inflation and income level, restricting or banning price promotions or discount sales, or establishing minimum retail prices for alcohol.
Countries may impose restrictions on the marketing of alcoholic beverages, particularly to young people and adolescents. This may extend to a comprehensive ban on all alcohol marketing, promotion and sponsorship; restrictions on the time, place or content of alcohol advertising; and limits on sponsorship. To prevent the harmful use of alcohol, laws may also require alcohol products to clearly show the quantity of alcohol in a bottle or container, and warning labels about the harm related to alcohol, especially for pregnant and breastfeeding women.
Chapter 13: Tobacco control

This chapter discusses how laws can be used to control tobacco use globally (Section 13.1), through pricing, labelling and advertising (Sections 13.2–13.4) and by reducing exposure to second-hand tobacco smoke (Section 13.5). It also considers ways to resist industry interference in such legislation (Section 13.6).

13.1 Global tobacco control

There are currently around 1.3 billion smokers in the world, mostly living in low- and middle-income countries. Unless they quit, up to half of these people will die prematurely from tobacco-related diseases. Tobacco killed 100 million people during the 20th century, and currently causes more than 7 million deaths each year (32: p1682), about 10% of which are deaths among non-smokers that are attributable to exposure to second-hand tobacco smoke (32: p 1684).

(a) The Framework Convention on Tobacco Control

Tobacco use is an “industrially created epidemic” that is sustained by the activities of the global tobacco industry (33). The foundation for effective national tobacco control policies lies in comprehensive implementation of the WHO FCTC, which requires Parties to implement measures to reduce both the demand for, and the supply of, tobacco products. In many countries, significant law reform efforts are still needed in order to fully implement the provisions of the WHO FCTC. Table 13.1 shows how the law can be used to reduce the supply of and demand for tobacco (Box 13.1).

Table 13.1. Reducing death and disease by implementing the WHO Framework Convention on TobaccoControl

<table>
<thead>
<tr>
<th>Supply reduction provisions</th>
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</thead>
<tbody>
<tr>
<td>▪ Enact legislation to reduce illicit trade in tobacco (Article 15).</td>
</tr>
<tr>
<td>▪ Enact legislation or other measures to prevent sales of tobacco to and by minors (Article 16).</td>
</tr>
<tr>
<td>▪ Provide economically viable alternatives to working in tobacco (Article 17).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demand reduction provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Implement taxes and price policies to reduce consumption of tobacco (Article 6).</td>
</tr>
<tr>
<td>▪ Ban smoking in indoor workplaces, public transport and other public places (Article 8).</td>
</tr>
<tr>
<td>▪ Test and regulate tobacco product contents and emissions (Article 9).</td>
</tr>
<tr>
<td>▪ Require manufacturers and importers to disclose contents and emissions of tobacco products, and implement public disclosure of toxic constituents and emissions (Article 10).</td>
</tr>
<tr>
<td>▪ Prohibit false, misleading and deceptive labelling and advertising of tobacco products (Article 11.1(a)).</td>
</tr>
<tr>
<td>▪ Require clearly visible, rotating warnings about the harmful effects of tobacco use on tobacco packaging (Article 11.1(b)).</td>
</tr>
<tr>
<td>▪ Implement public education campaigns (Article 12).</td>
</tr>
<tr>
<td>▪ Where permitted by each country’s constitution, ban or restrict all tobacco advertising, promotion and sponsorship, including a comprehensive ban on cross-border advertising, promotion and sponsorship (Article 13).</td>
</tr>
<tr>
<td>▪ Promote cessation of tobacco consumption and treatment for tobacco dependence (Article 14).</td>
</tr>
</tbody>
</table>

The WHO MPOWER package, while not a substitute for the obligations countries have assumed under the WHO FCTC, may assist Parties to prioritize their actions towards full implementation. MPOWER prioritizes six areas:

- monitor tobacco use and prevention policies;
- protect from tobacco use;
- offer help to quit tobacco use;
- warn about the dangers of tobacco;
- enforce bans on tobacco advertising and sponsorship; and
- raise taxes on tobacco.

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2 See http://www.who.int/tobacco/mpower/en/
Turkey has achieved rapid reductions in smoking through political commitment and implementation of all six MPOWER priority areas, and the Russian Federation has shown leadership in tobacco control through legislation creating smoke-free environments and restricting tobacco advertising (Section 13.1).

(b) The Protocol to Eliminate Illicit Trade in Tobacco Products

The Protocol to Eliminate Illicit Trade in Tobacco Products aims to eliminate all forms of unlawful activity relating to the production, shipment, receipt, possession, distribution, sale or purchase of tobacco products. Once it enters into force, the Protocol could provide a comprehensive framework for national legislation to eliminate smuggled, counterfeit and illicit tobacco products (which increase the accessibility and affordability of tobacco, and undermine government revenues).

(c) World Trade Organization agreements and domestic tobacco control laws

The implementation of WHO FCTC obligations often takes place against the backdrop of the obligations countries have assumed as members of the World Trade Organization (WTO). WTO agreements that are potentially relevant to national tobacco control laws and policies include the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (the TBT Agreement), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Countries should ensure that trade and investment agreements do not unduly restrict their health sovereignty or unduly diminish their capacity to implement and enforce effective tobacco control measures.

Trade agreements seek to foster a predictable, competitive global marketplace that eliminates discriminatory practices and reduces unnecessary regulatory obstacles to international trade in goods and services, and to the global protection of intellectual property rights. These goals are not inherently opposed to the protection of public health; however, some aspects of trade agreements require particular scrutiny. For example, complaint mechanisms in trade agreements provide opportunities for national governments to challenge tobacco control laws in other countries, including import bans, labelling requirements and product regulation.

(d) Bilateral and regional investment agreements and domestic tobacco control laws

Trade and investment agreements cover a wide spectrum of agreement types. Investment agreements may give tobacco companies the right to make complaints against national governments for harm to the value of their investment in a host country (e.g. through investor–State dispute settlement rights). This is a particular risk for countries that lack the financial resources to defend complaints, or lack the human resources to provide accurate advice about the scope of global trade laws and investment agreements.

Recent challenges brought by tobacco companies under bilateral investment agreements illustrate how these agreements may be used as a weapon to resist implementation of the WHO FCTC and effective national tobacco control laws. For example, in 2010, a Philip Morris subsidiary brought a claim against Uruguay under a Switzerland–Uruguay bilateral investment treaty. The claim argued that Uruguay’s tobacco control laws (which restrict tobacco brands to a single presentation, and require health warnings to cover 80% of the front and back of the pack) reduced the value of their investment in Uruguay; this claim was dismissed in 2016.

13.2 Pricing and taxation

Tax and price measures are powerful tools for reducing affordability and demand for tobacco products. Uniformly high tobacco prices help to discourage initiation, encourage quitting and reduce the amount of tobacco consumed by those who do not quit. Countries can use tobacco excise tax increases, applied to all brands and forms of tobacco (imported or locally produced), to reduce the death and disease caused by tobacco use. An excise tax that comprises at least 70% of the retail price is a useful benchmark. Tobacco taxes may also generate revenues that governments can use to fund tobacco control, and other health or social development programmes. Linking the tobacco tax to inflation or increases in cost of living is an important strategy to prevent the impact of the tax diminishing over time. Thus, in Australia, the federal tobacco excise tax is indexed twice annually to take account of inflation and earnings growth (Section 13.2).

See http://www.who.int/fctc/protocol/about/en/
Chapter 13  Tobacco control

13.3 Labelling and packaging of tobacco products

Prominent health warnings on tobacco packages help to communicate the specific risks of tobacco use. Article 11(a) of the WHO FCTC requires Parties to implement laws to ensure that tobacco labelling is not false, misleading or deceptive. For example, the description of tobacco products as “light”, “mild” and “low tar” is misleading, and encourages the false belief that such products are less harmful than regular products.

Article 11(b) of the WHO FCTC requires that Parties implement measures to ensure that tobacco products and packages carry health warnings describing the harmful effects of tobacco use. Warnings must cover at least 30% and should cover more than 50% of the principal display area of each tobacco package.

The Conference of the Parties (COP) to the WHO FCTC has issued guidelines urging Parties to use colour pictorial warnings to emphasize text-based warnings, and to periodically rotate health warnings to ensure that they retain their impact (34). Parties are also recommended to adopt “plain tobacco packaging” measures that restrict the use of trademarks, logos, brand colours and images, other than the brand and product names in a standard colour and font (35). In 2011, Australia became the first country to pass tobacco plain packaging legislation, a move that has been effective in reducing the appeal of smoking and increasing thoughts about quitting (Section 13.4). In 2015, France, Ireland and the United Kingdom introduced plain packaging, as did Hungary and New Zealand in 2016, and Norway and Slovenia in 2017.

13.4 Advertising, promotion and sponsorship

Comprehensive bans on tobacco advertising can significantly reduce demand. Article 13 of the WHO FCTC requires Parties to implement a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship within 5 years, to the extent that this is possible under their national constitutions (Box 13.2). The COP to the WHO FCTC has issued guidelines to assist Parties in implementing this obligation (36). Such a ban reduces the influence of the tobacco industry over media, entertainment, cultural and sporting organizations, which would otherwise become proxies for the tobacco industry in resisting tobacco control laws and policies.

Smoking in films and interactive games, and the promotion of tobacco products through entertainment products has a powerful impact on young people. Parties may prohibit the depiction of tobacco brand images in entertainment, implement a classification or ratings system that takes account of tobacco use, and require the display of anti-tobacco advertisements at the beginning of any entertainment depicting tobacco products or use (Section 13.4). For example, India has regulations to counteract the depiction of tobacco use in films and television programmes (Box 13.3).

13.5 Second-hand tobacco smoke

Reducing exposure to second-hand tobacco smoke significantly reduces tobacco consumption and reduces the likelihood that young people will progress to established smoking. Article 8 of the WHO FCTC requires Parties to implement legislative, executive and administrative measures that provide protection from exposure to tobacco smoke in “indoor workplaces, all public transport, indoor public places and, as appropriate, other public spaces”; thus, Turkey, for example, has instituted a ban on indoor smoking (Section 13.5).

The COP to the WHO FCTC has issued detailed guidelines to assist Parties in passing national laws for effective measures to protect against second-hand tobacco smoke, and protect fundamental human rights and freedoms (37). Governments may also consider extending smoke-free laws to smokeless forms of tobacco and to electronic cigarettes in countries where these are commonly used, because use of such products may undermine the denormalizing effects of smoke-free laws, reduce quitting incentives and expose bystanders to exhaled aerosol toxicants. Thus, for example, Maharashtra in India has banned smokeless tobacco in public places. The State of California in the USA has extended the application of smoke-free laws to electronic cigarettes, and has raised the minimum purchasing age for all forms of tobacco, including electronic cigarettes, to 21 years (Section 13.6).
13.6 Resisting industry interference in tobacco control laws and policies

The interests of the tobacco industry are in irreconcilable conflict with public health. Article 5.3 of the WHO FCTC requires that Parties protect the development and implementation of their public health policies with respect to tobacco control from the “commercial and other vested interests of the tobacco industry in accordance with national law”. For example, governments should limit their interaction with the tobacco industry, ensure that any interactions that do occur are transparent, avoid conflicts of interest, and ensure that the industry is excluded from law reform and law-making processes. Thus, the Russian Federation has legislation that requires all correspondence between government agencies and the tobacco industry to be publicly available (Section 13.6).

The COP to the WHO FCTC has issued guidelines to assist Parties to implement Article 5.3 of the WHO FCTC in an effective, evidence-based manner (29).
Chapter 14: Migration and retention of health-care workers

An effective health workforce – including medical practitioners, nurses, midwives, allied health-care professionals and other public health personnel – is one of the foundations of a successful health system. Challenges have arisen from increased international trade in skilled services, including through the emigration of domestically trained health-care workers, and rapidly growing markets for health-care services as a result of “medical tourism”. WHO estimates that there is a global shortage of about 4.3 million health-care workers. African countries are disproportionately affected, with some countries not even having one physician per 10,000 population. This chapter discusses strategies for recruiting and retaining health-care workers.

14.1 International strategies

The WHO Global Code of Practice on International Recruitment of Health Personnel (38) sets out voluntary principles for ethical international recruitment of health-care workers. It is intended to improve the legal and institutional framework for recruitment practices at the country level (Box 14.1). Member States should consider establishing or designating a national authority responsible for the exchange of information about the migration of health-care workers and implementation of the code.

The code discourages WHO Member States from recruiting health-care workers from countries facing critical shortages. It recognizes the benefits of circular migration, but encourages Member States to develop a sustainable workforce that will reduce long-term reliance on migrant health workers. The code also encourages Member States to scale up the training of health personnel, consider measures to address the geographical misdistribution of health workers in underserved areas, and monitor the national health labour market. Both source and destination countries can develop laws and policies to meet these objectives; an example is the United Kingdom’s Code of Practice for the International Recruitment of Healthcare Professionals (Box 14.2).

14.2 Retention strategies for source countries

Often, the countries from which health workers migrate face critical shortages and large disparities in access to health-care workers. Various strategies may assist these source countries to retain and build their health workforce, while also ensuring a better distribution of health workers between urban, rural and remote areas. These include:

- **compulsory service requirements** – for example, Indonesia has a voluntary service scheme, coupled with short contracts and financial incentives based on remoteness (Section 14.2);
- **bonding schemes** – for example, Australia has a bonding scheme for State-funded medical education (Box 14.3); and
- **improvements in human resource management** – for example, Guinea and Kenya decentralize human resource management to local health-care providers (Box 14.4).

Other strategies for workforce retention include:

- ensuring a safe working environment, including clean water, a safe electricity supply and freedom from violence;
- greater investment in facilities and equipment, including protective equipment;
- improved pay and conditions; and
- career development opportunities.

For example, Haiti has attracted staff to rural clinics by providing safe working conditions, improved facilities and increased incentives beyond pay (Box 14.5).
Chapter 15: Access to essential medicines, TRIPS and the patent system

Ensuring universal access to free or affordable essential medicines is a core obligation for fulfilling the right to health, and WHO has encouraged countries to amend their national legislation or constitutions accordingly. Countries should develop a national drugs policy that includes a list of essential medicines that considers national needs (Section 15.1), and should legislate on pricing and procurement (Section 15.2) and on access to medicines (Section 15.3). Panama and the Philippines are examples of countries with constitutional provisions requiring the State to provide affordable access to medicines (Box 15.1).

In some countries, treaty obligations, including the right to health, are enforceable through the domestic courts, providing members of the population with a legal pathway for seeking access to essential medicines at affordable prices. Argentina’s Constitution refers to a number of human rights treaties that supersede domestic law, imposing obligations that are enforceable through that country’s courts (Box 15.2).

15.1 Establishing a national drugs policy

WHO has released comprehensive guidance on creating a national drugs policy that addresses access to, and the quality and rational use of, medicines (39). The WHO model list of essential medicines can help to guide drug selection (25); however, the development of a national list should consider national priorities and disease challenges.

A national drug policy, including a list of essential medicines and standard treatment guidelines, can increase the use of generics, improve prescribing practices and protect against drug resistance. An example is South Africa’s development of a comprehensive national drug policy (Section 15.1).

15.2 Pricing and procurement

A national procurement strategy set out in legislation or administrative guidelines may help governments to formalize a range of measures to purchase quality medicines at cheaper prices. For example, Sri Lanka has an objective-based national procurement strategy (Box 15.3).

Up to a quarter of public spending on procuring pharmaceutical drugs is lost to corruption. WHO has published guidance to assist governments to avoid this (40). Steps for reducing corruption include registering medicines on the national list; licensing importers, pharmacists and drug dispensers; inspecting facilities; and developing comprehensive procurement plans that include transparent tender processes. Kenya, for example, has applied the principles of good governance to its procurement strategies (Box 15.4).

A national drugs policy can reduce barriers to access to essential medicines by eliminating tariffs on the import of drugs that are not domestically produced, and by controlling the mark-ups on drugs at wholesale and retail levels. Thus, South Africa’s national drugs policies include monitoring of pharmaceutical pricing (Box 15.5).

Policies may establish incentives or requirements for pharmacists and medical practitioners to dispense or prescribe generic versions of drugs. For example, some South American countries have reduced cost barriers to improve access through generic prescribing requirements (Section 15.2). To reduce patient demand for unnecessarily expensive drugs, laws may ban or limit the advertising of pharmaceuticals directly to consumers. Alternatively, laws may provide for faster, preferential regulatory approval processes for generic or bio-equivalent drugs.

15.3 Access to medicines, patents and TRIPS

The national drugs policy adopted by each country needs to be consistent with international law governing intellectual property rights. Medicines, as well as the processes required to produce them, are patentable under the WTO TRIPS Agreement, which requires Members to enforce national legislation that recognizes and enforces pharmaceutical patents.
(a) The purpose of patents

A patent is an exclusive right that enables the patent holder to exclude competing suppliers during the term of the patent. In return, the patent holder publicly discloses their invention, to facilitate free use of this information when the patent expires. Effective patent regimes promote technological innovation while ensuring the dissemination of technology and availability of generic medicines after the patent has expired. However, since patents eliminate competition, they can also lead to high prices for medicines during the term of the patent.

(b) The TRIPS Agreement and intellectual property rights

WTO Members have different dates by which to amend their domestic laws to protect patent rights on pharmaceuticals under TRIPS. Least developed countries have until 2033 to recognize and enforce patents on pharmaceuticals. Under TRIPS, domestic laws must allow for patents (with a 20-year protection period) on both products and processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Most essential medicines are not under patent; hence, generic versions can be produced or imported without infringing patent rights. Patent laws covering pharmaceuticals should not constitute a barrier to access for most drugs included in a national list of essential medicines. Affordable access to essential medicines that are under patent depends on the terms of national patent laws and the actions of the patent holder, including whether terms can be negotiated for importing the medicine or for a licence to manufacture the medicine domestically.

Under TRIPS, WTO Members can adjust their patent laws to achieve public health objectives (Box 15.6). For example, national laws may authorize courts, the executive or an administrative body to issue a compulsory licence to manufacture or import a patented drug where negotiations have failed, or in cases of emergency or government use, to achieve the government’s policy of providing universal access to medicines, diagnostics, vaccines or medical devices. This was affirmed in the Doha Declaration on the TRIPS Agreement and Public Health (2001).\footnote{See https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm}

National laws may authorize compulsory licences without the patent holder’s permission on additional grounds; for example, during a health threat caused by a natural disaster, epidemic or security threat, or physical interruption of supplies at affordable prices. Thus, Zimbabwe has legislation that authorizes public, non-commercial use of patents (Box 15.7).

(c) Awareness of TRIPS flexibilities

TRIPS includes flexibilities that can be used to reduce the prices of essential medicines and to better meet the goal of universal access. TRIPS does not prevent national governments from issuing compulsory licences in order to meet national health objectives, from choosing an exhaustion regime that best suits national circumstances (allowing parallel importing for example), or from defining patentability criteria in national patent legislation.

Article 31 requirements

Where the national law of a WTO Member permits a compulsory licence to be issued, the Member must first seek permission to use the patent from the patent holder on reasonable commercial terms. This is not required during a national emergency, in other circumstances of extreme urgency, or in cases of public, non-commercial use (e.g. where the government is seeking to ensure universal access to essential drugs, or is using the patent for some other government purpose). Thus, Thailand has issued government-use licences for seven HIV and cancer medicines (Section 15.3). WTO Member States should enact legislation that sets out the circumstances in which the government may issue a compulsory licence. Brazil’s legislation provides an example of this (Box 15.8).

WTO General Council Decision of 6 December 2005 requirements

In 2005, TRIPS was amended to allow a WTO Member to issue a compulsory licence for the manufacture and export of a generic version of a patented medicine to a WTO Member that lacks adequate domestic manufacturing capacity. Certain conditions apply to such licences (Box 15.9).

\footnote{See https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm}
Exhaustion of patent rights

National patent laws dealing with the exhaustion of patent rights may also influence the price and availability of essential medicines. A country's laws governing exhaustion of patents will affect whether a patent holder can prevent the resale and importation of patented drugs once they have been placed on the market in that country or elsewhere. National patent laws may be framed so that once a patent holder has exported a drug into a national market, or licensed its manufacture within that country, the patent holder's intellectual property rights in that drug are considered exhausted (so-called international exhaustion).

The practice of importing genuine products that have been placed on the market by the patent holder in another country without the patent holder's permission is known as “parallel importing”. A country may use parallel importing to obtain patented drugs at cheaper prices than are available on the domestic market. Although parallel importing does not breach TRIPS, it may be an infringement of a country's patent laws, depending on how the principle of exhaustion has been incorporated into national laws. Kenya, for example, has legislation that authorizes parallel imports, implementing the principle of international exhaustion (Box 15.10).

Restrictions on incremental patents

Patent holders may seek patents for minor improvements or adjustments to a drug (e.g. an alteration of the form of delivery or a different dosage), or for new uses of an existing drug. Although incremental innovations can bring important benefits to patients, some patents may simply delay the entry of cheaper, generic versions into the marketplace. To ensure access to essential medicines at the lowest prices, governments may consider amending their patent laws or guidelines for patent examiners in order to restrict the award of patents to products that can truly be said to involve an inventive step and to be “novel”. For example, the Andean Community has prohibited patentability of minor adjustments to pharmaceutical products (Box 15.11), and India has prohibited incremental patents (Section 15.3).

Regulatory review exception

During the patent protection period, WTO Members may pass legislation creating limited exceptions to patent rights. This includes legislation authorizing research on the patented invention, as well as use of the patent to produce the drug or active ingredient, and to seek approval to market a generic version of the drug after the patent has expired. For example, both the Andean Community and Kenya have legislative exemptions authorizing use of a patent for research purposes (Box 15.12), and Canada has legislation authorizing use of the patent to seek marketing approval for a generic version of a drug (Section 15.3).

Protections of test data

Even if a patent has expired, manufacturers may be prevented from manufacturing or marketing a generic drug because national laws may regulate the use of test data submitted to regulatory agencies for marketing approval. If a country requires test data to be submitted as part of marketing approval, TRIPS requires WTO Members to protect the data from disclosure, except where steps have been taken to protect such data from unfair commercial use. Depending on how unfair commercial use is defined in national laws, regulatory authorities may be unable to rely on test data in an application for marketing approval during the period of data exclusivity (typically 5–10 years from the date the originator product obtained marketing approval).

(d) Voluntary licence agreements for essential medicines

Voluntary licences are part of a broader set of strategies that pharmaceutical companies can use – as part of their corporate social responsibility or humanitarian programmes – to increase access to essential medicines at affordable prices. A patent holder may enter into a voluntary licence with third parties (e.g. generic producers) to produce, market and distribute a particular drug within a specified territory. Royalty-free, non-exclusive licences that include numerous countries within the licensed territory, permit sale to both the public and private sector, and permit licences to source active pharmaceutical ingredients from anywhere in the world are more likely to encourage robust competition and the economies of scale that are needed to substantially reduce prices.

Other strategies that support access to essential medicines include tiered pricing, donation of drugs, non-filing of patents in least developed countries and non-enforcement of patents.
Chapter 16: Legal responses to poor nutrition: undernutrition, overweight and obesity

The human right to food, as recognized in the ICESCR, encompasses a right to be free from hunger, and to have an adequate supply of safe and nutritious food. Discharging this obligation is one of the core obligations owed by States under the right to health. SDG 2 contains several targets intended to measure progress towards the right to food.

**Goal 2:** End hunger, achieve food security and improved nutrition and promote sustainable agriculture

**SDG 2, Target 1:** By 2030, end hunger and ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round

**SDG 2, Target 2:** By 2030, end all forms of malnutrition, including achieving, by 2025, the internationally agreed targets on stunting and wasting in children under 5 years of age, and address the nutritional needs of adolescent girls, pregnant and lactating women and older persons

Many low- and middle-income countries are moving towards a “western diet” that is higher in fats, sugars, refined carbohydrates, meat and animal products, but poorer in vegetables, legumes and coarse grains. Obesity and diet-related risk factors are contributing to the rapid rise of diabetes and other NCDs, even in countries that continue to face a substantial burden from infectious diseases and undernutrition. This chapter discusses various ways in which laws can respond to poor nutrition (Sections 16.1–16.4), shape environments (Sections 16.5 and 16.7), regulate the manufacture and sale of food (Section 16.6), and address hunger and food insecurity (Section 16.8).

16.1 Food policy domains

Legal and regulatory policies can support the right to food in numerous ways. First, governments can implement laws that aim to create healthier food environments offering easier access to food at affordable prices. For example, laws can set nutritional requirements for food sold in schools, or create incentives for farmer’s markets and community gardens. Second, governments can impose standards to improve the nutritional content of food, and regulate the systems responsible for production and distribution of food. For example, laws can target agricultural subsidies or restrict levels of harmful nutrients in food. Third, governments can pass laws that help consumers to make healthier choices. For example, laws can regulate food labelling or restrict the advertising of certain foods.

16.2 Economic instruments

The WHO Global Strategy on Diet, Physical Activity and Health recognizes that fiscal policies, including taxes and subsidies, can help to fight obesity and poor nutrition. Consumption can be reduced by imposing taxes on sugar-sweetened beverages (SSBs), and on foods that are high in saturated fat, added salt or added sugar. Tax increases may also encourage food and beverage reformulation by manufacturers, resulting in healthier products and generating additional revenues for governments. Food and beverage taxes need to be designed carefully. The overall health benefits of the tax will depend on whether:

- the tax is entirely passed on to the consumer;
- the price increases are substantial enough to alter levels of consumption; and
- there are other cheaper and healthier products in substitution for the taxed product.

SSBs have been suggested as an appropriate candidate for taxation because they have no nutritional benefit, are a major source of calories in many countries, and are associated with weight gain and diabetes; also, people do not compensate for the calories they consume through SSBs by reducing their calories from other sources. The WHO’s Commission on Ending Childhood Obesity included an effective tax on SSBs among a suite of policy
recommendations designed to reduce childhood obesity rates. In 2015, in its second year of operation, Mexico’s one penny per litre tax on SSBs resulted in a 9.7% reduction in purchases of taxed beverages (41) [Section 16.2]. Governments may also consider subsidizing less energy-dense foods, such as fresh fruit and vegetables, especially among low-income groups.

16.3 Food advertising controls

Laws that restrict the advertising and promotion of foods that are high in saturated fat, salt or added sugar may be an effective way of moderating demand for foods that are overconsumed and that contribute little to a healthy diet. This is particularly the case for advertising aimed at children. Several countries have implemented legal controls to protect children from excessive exposure to advertising and promotion of energy-dense but nutrient-poor foods (Box 16.1).

Food companies use sophisticated advertising and promotional techniques to manipulate and shape children’s food preferences. These include television, websites and mobile electronic communications, product placement, sponsorship, point-of-purchase displays, competitions and prizes, toys and other incentives. In response, some countries have legislated against these approaches. For example, the Republic of Korea prohibits free, non-food items such as toys in the advertising of children’s “preferred foods”, and Chile prohibits advertising directed at children using characters, cartoons, figures, games, music and animals where the food exceeds certain nutritional limits (Section 16.3).

WHO has recommended that settings where children gather should be free from “all forms of marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt” (42). Governments can improve the school food environment by directly restricting the advertising and promotion of unhealthy foods in schools, and by ensuring that all food sold or made available on school grounds during the school day meets minimum nutritional criteria.

16.4 Nutrition labelling laws

Food labelling may help consumers to choose more nutritious foods through, for example, nutritional information panels, front-of-pack interpretive labelling schemes, warning labels and suitably regulated health claims. Legislation in Australia and New Zealand sets out the labelling requirements for the nutritional panel that appears on packaged food (Box 16.2).

Regulations should require manufacturers to list the nutrients in a standardized unit or quantity (e.g. grams of fat per 100 g), so that consumers can compare foods and choose products with lower levels of overconsumed nutrients. An example is the European Union’s requirements for mandatory nutrition declarations on food packaging (Section 16.4).

(a) Front-of-pack nutrition labelling

Nutrition labels on the front of a food package are a highly visible way of informing consumers of the nutritional characteristics of food products, and helping them to make healthy choices rapidly. Interpretive nutrition labelling can also be extended to restaurants and food stalls. The “traffic light” food labelling system, originally developed in the United Kingdom, has been adopted in the Republic of Korea on a voluntary basis for “children’s preferred foods” (Section 16.4).

(b) Nutrition warning labels

Legislation can require that products high in energy, sodium, sugar or saturated fat carry warning labels. Such labels may help consumers to make healthier choices, and encourage reformulation by manufacturers. For example, Finland has legislation that requires warning labels for products high in salt, and permits “low salt” labels for reduced-salt products, and Chile has labelling requirements for products exceeding set limits of energy, sodium, sugar or saturated fat (Section 16.4).
(c) Prevent misleading and deceptive health claims

To prevent misleading and deceptive health claims, national governments may consider introducing laws that only permit manufacturers and advertisers to make health claims about foods that satisfy minimum criteria for good nutrition. The International Code of Marketing of Breast-milk Substitutes (43) contains provisions designed to prevent misleading and deceptive practices by manufacturers and distributors of infant formula and breastmilk substitutes (Section 16.4).

(d) Menu labelling

In countries where restaurant chains are common, and where an increasing proportion of meals are eaten outside the home, nutrition labelling laws can be extended to the standard menu items sold in such restaurants. For example, in the USA, federal law requires calorie counts to be shown beside standard food items on menus of restaurant chains (Section 16.4), and in Singapore, healthier choice options on menus are identified by a government-licensed logo (Section 16.5).

16.5 The school environment

School lunch programmes provide an important opportunity for children (particularly those from poor and dis advantaged backgrounds) to receive sufficient nutrients. Governments and school authorities can use various legal tools to ensure that the foods made available on school premises are nutritious and consistent with dietary goals. For example, school meals and foods sold in schools can be required to meet nutritional criteria, as a condition of federal food assistance subsidies paid to education authorities. Thus, in the USA, Kentucky has laws that impose minimum nutritional standards for foods and beverages available on school campuses (Box 16.3), and Costa Rica has regulations that restrict the use of certain ingredients in food prepared in schools (Section 16.5).

Governments may also choose to regulate food retail businesses within the immediate environment of a school. For example, the Republic of Korea has a law that establishes “green food zones” (within 200 metres of schools), to improve the nutritional quality of foods sold to children (Section 16.5).

16.6 Mandatory food standards, and restrictions on sale

(a) Eliminating harmful substances from the food supply: trans-fats

Governments may consider sales bans or mandatory food standards to eliminate harmful substances from the food supply. WHO has identified the elimination of trans-fats and their replacement with unsaturated fats as a cost-effective priority for reducing CVDs, diabetes and other conditions associated with trans-fat intake. To help in removing trans-fats from the food supply, the USA now requires manufacturers of foods containing partially hydrogenized oils to obtain pre-market approval from the Food and Drug Administration (Section 16.6). Similarly, in Canada, British Colombia has limited the trans-fat content of restaurant food through regulations addressing “health impediments” (Box 16.4).

(b) Mandatory food fortification

To improve micronutrient deficiencies, governments may also adopt regulations or mandatory standards to implement food fortification programmes. Examples include universal iodization of salt, and mandatory fortification of wheat flour with iron, folic acid or zinc. In Nigeria, mandatory iodization of all food-grade salt is enforced through multisectoral collaboration (Section 16.6).
(c) Regulatory measures to reduce overconsumed nutrients

Regulatory efforts to moderate the consumption of overconsumed nutrients (e.g. salt, sugar and saturated fat) can take many different forms. For example, laws can require the elimination or reduction of particular nutrients.

Excess salt consumption has been estimated to cause over 3.1 million deaths each year. In 2010, global average salt consumption was estimated to be about 9.9 g/day, nearly twice the WHO recommended limit of 5 g/day. Legislation may set mandatory, maximum salt levels for particular products or categories of food; both Argentina and South Africa have adopted this approach (Section 16.6). Laws may also be used to discourage consumers from adding salt to food; for example, in Uruguay, Montevideo has municipal laws that place limitations on the availability of salt shakers and condiments high in salt (Section 16.7).

Mandatory standards may be considered appropriate where voluntary or co-regulatory processes for food reformulation are moving too slowly or have proved ineffective in meeting national nutritional goals and targets.

16.7 Regulating the built environment

Regulation of the physical and built environment provides opportunities to improve nutrition and reduce overweight and obesity. Using zoning and development regulations, governments can control the kinds of land use that are permissible in a local area, and can build specific design features into new developments (e.g. wide sidewalks, dedicated bike lanes, parkland, children’s playground areas and community spaces).

Zoning and development regulations, in conjunction with economic policies, can also be used to improve the food environment. For example, governments can create tax and other economic incentives to encourage grocery stores to carry fresh produce, or supermarkets to locate in underserved areas. Some cities in the USA have used municipal laws to prevent fast food restaurants being located close to schools, and have supported the introduction of “green carts” selling fresh produce on city streets. New York City has zoning and tax incentives for local grocery stores to carry fresh produce, dairy products and meats (Box 16.5).

16.8 Addressing hunger and food insecurity

Undernutrition remains a major problem in many countries, particularly developing countries. Legal recognition of the right to adequate food and to nutritional security provides the basis for holding governments accountable for policies to address hunger and micronutrient deficiencies. For example, Brazil has legislation that recognizes the right to adequate food and nutritional security (Box 16.6). In some countries, these rights may be enforced through national courts. This is the case in India, where the constitutionally protected right to life includes a right to food (Section 16.8).

Government programmes to improve food security for women and children are an important strategy for fulfilling the right to adequate food and nutrition. Examples include Brazil’s cash transfer programme, which involves payment of a monthly cash stipend to the female head of the household (Section 16.8), and Ethiopia’s comprehensive food aid programme (Box 16.7).
Chapter 17: Maternal, reproductive, child and adolescent health

In 2015, about 303 000 women died from causes related to or aggravated by pregnancy and the management of pregnancy. In addition, 5.9 million children and 1.2 million adolescents died from preventable causes (44). Progress in maternal, child and adolescent health requires action in areas both within and beyond the health sector. The SDGs include specific targets for maternal and child health. In addition, under the Global Strategy for Women’s, Children’s, and Adolescents’ Health (2016–2030), countries have committed to a set of objectives and targets, aligned with the SDGs, to end preventable deaths, enable health and well-being, and expand enabling environments (45).

This chapter discusses how the law can help to prevent discrimination and violence (Sections 17.1 and 17.2), and the law’s role in maternal and child health (Sections 17.3–17.5), education (Section 17.6) and adolescent health (Section 17.7).

17.1 Preventing discrimination

Women and children are entitled to the highest attainable standard of health, including access to adequate health-care services, and to a fair and adequate allocation of resources. Discrimination is a formidable barrier to improvements in maternal and child health. SDGs 5 and 6 include specific targets for ending such discrimination.

Women and children may face discrimination in accessing health-care services through direct, physical exclusion, and through unequal access and self-exclusion because of the stigma associated with particular conditions, and lack of courtesy and mistreatment from service providers. Discrimination and stigma may result in a loss of control over fertility (see SDG 5, Target 6).

State Parties to the ICESCR have an immediate obligation to respect the right to health by preventing discrimination (see Section 1.1(a) in Chapter 1). In many countries, a legal entitlement to protection from discrimination has been included in constitutions and domestic laws. For example, the national constitutions of Germany, Portugal and Uganda all include legal protection from stigma and discrimination (Box 17.2).

In some countries, reproductive and maternal health is expressly protected by constitutional provisions that are enforceable through the courts. For example, Uganda’s national constitution contains legal protection for women’s health rights (Section 17.2).
17.2 Freedom from violence

Violence against women is a serious form of discrimination that violates the right to health and is prohibited by the Convention on the Elimination of All Forms of Discrimination Against Women (46). Such violence includes domestic violence within the family, rape and sexual assault, coercion and deprivation of liberty, sexual harassment, trafficking and forced prostitution, forced marriage, acid attacks, so-called “honour killings” and female genital mutilation.

Legal responses to violence should address both the causes and consequences of violence, and should include primary, secondary and tertiary prevention, as explained below. Countries must take steps to improve their capacity to deliver justice to victims of violence, by investigating cases and enforcing remedies and penalties. India has taken a whole-of-government approach to acid attacks against women (Box 17.3).

WHO has released a comprehensive strategy that takes a life-course approach to preventing domestic violence. Recognizing that girls, female adolescents and women face specific vulnerabilities from gender-based violence, the strategy encompasses the following:

- **Primary prevention strategies** seek to prevent violence from occurring by promoting gender equality and by legislation recognizing equal rights for men and women. An example is Kyrgyzstan, which has strategies for promoting equality in property rights (Box 17.4).
- **Secondary prevention strategies** seek to respond swiftly to cases of violence and to provide appropriate support to victims through adequate resourcing of police and the courts, police training, criminal justice reform, safe havens for victims of violence and other measures. Examples include Costa Rica’s legal protections for victims of domestic violence (Section 17.2); and Pakistan’s legislative protection from sexual harassment (Box 17.5).
- **Tertiary prevention strategies** seek to prevent women from being pulled back into abusive relationships and environments by providing access to services and rehabilitation.

17.3 Prenatal and maternal health-care services

The provision of reproductive, prenatal and postnatal health-care services is a critical part of the right to health, comparable with the core obligations that are subject to immediate effect (see Section 1.1(a) in Chapter 1). Universal access to prenatal care is a cost-effective way to reduce mortality and morbidity during pregnancy and birth, for both mother and child. Such care can include folic acid supplements, HIV testing, malaria prevention and prenatal assessments (e.g. for diabetes). Legislation can recognize women’s entitlement to prenatal and maternal health services, and commit governments to developing strategies to fund such services and to addressing barriers to care. Vital statistics legislation should require all births to be registered. Perinatal and neonatal deaths should be investigated. Ecuador has addressed economic barriers to care by eliminating user fees for prenatal and obstetric care (Box 17.6), and Zambia has addressed geographical barriers to care by constructing maternal waiting homes (Box 17.7).

Giving women the ability to control their fertility through family planning substantially reduces the number of maternal deaths and improves the health of infants. WHO has estimated that 214 million women globally have an unmet need for contraception; in Africa, this extends to more than 24% of women of reproductive age (47). Components of an effective family planning strategy include knowledge about and access to effective methods for family planning (48), treatment for sexually transmitted infections, and counselling and strategies for dealing with violence against women. Legislators should ensure that family planning programmes are adequately funded and that women have full access to the fertility methods they choose.

Countries have an obligation to monitor the performance of private health-care organizations, including private insurers, to ensure that they do not exclude services essential to women’s health (e.g. prenatal assessment, attended birth, postnatal care and family planning). For example, in Colorado, USA, it is mandatory for health insurers to cover women’s reproductive health needs (Box 17.8).
17.4 Maternal and child nutrition

Improving nutrition during pregnancy is critical, both to reduce the incidence of low birth weight and improve long-term childhood development. In 2017, 155 million children aged under 5 years were stunted (i.e. too short for age), 52 million were wasted (i.e. too thin for height), and 41 million were overweight or obese (49). The Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition, adopted by the World Health Assembly in 2012, includes a range of global targets for mothers and children, as shown in Box 17.1. Progress towards these targets requires both nutrition-specific interventions (e.g. support for breastfeeding) and nutrition-sensitive interventions across various sectors.

Box 17.1 Global targets for maternal and child nutrition (50)

By 2025:
- a 40% reduction in the number of children aged under 5 years who are stunted;
- a 50% reduction in anaemia in women of reproductive age;
- a 30% reduction of low birth weight;
- no increase in child overweight;
- increase the rate of exclusive breastfeeding in the first 6 months up to at least 50%; and
- reduce and maintain childhood wasting to less than 5%.

The International Code of Marketing of Breast-milk Substitutes, adopted by the World Health Assembly in 1981, supports infant nutrition by reducing commercial marketing practices that undermine breastfeeding (43). Achieving near-universal levels of breastfeeding could, annually, save more than 820,000 deaths in children aged under 5 years, and 20,000 deaths from breast cancer (51). In 2016, WHO reported that 136 countries had included some aspects of the code in legislation. However, legislation alone is unlikely to be sufficient, and governments should actively monitor the marketing practices of companies that manufacture and market infant formula and breast-milk substitutes.

17.5 Maternity leave

Laws and policies requiring employers to provide women with paid maternity leave are an important component of a comprehensive strategy for maternal and infant health, and can significantly reduce infant mortality, low birth weight and post-neonatal mortality. The International Labour Organization Maternity Protection Convention (2000) (52) provides standards for maternity protection (Box 17.10).

17.6 Education

Universal primary and secondary education is critical for improving maternal and child health. The education of women benefits women themselves, but also improves the survival and development of children. Laws can mandate primary and secondary school attendance, committing governments to spending the resources needed to ensure that all children can attend school without discriminatory barriers, and regardless of the economic position of their family. For example, Indian legislation recognizes the right of the child to free and compulsory education (Box 17.11).

17.7 Adolescent health

The realization of the right to health requires special attention to the health of adolescents (those aged 10–19 years), given the rapid physical, cognitive, social, emotional and sexual changes they experience. Every day, more than 3000 adolescents die from largely preventable causes. There is a pressing need for greater investment in the health of adolescents, both to improve their health and survival now (see Box 17.2), and to create the foundations for healthy future generations. Several of the SDG targets depend on investments in adolescent health (53).
Box 17.2 Leading causes of death of adolescent males and females (53)

For females aged 10–14 years, the leading causes of death are lower respiratory infections, diarrhoeal diseases, meningitis, and HIV and AIDS. For those aged 15–19 years, complications from pregnancy and childbirth, self-harm and road injury feature most prominently. Adolescence is a particularly vulnerable time for girls. For example, child or young marriage can interrupt schooling and education, contribute to higher rates of HIV and AIDS, and limit access to health care, including reproductive and sexual health services.

For boys aged 10–14 years, the leading causes of death are road injuries, drowning, lower respiratory diseases and diarrhoeal diseases. For those aged 15–19 years, death rates for road injury, interpersonal violence and self-harm rise sharply.

WHO has recommended that countries take the following three steps in relation to adolescent health:
1. Identify the conditions and health risks that have the greatest impact on adolescents.
2. Analyse existing programmes, policies, legislation, capacity and resources.
3. Identify national priorities for action.

In 2017, WHO identified a set of evidence-based priority areas for adolescent health (53). These priorities encompass many of the topic areas discussed in the report; for example:

- prevention of violence and injuries;
- provision of confidential sexual, reproductive and mental health-care services;
- prevention of harmful practices, including female genital mutilation and forced marriage;
- prevention and treatment of sexually transmissible infections;
- routine vaccination;
- addressing the risk factors for NCDs, including poor nutrition, tobacco use, harmful use of alcohol and lack of physical activity; and
- improvements in water, sanitation and hygiene.

Law has an important role in supporting each of these areas, and in reducing stigma and discrimination against adolescents based on the health conditions that affect them.


