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Western Pacific Regional Action Agenda on Strengthening Legal Frameworks for Health in the Sustainable Development Goals

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EXECUTIVE SUMMARY

Legal frameworks – both the instruments of law and the institutions responsible for putting them into effect – are essential to advance universal health coverage (UHC) and achieve health in the Sustainable Development Goals (SDGs). Laws are critical to organizing and regulating health systems and services, protecting rights, and preventing and managing public health risks. However, in many countries, legal frameworks are out of date, have been developed in a reactive fashion, are not coherent or consistent with existing evidence and the relevant country context, and/or are not consistently implemented and enforced. More attention is needed on improving the processes and the capacities of stakeholders to implement and review legal frameworks effectively to promote and protect public health.

The importance of legal frameworks was reaffirmed by the WHO Regional Committee for the Western Pacific through the endorsement of *Universal Health Coverage: Moving Towards Better Health – Action Framework for the Western Pacific* (2016) and the *Regional Action Agenda on Achieving the Sustainable Development Goals in the Western Pacific* (2017). This *Western Pacific Regional Action Agenda on Strengthening Legal Frameworks for Health in the Sustainable Development Goals* builds on these agendas.

Setting the Regional Action Agenda

The Action Agenda provides guidance on strengthening legal frameworks to achieve UHC and advance health in the SDGs by providing a range of options countries may consider as part of their broader strategies. The options are presented across three pillars in response to the following questions:

(1) What can be done – areas where law plays an essential role in impacting health, such as health governance, health services, and public health, which countries may prioritize for action.
(2) How to do it – processes in the development, implementation, and evaluation of laws for health, which countries may prioritize for improvement.
(3) Who is involved – capacities of stakeholders involved, which countries may prioritize for enhancement.

While each country is different, there are many shared challenges and opportunities to use legal frameworks more effectively to drive health and development.

Pillar 1: What can be done?

The priorities for strengthening legal frameworks across a wide range of potential action areas will be different from country to country. Actions should be informed by available evidence and knowledge, consistent with international obligations, integrated with non-legislative strategies, and responsive to the needs and feasible within the capacities of the country. Countries should consider actions to enhance health system governance and stewardship; respect, protect, and fulfil the right to health, particularly for the most vulnerable; improve access to affordable, safe and high-quality health

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services; prevent and manage public health risks; and foster multisectoral collaboration to address the social determinants of health.

Action Areas	1.1 Enhance health system governance and leadership
	1.2 Respect, protect and fulfil the right to health
	1.3 Improve access to affordable, safe and quality health services
	1.4 Prevent and manage public health risk
	1.5 Foster multisectoral collaboration to address the social determinants of health

Pillar 2: How to do it?

Countries will have different priorities in improving various processes to strengthen legal frameworks for health. Processes should address the full cycle of legal development, including problem analysis, stakeholder engagement, drafting and enactment, implementation, and evaluation. Each of these processes can occur together or serially, and are affected by technical, political and other factors. Careful mapping and navigation are essential in successfully strengthening legal frameworks.

Processes	2.1 Analyse the problem(s) and identify viable options
	2.2 Overcome obstacles and get to a decision
	2.3 Design the law
	2.4 Implement the law
	2.5 Monitor and evaluate the legal framework

Pillar 3: Who is involved?

Countries have different priorities for enhancing the capacities of various stakeholders involved in strengthening legal frameworks for health. Policy-makers and regulators are essential players in developing and implementing laws for health. Parliamentarians are critical with their powers to enact law, approve budgets and provide oversight. The integral role of health providers and communities demand transdisciplinary approaches to public health law can help break down disciplinary, cultural and resource barriers.

Capacities	3.1 Build the capacity of policy-makers
	3.2 Build the capacity of regulators
	3.3 Engage with parliamentarians
	3.4 Empower and ensure the participation of communities
	3.5 Coordinate with health providers

Recommendations

Member States and WHO have complementary roles and commitments in strengthening their legal frameworks for health.

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As appropriate to national needs and capacities, Member States may consider taking the following actions towards strengthening their legal frameworks for health:

- Review legal frameworks for health in aligning their national health strategies with broader efforts to advance UHC and achieve health in the SDGs
- Set priorities for action areas and develop a programme for strengthening their legal frameworks for health.
- Improve processes in the development, implementation and evaluation of legal frameworks for health.
- Enhance the capacities of stakeholders involved in strengthening legal frameworks within and beyond the health sector.
- Cooperate with other countries to ensure health is considered in developing international legal instruments, such as agreements on trade and environment.
- Enable action on cross-border health risks and issues through legal frameworks.

Upon request, WHO may support Member States in strengthening their legal frameworks for health, as follows:

- Raise awareness on the importance of law for health and advocate the strengthening of legal frameworks to advance UHC and achieve health in the SDGs.
- Enhance access to evidence and knowledge to support Member States in their efforts to review existing legal frameworks for health and determine priorities for action.
- Provide technical assistance to Member States in their efforts to improve processes and enhance capacities for strengthening legal frameworks for health:
- Facilitate dialogue and cooperation between Member States to address cross-border health issues, foster regional collaboration opportunities, and engage in joint advocacy and action to shape international agendas.
- Mobilize legal expertise for health.

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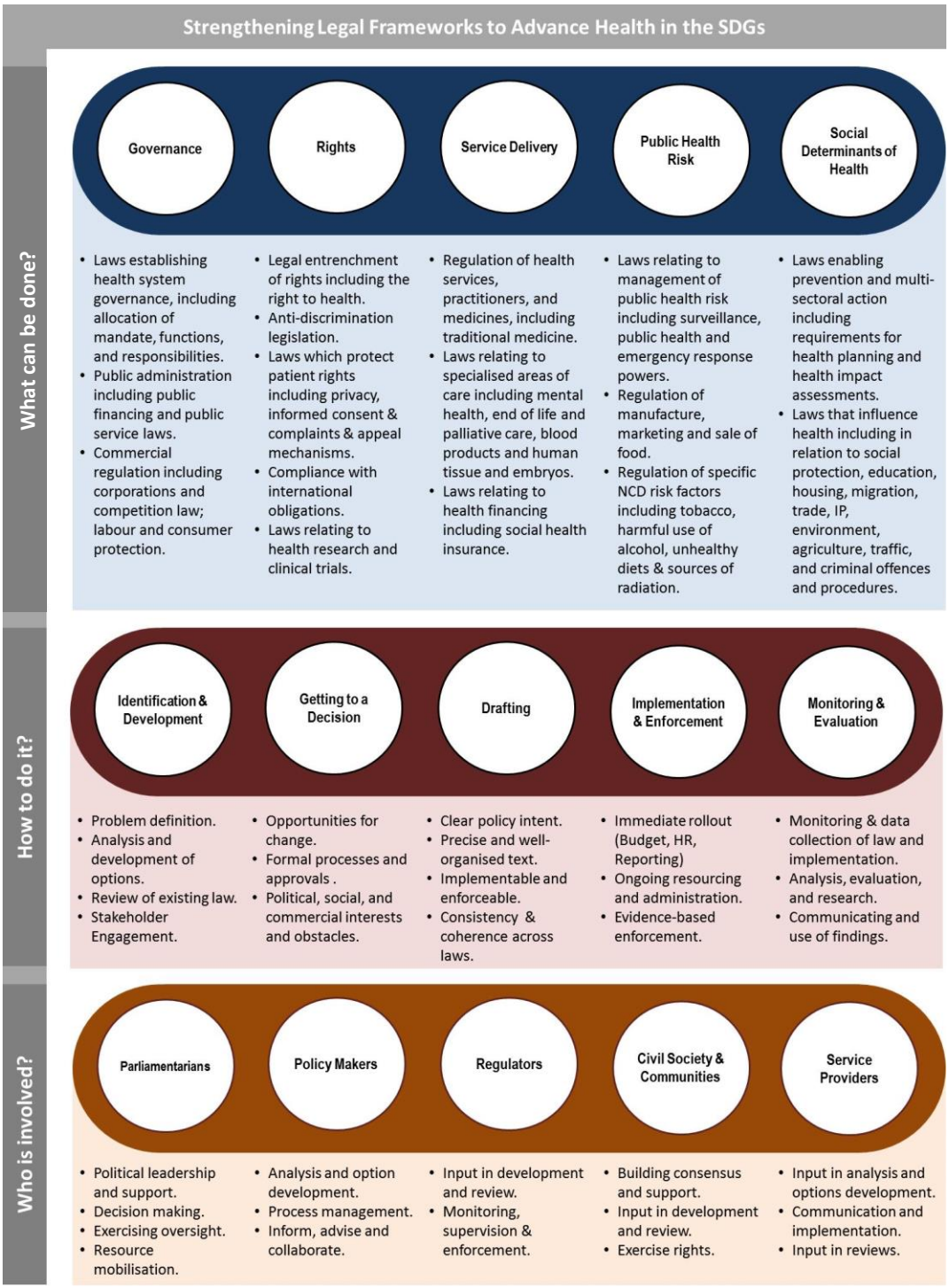
Overview of the Regional Action Agenda



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1. INTRODUCTION AND BACKGROUND

Legal frameworks – both the instruments of law and the institutions responsible for putting them into effect – are essential to advance universal health coverage (UHC) and achieve health in the Sustainable Development Goals (SDGs). Law has played a key role in many great public health achievements, including vaccination programmes, motor vehicle safety, reducing smoking, the control of infectious diseases, and food and pharmaceutical safety. However, countries often struggle to develop, implement and evaluate effective legal frameworks to improve public health. While each country differs, there are many shared challenges and opportunities to harness the law effectively to drive health and development.

The *Western Pacific Regional Action Agenda on Strengthening Legal Frameworks for Health in the Sustainable Development Goals* provides guidance to more effectively use law to advance UHC and achieve health in the SDGs. This includes: setting priorities for action areas; improving processes in the development, implementation and evaluation of laws; and enhancing the capacity of stakeholders. This document provides an overview of the diversity and commonalities of approaches to legal frameworks in the Western Pacific Region in relation to health and the challenges involved. The document is not designed to be prescriptive, but rather to provide specific options countries may consider as part of their broader strategies.

The Action Agenda is presented across three pillars in response to the following questions:

(1) What can be done – areas where law plays an essential role in impacting health, such as health governance, health services, and public health, which countries may prioritize for action.
(2) How to do it – processes in the development, implementation and evaluation of laws for health, which countries may prioritize for improvement.
(3) Who is involved – capacities of stakeholders involved, which countries may prioritize for stronger engagement.

Guidance and suggested actions are provided for each pillar, as well as a set of key questions for countries to consider in taking action.

1.1 What is law?

Throughout this document, the broad term “legal frameworks” includes both the various instruments of law and the institutions responsible for putting them into effect. Instruments of law may include national constitutions, legislations enacted by Parliament, ministerial by-laws or regulations, presidential decrees, agency guidelines, administrative rules and other forms of official order. Depending on the jurisdiction, laws may also include court rulings by judges, as well as interpretations and actions of regulatory bodies or other bureaucratic institutions. In limited cases, so-called co-regulatory schemes involving combined authority between the state and non-state actors for making and enforcing rules, such as accreditation of medical specialists by practitioner associations or restrictions on television advertisement to children by the food industry, may take the place of formal legal frameworks. Such self-regulation often has weaker remedies or lax oversight to ensure compliance compared to traditional “command and control” systems maintained exclusively

by the government. Laws exist at local, national or international levels. These instruments, often working in some combination with each other, prescribe duties and rights, powers and limitations for specific actors in specific contexts, and provide for coordination, implementation and enforcement mechanisms.

At a more fundamental level, the rule of law refers to a principle of governance in which all persons, institutions and entities, public and private, including the state itself, are accountable to laws that are publicly promulgated, equally enforced and independently adjudicated, and which are consistent with international human rights norms and standards. It requires, as well, measures to ensure adherence to the principles of supremacy of law, equality before the law, accountability to the law, fairness in the application of the law, separation of powers, participation in decision-making, legal certainty, avoidance of arbitrariness, and procedural and legal transparency.

Member States across the Western Pacific Region have different legal systems and traditions (see Appendix 3), including civil law, common law, customary law and Sharia law; further, many incorporate a mix of legal systems. These traditions have been shaped by diverse political, economic, social, cultural and historical circumstances. There is also variation in systems of government, including federalist systems of government.

These different legal systems and legacies have an impact on the relationship between the law and health. While in all countries the law plays some role in relation to establishing health system governance and leadership, protecting rights, and managing public health risks, the understanding of what law is and approaches to its use vary. This translates into the types of provisions that appear in health laws and how they are understood and implemented. For example, certain countries have orders and decrees, which provide guidance through statements of principle and direction which differ from other traditions that specifically emphasize the articulation of rights, responsibilities and powers in law. Whereas federalism relates to the allocation of functions and authority to different level of governments, and the relationships between these governments, the health sector is particularly challenging to manage in federal systems due to the complexity of health-care provision, the importance of maintaining public health functions, its cross-jurisdictional nature and its significant proportion of public spending.

Legal frameworks are not, however, an end in themselves. The relationship between law and health is shaped by the knowledge, attitudes and practices of individuals and institutions, as well the social context and political environment. Laws need to be understood as a behaviour change intervention, and they need to be developed, implemented and evaluated as part of broader public health strategies. In public health practice, law is not just something that lawyers do. It is part of the basic job description of any public health professional, whether studying health threats, developing solutions, working with governments, or monitoring and evaluating initiatives, policies and programmes.

1.2 Increasing linkages between law and health

Legal frameworks are an important tool for organizing and managing health systems. They codify and allocate responsibilities, foster cooperation and coordination, set standards, and authorize or constrain action. The law can be used to shape markets, for instance, by banning dangerous products or mandating government procurement practices that give incentives to producers to make healthier

products. Passing a law can also be a good way to convey information, to alert people to particular health risks, and to influence social norms and behaviours.

Overarching health system legislation is receiving increasing attention in the Region, in particular in transitional economies as part of broad economic and legal reforms (see Box 1). It is a feature of Pacific island country legislation that the responsible minister is generally granted strong powers for implementation, administration and enforcement. Health boards aim to promote better linkages within the health sector, as demonstrated in Fiji, Papua New Guinea and the Republic of Korea, but how far these can be leveraged depends on the extent to which such boards are supported by and engage the senior officers and other participants. In the Lao People's Democratic Republic, broad powers are granted to the Ministry of Health including research, planning, regulation, administration and issuing of authorization to practice.

Box 1. Development of the Essential Healthcare and Health Promotion Law in China

China is developing an Essential Healthcare and Health Promotion Law, which seeks to provide a comprehensive and coordinating legal framework to guide future health reform and health system development. The draft Law that was released for public consultation on 29 December 2017 contains nine chapters that include provisions in relation to general principles, citizen health rights and obligations, major measures of health promotion, organization and supply of public health medical services, health-care professionals, drug supply, financing and payment, comprehensive supervision and management, legal responsibilities, and other supplementary provisions. There is a clear intention under the Law that government at all levels and across all sectors consider health in formulating and implementing policy. Further, it supports effective stewardship by government across both public and private providers.

Many countries are choosing to adopt a Health in All Policies approach to policy development, implementation and agenda-setting. However, this has not often been integrated into legislative mechanisms. For example, only a few countries in the Region have specific requirements for health impact assessments. Some countries have also used mechanisms such as declarations on noncommunicable diseases (NCDs) with powers to formulate and implement orders and guidelines. The Korean Framework Act on Health and Medical Services requires state and local governments to implement projects of lifelong health care for citizens which take into account health characteristics of the life cycle and major factors harmful to health.

Historically, legal frameworks have been well established in most countries for the management of communicable diseases. Nearly every country in the Region has a system for identifying and notifying diagnosis of specified communicable diseases to a health authority with accompanying powers to address a possible outbreak. The particular systems, the notifiable diseases, and the authorities to whom they are reported and their available powers differ, but use of this approach is almost universal, with strong reliance on command-and-control mechanisms, but often without adequate provisions limiting the breadth of such powers and protecting the rights of those affected. In many cases, lists of notifiable diseases are outdated and systems not in place to effectively operationalize them.

However, few countries have taken the opportunity to align powers to manage communicable disease with those for other health risks, particularly in a multihazard incident. Without such an alignment of powers, a country may, especially at a time when coordinated and rapid action is needed, be trying to utilize different powers based on different laws with different triggers and empowering different officers across different authorities, be they health, agriculture, food safety, quarantine or other.

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Innovations from countries may serve as useful examples. Furthermore, at a time when health systems are becoming more complex with existing providers and new entrants, a broader scope of the legislative mandate and oversight may be necessary to cover communicable disease management, as well as NCD management, emergency management, and multisectoral approaches to priorities such as antimicrobial resistance, compliance with the International Health Regulations (IHR) and UHC.

Countries are increasingly relying on legal frameworks to help address NCDs, including measures such as excise taxes, restrictions on marketing, restrictions on commercial availability, restrictions on public consumption and labelling requirements. These target products associated with NCD risk factors, including tobacco, alcohol and unhealthy foods. All Member States in the Western Pacific Region are Parties to the WHO Framework Convention on Tobacco Control, which took effect in 2015 as the world's first global health treaty negotiated under the auspices of WHO and commits Parties to implement a wide range of supply and demand reduction measures, many through law. Australia, Hong Kong SAR (China), New Zealand and Singapore continue to stand as leaders in reducing tobacco use. China is taking innovative approaches with legal reform at the city level, particularly with respect to smoke-free zones. The Philippines has successfully implemented increased taxes on tobacco, alcohol and sugar-sweetened beverages, with revenues allocated to supporting national programmes for UHC. The Republic of Korea has successfully banned marketing of specific types of food to children and is a leader in cancer surveillance, screening and referral systems. Countries are also strengthening legal frameworks to address other health issues through the life course, including child and maternal health, reproductive health, disabilities and rehabilitation, mental health, road traffic safety, injuries and violence prevention, workers' health, environmental health and healthy ageing.[1]

1.3 Role of law in UHC and the SDGs

Since the adoption of the 2030 Agenda for Sustainable Development in 2015, development has been guided by the 17 bold and transformative Sustainable Development Goals. They contain 169 targets "to ensure that all human beings can fulfil their potential in dignity and equality and in a healthy environment". The SDGs are owned by Members States. There is no single path that they should take in pursuing them. Rather, Member States will plan, design and stage interventions based on national and local contexts and the most pressing health challenges. Similarly, as health systems reflect the social, economic and political contexts of the country, as well as decisions about national priorities, there is no one-size-fits-all formula to achieve UHC. In pursuing the vision of UHC and the aspirations of the SDGs, Member States are encouraged to take evidence-based actions on multiple fronts that are mutually reinforcing and to embed them in their national health policies and reforms. SDG 3 is to "ensure healthy lives and promote well-being for all at all ages". But health in the SDGs goes well beyond SDG 3. All the SDGs – such as those addressing clean water and energy, education, gender equality, hunger and poverty – influence and are influenced by health.

In October 2016, the *Regional Action Agenda on Achieving the Sustainable Development Goals in the Western Pacific* was endorsed by the WHO Regional Committee for the Western Pacific. The Action Agenda presents a menu of options for countries towards achieving health in the SDGs. It articulates a vision that requires a comprehensive approach, bringing together relevant government sectors, stakeholders and communities. Table 1 provides an overview of the guiding questions and action domains.

[1] See also Appendices 5–8.

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Table 1. Guiding questions and action domains to advance the SDGs

Guiding questions	Action domains
1. What are countries aiming to achieve, and how will they know?	1.1 Country-led selection of health goals, targets and indicators
	1.2 Robust monitoring and review process
	1.3 Adequate information capacity
2. What are the policy and programme priorities for leaving no one behind?	2.1 Equity in health services
	2.2 Realizing win–wins through collaboration across sectors
	2.3 Financing strategies for promoting equity of access
3. How will countries put their priorities into effect?	3.1 Collaboration across government
	3.2 Engagement of stakeholders beyond government
	3.3 Participation of affected communities
4. How can the health sector drive the agenda?	4.1 Capabilities for knowledge exchange
	4.2 Leadership skills to navigate the policy system
	4.3 Institutional capacity for present and future challenges

Source: Regional action agenda for achieving the Sustainable Development Goals in the Western Pacific. Manila: WHO Regional Office for the Western Pacific; 2017.

UHC is a target in the SDGs, but it also serves as a platform to bring together diverse programmes and actions for health and development. The vision for UHC is of all people being able to obtain high-quality health services without suffering financial hardship. The structure and implementation of UHC will differ according to the local context; however, Member States are encouraged to take a comprehensive whole-of-system approach. Advancing UHC and the SDGs requires collaborative partnerships across sectors of government, diverse stakeholders and communities to address many interconnected health and development challenges.

Universal Health Coverage: Moving Towards Better Health – Action Framework for the Western Pacific was endorsed by the Regional Committee for the Western Pacific in October 2015. Table 2 summarizes the 15 action domains across five essential health system attributes.

Table 2. Health system attributes and action domains for achieving UHC

Health system attributes	Action domains
Quality	1.1 Regulations and regulatory environment
	1.2 Effective, responsive individual and population-based services
	1.3 Individual, family and community engagement
Efficiency	2.1 Health system architecture to meet population needs
	2.2 Incentives for appropriate provision and use of services
	2.3 Managerial efficiency and effectiveness
Equity	3.1 Financial protection
	3.2 Service coverage and access
	3.3 Non-discrimination
Accountability	4.1 Government leadership and rule of law for health
	4.2 Partnerships for public policy
	4.3 Transparency, monitoring and evaluation (M&E)
Sustainability and resilience	5.1 Public health preparedness
	5.2 Community capacity
	5.3 Health system adaptability and sustainability

Source: Universal health coverage: moving towards better health – action framework for the Western Pacific. Manila: WHO Regional Office for the Western Pacific; 2016.

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Legal frameworks play an important role in creating a mandate for UHC, strengthening the rule of law for health, establishing the principles upholding the health system, and defining roles and core service packages. Laws are central to creating and enforcing standards for health infrastructure and the health workforce, developing and implementing regulatory interventions for health protection, and strengthening the regulation of medicines and technologies. They are also essential tools for protecting patient rights, preventing discrimination and promoting equity. More broadly across the SDGs, legal frameworks support multisectoral collaboration for achieving potential win–win situations.

1.4 Common challenge and issues

In many countries, laws are out of date and not consistent with evidence in relation to public health. The result is inconsistencies between domestic and international laws and commitments. This is compounded by the fact that the countries with the oldest laws tend to be less developed countries, with fewer resources to modernize laws. There are numerous statutes, regulations and other instruments that have been passed reactively over a long period of time, usually in response to specific issues or threats. These separate pieces of legislation often contain conflicting or redundant provisions. The use of models from other countries, cut and pasted into existing laws, also leads to unworkable or ineffective public health laws in the statute book. Many countries have passed primary legislation in particular areas of health law but have not developed the necessary subsidiary legislation that enables implementation and enforcement.

In efforts to strengthen these existing legal frameworks, legislative review processes may not be robust and may not involve necessary stakeholders. Policy documents may be drafted as legislation without a clear understanding of the purpose, the context, the relevant evidence or stakeholder feedback. This is particularly an issue in countries that lack in-country expertise and thus need to draw on external consultants who may not be well grounded in local knowledge or important contextual information. Furthermore, the evidence base for effective legal interventions, as well as aspects of the policy development process, and its implementation and enforcement, may be limited. Weak implementation and enforcement may result from lack of sustainable resourcing and technical capacity of the public sector, conflicts with cultural appropriateness and norms, resistance to perceived abuse of power (corruption) or infringement of rights (nanny state), lax regulatory systems and administration, and lack of coherence with other policies, legal frameworks and incentives.

While creating opportunities for health, globalization also presents serious risks. Existing domestic legal frameworks are often inadequate to cope with the vast potential health impacts of international trade. For example, it increases access, availability, affordability and, through online and other globalized marketing platforms, attractiveness of products associated with NCDs such as tobacco and ultra-processed foods high in sugar, salt and fat. Even when taking steps to develop and implement new legal frameworks, countries are often ill-equipped and under-resourced to overcome challenges from the private sector, such as through litigation. Infectious diseases spread as human beings and disease vectors congregate, migrate and travel. Within the health system, trade in goods and services is increasingly globalized. Along with climate change, this places greater emphasis on the need for preventive environmental health interventions as well as surveillance and response systems that are responsive to these changes. The formulation and breadth of the SDGs reflect the growing recognition that current health and development challenges are complex and interlinked and that they demand coherent and inclusive strategies. Member States and WHO are being challenged to develop new ways of working that address the underlying determinants of health and well-being through the strengthening of legal frameworks.

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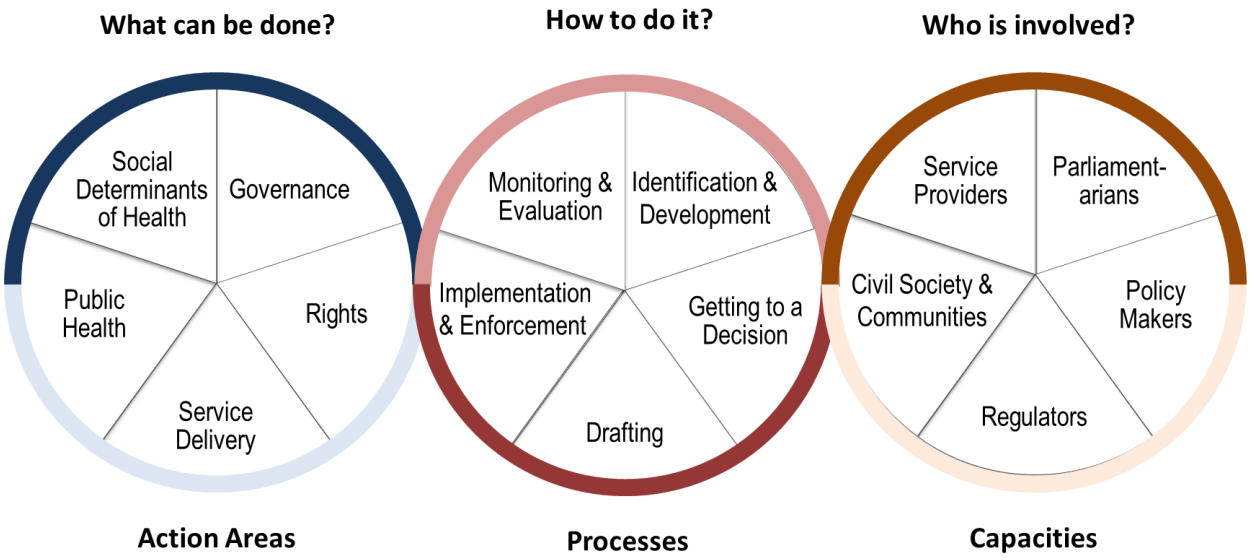
2. ACTING ON THE AGENDA

This Action Agenda is not intended to be prescriptive. It is a starting point for Member States as they consider their responses to the expectations for achieving health in the SDGs. Strengthening legal frameworks should be based on evidence and knowledge, feasible and responsive to the country's context, and consistent with international commitments. Strengthening legal frameworks for health is not just a matter for lawyers, but rather an integral part of the work of all in public health (Fig. 1).

Fig. 1. Strengthening legal frameworks to advance health in the SDGs



2.1 What can be done?

The priorities for strengthening legal frameworks across a wide range of potential action areas will be different from country to country. Actions should be informed by available evidence and knowledge, consistent with international obligations, integrated with non-legislative strategies, and responsive to the needs and feasible within the capacities of the country. Countries should consider actions to enhance health system governance and stewardship; respect, protect, and fulfil the right to health, particularly for the most vulnerable; improve access to affordable, safe and high-quality health services; prevent and manage public health risks; and foster multisectoral collaboration to address the social determinants of health.

2.1.1 Potential actions to better enhance health system governance and leadership

Legal frameworks can help drive a country's endeavours to improve the health and well-being of its people. It is through law that government institutions are assigned their powers and functions, as well as the limits to their powers defined. Clarity, certainty, coordination and leadership are needed to manage the matrix of factors that shape health, provide for the basic needs and rights of the population, coordinate policy responses across sectors, promote the rule of law for health, and ensure sustainable development.

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Member States may consider the following, as appropriate to their context (select country examples are provided in the boxes):

- Setting a clear mandate to assure population health and well-being:
    - Grant a mandate to the responsible minister (or relevant authority), ministry of health and head of department.
    - Ensure the mandate extends to addressing current and future health and demographic changes.
    - Grant power to provide guidance across other sectors in relation to health matters.
    - Extend the scope of the mandate to subnational (local and region in-country) governments and agencies, as appropriate.

Box 1. Papua New Guinea Provincial Health Authorities Act

The Provincial Health Authorities Act was passed in Papua New Guinea in 2007 to provide the foundation for integrating health service delivery in each province. Described as One System Tasol – provincial health authorities are a mechanism whereby provincial governors may bring together provincial health service delivery and hospital service delivery under one authority together with health financing and human resources. Provincial health authorities are designed to enable integrated service delivery and overcome fragmentation caused by successive decentralization reforms.

- Allocating health system functions and powers across government agencies and officers, and promoting roles for non-state actors:
    - Allocate functions at both national and subnational levels consistent with other relevant laws.
    - Be specific so that institutions and individuals have a clear understanding of their role and available powers.
    - Include the power to delegate powers.
    - Establish the legal parameters for relationships with non-state actors such as private providers, civil society and international agencies.

- Establishing coordination and accountability mechanisms, with service users and communities at the core:
    - Define the criteria for the use of powers.
    - Define planning and reporting requirements, including public reporting.
    - Establish appropriate systems for the investigation, suspension and dismissal of officers
    - Establish systems for the review of decisions and appeals in keeping with wider legal and judicial systems and oversight bodies.
    - Ensure non-state actors, such as private providers, and service users are actively encouraged and engaged in the processes of review and accountability, while protecting against vested interests that may conflict with public health objectives and duties.

Box 2. Role delineation policy in Solomon Islands

The health system in Solomon Islands is in transition and the Ministry of Health and Medical Services has embarked on an ambitious reform process based on its newly drafted Role Delineation Policy. The Policy, reflecting the principle of UHC as the backbone of the National Health Strategic Plan 2016-2020, was developed through a series of consultations and meetings beginning in 2011. It is a tool for better defining the range and level of services – or packages of care – to be delivered to given populations across the country. The Government is structuring its legislative reform programme in health to support the roll-out of the Role Delineation Policy. In particular, it is reviewing overarching health administration and service delivery legislation taking into consideration the timing of the roll-out, the capacity and readiness to implement reform, and the importance of establishing policy coherence across government and balancing other concurrent priorities under the national legislative reform programme.

2.1.2 Potential actions to respect, protect and fulfil the right to health

Legal frameworks can help advance the right to health, particularly for the most vulnerable. Law can be a tool, for example, to prohibit and criminalize violence, especially against women and children. It can prescribe the right to privacy, which is core to good public health. A rights-based approach can strengthen the effectiveness of health programmes and services by mandating the effective participation of affected communities.

Member States may consider the following, as appropriate to their context:

- Enshrining the rights of health-care users, families and communities:
    - Entrench the right to health and other health-related rights.
    - Set standards to respect the dignity of patients and protect them from discrimination, abuse or degrading treatment.
    - Protect the privacy, confidentiality and security of personal health information and promote a person's access to their own health information.
    - Require informed consent for medical procedures and promote informed choices by patients, families and communities, particularly for people with an impaired capacity for decision-making.
    - Establish new (or strengthen existing) mechanisms to collect and process complaints and provide redress.
    - Strengthen coherence between international, regional and national commitments to health-related rights and health justice.
    - Consider ratification of existing international instruments related to health and strengthen engagement with international mechanisms that promote health rights.

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Box 3. Recognizing the rights of indigenous and vulnerable populations in New Zealand

Specific provision is made in the New Zealand Public Health and Disability Act 2000 that the objectives of the public health system expressly include the reduction of health disparities by improving the health outcomes of Maori and other population groups in the country, to be pursued to the extent that they are reasonably achievable within the funding provided. One of the key means by which this is achieved is by ensuring performance of these objectives is integrated into planning by health sector participants. To this end, the Act includes mechanisms to enable Maori to contribute to decision-making on, and to participate in the delivery of, health and disability services. These include an objective on District Health Boards: to meet the objectives under the Act; to provide processes for Maori to participate in, and contribute to, strategies for Maori health improvement; and to continue to foster the development of Maori capacity for participating in the health and disability sector and for providing for the needs of Maori.

- Protecting all persons equally and effectively from discrimination:
    - Prohibit discrimination on any ground (including based on race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, disability, health status (including HIV/AIDS), sexual orientation, and civil, political, social or other status).
    - Take immediate action to eliminate discrimination, including by reducing barriers in access to needed services with particular attention to disadvantaged population groups.

- Allowing for human rights derogations in line with the Siracusa principles:[2]
    - Scale the availability of legislative actions in proportion to the assessed risk of the situation.
    - Require officials to choose the alternative that least restricts the liberty/freedoms of the affected populations that will accomplish the public health goal.
    - Provide strong protections for privacy and security of information.
    - Incorporate procedural due process protections including access to appeal.

2.1.3 Potential actions to improve access to affordable, safe and quality health services

Legal frameworks can help provide accessible and acceptable health services that are safe and of good quality. Laws may include regulations specifying standards of health service delivery including the qualifications and capability of staff, the adequacy of infrastructure, the safety of medicines and health technologies, as well as the way people are treated when seeking health services. Regulations for the public and private provision of health services will depend on the way the country's health system is organized. It may include the assignment of particular responsibilities, standard-setting, licensing and registration, the location of health services, consistency with state planning requirements, and conditions on partnerships and contracting arrangements. Governments are increasingly reliant on regulatory strategies to promote health and provide health care, as the role of non-state actors, such as private providers of health services, expands and changes. The environment is also becoming more complex and regulators needs to take into account such complicating factors as the mobility of people and medicines across national borders.

[2] Commission on Human Rights. The Siracusa principles on the limitation and derogation provisions in the International Covenant on Civil and Political Rights; 28 September 1984 (E/CN.4/1985/4, http://www.unhcr.org/refworld/docid/4672bc122.html).

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Box 4. Development of a subdecree on traditional medicine practitioners in Cambodia

Traditional medicine is extensively used in Cambodia. While production and sales of traditional medicines have been regulated for some time, ensuring quality and safety has been challenging. To ensure the quality of traditional health services and to protect patient safety, the National Assembly in Cambodia adopted a new "Law on regulation of health practitioners" on 7 October 2016, and a multi-stakeholder Joint Coordinating Committee to oversee its implementation was created. The scope of this law included traditional medicine practitioners. The Government is now developing a subdecree on traditional medicine practitioners. Regulation of traditional medicine practitioners (Kru-khmer) is a key strategy in the Traditional Medicine Policy of the Kingdom of Cambodia and the Traditional Medicine Strategic Plan 2012–2020. The draft subdecree is composed of eight chapters, which include such matters as definitions, governance, registration requirements and disciplinary processes. The subdecree is expected to play a critical role in improving the safety and quality of traditional medicine services as a significant part of primary health care in the country. In developing and implementing the subdecree, the Government is seeking to balance the need to improve quality and safety of traditional medicine services on the one hand, and ensuring access to traditional medicine services on the other.

Member States may consider the following, as appropriate to their context:

- Regulating the public and private provision of health services to ensure public safety:
    - Regulate public and private facilities including assuring compliance with minimum standards.
    - Regulate the health workforce to ensure that the public has access to competent and safe health workers.
    - Regulate medicines to ensure equitable access to medicines that are of a required quality, safety and efficacy.
    - Regulate traditional medicine products and practitioners to ensure that the public has access to quality, safe and effective traditional medicine products and services, while integrating them into national health systems.
    - Regulate the use of blood products and human tissue to protect donors, recipients and the national supply of these products.

- Establishing quality assurance mechanisms in health facilities:
    - Establish independent mechanisms vested with the power to investigate adverse events.
    - Allocate functions including the power to assess health services, make recommendations concerning quality and monitor the implementation of the recommendations.

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Box 5. Laws in relation to hospitals

A wide range of laws relating to the operation of hospitals need to be considered in efforts to improve quality, safety, efficiency and equity of access to hospital services. Some countries have dedicated hospital legislation. However, in most countries, the range of laws that need to be complied with include:

- regulations in relation to health practitioners, medicines, human organs and tissue, quality and safety, patient protection, and anti-discrimination;
- laws in relation health insurance including private health insurance;
- laws in relation to public health events and emergencies;
- laws that set out requirements in relation to ethics review and approval and the regulation of clinical trials and use of data;
- relevant constitutive and administrative laws for public hospitals including those relating to public finance and public workforce;
- business regulation including competition law, consumer protection, corporations law including directors duties, labour law, foreign ownership and investment restrictions, taxation and insurance requirements, occupational health and safety, and environmental impact regulations; and
- relevant torts law including matters of negligence, nuisance and misrepresentation, and contract law.

- Enabling and supporting partnerships and the engagement of service providers:
    - Define basic criteria and requirements for the establishment of partnerships between public entities, and public and private entities.
    - Set requirements regarding data collection needs, financial accountability and compliance with relevant standards under such partnerships.
- Promoting active engagement with non-state actors for the provisions of health care; mandating requirements for the provision of data and information from public and private facilities.
- Enabling pooled and integrated funding and transparency and accountability for public finances:
    - Set budgetary and expenditure controls, including delegations and procurement regulations.
    - Undertake pricing regulation, including transparency on services and goods pricing.
    - Undertake earmarking and taxation for public health.
    - Define governance arrangements, membership and benefits under social health insurance systems.
    - Ensure appropriate regulation of private health insurance.
    - Set reporting and audit requirements by external providers.

Box 6. Financing for UHC in the Philippines

In 2012, through collaboration between the Department of Health, Department of Finance, Congress and the Office of the President, the Philippines implemented Republic Act 10351, commonly referred to as the Sin Tax Law, which imposed a unitary tax regime on the sales of alcohol and tobacco products and allocated tax revenues to support a wide range of public health initiatives, including UHC, while aiming to decrease consumption of alcohol and tobacco as risk factors for NCDs. During the first three years of implementation, the reform generated a 114% increase in tax revenue amounting to an additional US$ 1.5 billion, tripled national health insurance coverage from 5.2 million to 15.3 million users, and reduced smoking rates among youth (18-24 years) from 35% to 22%. In 2018, the Philippines implemented Asia's first tax on sugar-sweetened beverages, which seeks to address diet-related NCDs, with focus on childhood obesity.

2.1.4 Potential actions to prevent and manage public health risk

Legal frameworks can help to address public health risks. For communicable diseases, this may include information collection and dissemination, surveillance, testing, screening, contact tracing, quarantine, isolation, vaccination and treatment. Law can also be a powerful tool for NCD prevention by shaping the information environment and commercial marketing activities, creating financial incentives and disincentives through taxation and expenditure, shaping the physical environment, and directly regulating the activities of individuals and institutions. Actions should be aligned to meet the country's international health commitments, such as under the International Health Regulations (2005), the WHO Framework Convention on Tobacco Control, and Codex Alimentarius.

Box 7. The adoption of the International Health Regulations (2005)

The International Health Regulations, or IHR (2005), are an international legal instrument designed to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. Revised and adopted by the WHO Member States at the World Health Assembly in 2005, they came into force in 2007 are legally binding upon 194 States Parties around the world (including all WHO Member States). They require States Parties to collaborate with each other in developing national legal, regulatory and administrative provisions for their implementation.

Many Member States in the Western Pacific Region have undertaken assessments of their existing legislation in relation to IHR (2005) compliance. For example, in Australia, amendments were made to the National Health Security Act 2007, and the Biosecurity Act 2015 was developed to further implement the IHR (2005) requirements. Cambodia initiated the development of laws governing communicable disease control in 2008. Though not yet enacted, the country has demonstrated its ability to act during public health emergencies, such as the quarantine of persons exposed to pandemic influenza in 2009, through administrative mechanisms. Viet Nam has an extended legal framework to support IHR (2005) implementation, comprising various laws, regulations, decrees, circulars and decisions. The country conducted an evaluation of the Law on Prevention and Control of Infectious Diseases in 2015 after 10 years of implementation, which is informing an ongoing process of legislative review.

Sources: Joint External Evaluation of IHR core capacities of Australia, Cambodia and Viet Nam.

Member States may consider the following, as appropriate to their context:

- Requiring specified persons to provide information to authorities about health issues of public concern:
    - Specify who should report and in what circumstances.
    - Specify what information should be reported and in what form.
    - Define the consequences for a failure to report.
    - Prescribe how information should be handled to maintain confidentiality and protect the rights of individuals and communities.
    - Grant powers to the person who receives the information to respond appropriately.
- Granting powers to appropriate authorities to effectively manage communicable diseases, including sufficient flexibility to investigate and address non-specific public health risks:
    - Specify who has the power to act or direct those suspected of having a communicable condition that present a major threat to public health.

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  - Define the range of powers necessary to manage public health risk, when these powers should be activated and criteria for their use.
  - Define consequences for failure to comply with lawful direction and relevant enforcement measures.
  - Define limits on powers including rights and avenues of appeal.
  - Specify the responsibilities of individuals with communicable conditions and related enforcement measures.

- Assigning power to the health minister or other responsible person for declaring a public health emergency and authorizing the necessary responses:
  - Define who has power to declare a public health emergency and in what circumstances they can use it.
  - Once declared, define who has which powers to manage the risk to public health, and what the respective role and responsibilities are.
  - Define enforcement measures, as well as relevant offences.
  - Consider relevant national emergency provisions.
  - Consider requirements for international support including expedited importation of approved medicines and supplies, urgent registration of health personnel, and delegation of particular powers, with appropriate safeguards and limitations.

- Assigning responsibility and powers to a relevant authority for the supply of clean water and public sanitation.
- Protecting the public from products that pose public health risks, for example unsafe foods, radiation sources.

Box 8. Incremental whole-of-government approach to strengthening legal frameworks for tobacco control in the Republic of Korea

In 2014, the National Health Insurance Service of the Republic of Korea, which manages the country's single national health insurance system, filed a lawsuit against the three largest tobacco companies in the country to recover approximately US$ 46 million in health-care costs resulting from tobacco use, claiming wrongful manipulation of tobacco products to addict consumers. While the National Health Insurance Service continues to pursue the litigation in court, the Ministry of Health and Welfare has leveraged the strong public support in the wake of the lawsuit to secure a tax reform leading to an 80% tobacco price increase in 2015 – the first in over a decade – and then the implementation of the country's first graphic health warnings in 2016.

- Strengthening health promotion and health education, and protecting the public from exposure to products associated with NCD risk factors, such as tobacco, alcohol, breast-milk substitutes, and foods high in sugar, salt and fat:
  - Ban or restrict marketing of products, including advertising, promotion and sponsorship, particularly to children.
  - Increase taxation on products.
  - Restrict sales to minors.
  - Implement labelling requirements, including content disclosures and warning labels.

- Facilitating the sharing of information between countries and collaboration in addressing regional health threats for more effective and coordinated prevention and management of public health risks.

Box 9. WHO Framework Convention on Tobacco Control – the global health treaty

The WHO Framework Convention on Tobacco Control (FCTC) is the first international treaty negotiated under the auspices of WHO. Having come into force in 2005, the FCTC currently includes 181 States Parties, including all Member States of the Western Pacific Region. From global commitment to national implementation, the WHO FCTC is a legally binding instrument of international law that obligates Parties to implement domestic policy on a wide range of supply and demand measures, including through legal frameworks, while protecting against the vested interests of the tobacco industry.

The Protocol to Eliminate the Illicit Trade in Tobacco Products is a "treaty within the treaty" to secure cooperation between countries in addressing illicit tobacco trade practices through the supply chain, often across borders, which requires collaboration across sectors, including health, trade, finance, customs, police and foreign affairs. Adopted by the Conference of the Parties to the WHO FCTC in 2012, the Protocol requires ratification by 40 countries before taking effect. It is currently at 35.

2.1.5 Potential actions to foster multisectoral collaboration to address the social determinants of health

Legal frameworks can help foster collaboration between the health sector and other sectors on the spectrum of issues that influence and are influenced by health. For example, the criminalization or stigmatization of particular behaviour can be a barrier to accessing treatment and care, trade law can impact on access to medicines, and finance and tax laws affect consumer choices for food, tobacco, alcohol and other products that influence health. These effects can be intended or unintended, more or less direct, and positive or negative.

Table 3. Role of law in multisectoral win–win solutions for health in the SDGs

Stimulating social development	Legal frameworks can: • promote healthy school environments with access to adequate and safe food, water and sanitation; • ensure improved working conditions for men and women in the formal and informal sectors based on internationally agreed standards to reduce their exposure to physical and psychosocial hazards; • mandate working and employment arrangements that include family leave, social protection, breastfeeding at work, and support for family and child care; and • strengthen actions to tackle forced labour, including child labour and human trafficking and to improve access to basic services for refugees and migrants.
Protecting the health of the environment	Legal frameworks can: • provide access to safe spaces and community settings free from violence, with particular attention to women and girls and other disadvantaged groups and incorporate these into urban design; • invest in and regulate for safe and accessible transport, road infrastructure and education to reduce injuries and road traffic accidents, and improve road and rail access to health and other facilities and services; and • support cities and rural areas to prepare for, respond to and recover from disasters.

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Promoting healthy urbanization	Legal frameworks can: • improve systems for food safety and food security, especially for low-income communities and other disadvantaged groups; • assess the health and health equity impacts of proposed infrastructure, mining and other industrial projects; and • strengthen mechanisms and processes to protect the environment from water, air, land and soil pollution and protect biodiversity and ecosystems.

Member States may consider the following, as appropriate to their context:

- Incorporating specific legislative requirements to facilitate cross-sectoral policy and action:
    - Define circumstances in which health impact assessments must be carried out and how these are to be undertaken.
    - Specify how and when the results of a health impact assessment are to be published.
    - Provide a statutory basis for cross-sectoral health plans, agreements and performance frameworks.
    - Establish intersectoral and intergovernmental bodies to work together on shared priorities.

Box 10. Health in All Policies and health impact assessments

Health in All Policies (HiAP) is an approach to public policies *across sectors* that systematically takes into account the health and health system implications of decisions, seeks synergies, and avoids harmful health impacts in order to improve population health and health equity. A HiAP approach is founded on health-related rights and obligations. It emphasizes the consequences of public policies for health determinants and aims to improve the accountability of policy-makers for health impacts at all levels of policy-making (Leppo et al., 2013).

Health impact assessments are an important tool available to governments to advance HiAP. Broadly speaking, health impact assessment is a process that evaluates the potential health effects of a particular policy or project before it is implemented. Legal frameworks can enable this through specific legislative requirements such as defining circumstances in which health impact assessments must be carried out and how. Legal frameworks may further specify in what form and in what circumstances the results of a health impact assessment are to be published.

Box 11. Nutrition in and around schools in the Republic of Korea

The Republic of Korea takes a multisectoral approach to promoting a healthy diet for children in and around schools. The Ministry of Health and Welfare leads implementation of the Child Welfare Act as well as the national obesity programme, which mandate government responsibility to discourage children consuming unhealthy foods. Under the Ministry of Education's School Meals Act and Early Childhood Education Act, school curricula are required to incorporate nutrition literacy, sales of sugary drinks are banned in schools, and nutrition labelling is required for all school meals. The Ministry of Food and Drug Safety implements the Special Act on the Safety Management of Children's Dietary Life, which establishes "Green Food Zones" where stores are subsidized to limit the sale of energy-dense nutrition-poor foods within 200 metres of schools. In recent years, Korean students have reported a decline in their consumption of fast food, instant noodles, confectionaries and carbonated beverages.

Source: Be smart, drink water. Manila: WHO Regional Office for the Western Pacific; 2016.

- Promoting healthier behaviours through laws:
    - Promote planning measures to establish safe and health-promoting environments.
    - Encourage healthy behaviours with subsidies or tax deductions.
    - Work with relevant sectors to protect public health in the negotiation of trade and other international and bilateral agreements.
    - Participate in the development of international conventions and standards and adopt these into domestic frameworks, including in relation to climate change, migration and labour protection.

Box 12. Multisectoral collaboration in tackling antimicrobial resistance

Antimicrobial resistance occurs naturally over time, usually through genetic changes. However, the misuse of antimicrobials is accelerating this process. In many places, antibiotics are overused and misused in people and animals, and often given without professional oversight. Antimicrobial-resistant microbes are found in people, animals, food and the environment (in water, soil and air). They can spread between people and animals, including from food of animal origin, and from person to person. Poor infection control, inadequate sanitary conditions and inappropriate food handling encourage the spread of antimicrobial resistance.

The use of law is one possible tool that may assist a country to manage and address antimicrobial resistance. One of the challenges facing countries is that the approach must be multisectoral given that the risk factors arise in areas administered by different sectors within a national or subnational government. There are several laws that have the potential to assist in a coordinated multisectoral approach. These include the following:

- Laws that establish the health system including allocation of national and subnational health functions and that establish a legal mandate for intersectoral action
- Public health laws that grant power to take or require action to mitigate public health risk
- Laws that establish regulatory systems for access to quality medicines, including licensing of pharmacies and pharmacists
- Laws that establish regulatory systems for health practitioner registration and licensing
- Food safety laws and laws that regulate the use of antibiotics in agriculture and animal husbandry
- Custom laws that regulate imports including in relation to medicines and animal feed.

2.2 How to do it?

Countries will have different priorities in improving various processes to strengthen legal frameworks for health. Processes should address the full cycle of legal development, including problem analysis, stakeholder engagement, drafting and enactment, implementation, and evaluation. Each of these processes can occur together or serially, and are affected by technical, political and other factors. As illustrated in Fig. 2, the players, processes and sequence of activities often overlap, circle back on one another, and have multiple iterations. Necessarily complex and inherently messy, careful mapping and navigation are essential in successfully strengthening legal frameworks.

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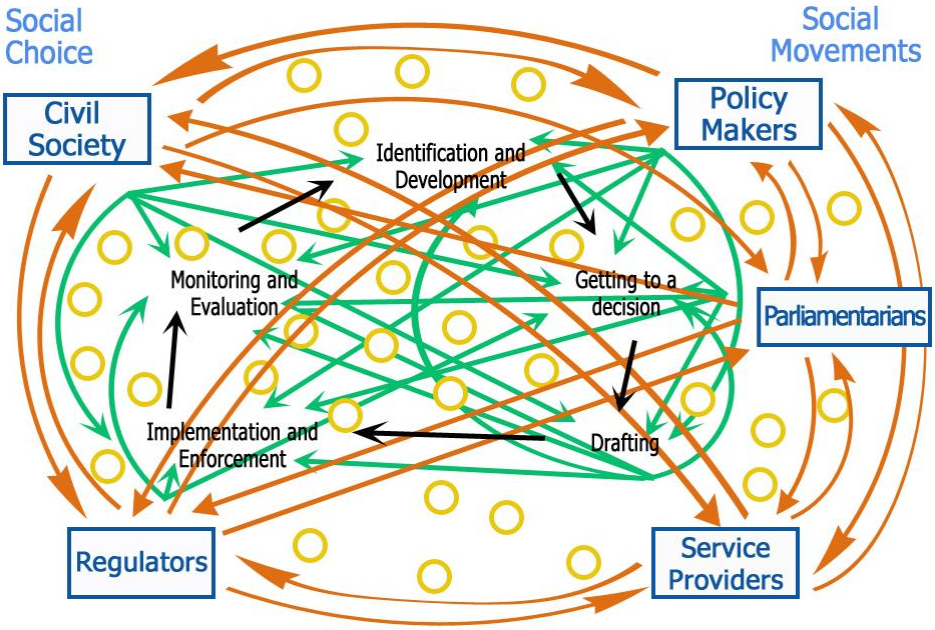
Fig. 2. Navigating the messiness of the legislative process



Source: Adapted from Overseas Development Institute (ODI), undated.

2.2.1 Potential actions to analyse the problem and identify viable options

Legal frameworks for health can be improved to better analyse the problem and identify viable options. The development of law should be based on a clear definition of the problem that the law is aiming to address, including clarity about root causes, objectives of the law, people likely to be affected and the intended (and possible unintended) consequences. This is critical to ensure that the legal framework is fit for purpose. The process should draw on available evidence and include consideration of different legislative and non-legislative options, as appropriate to country needs and capacities, as well as development strategy.

Member States may consider the following, as appropriate to their context:

- Gathering evidence and analysing the problem to be addressed:
    - Consider and focus on the underlying issues.
    - Consult with affected communities in identifying the problem and ways forward, for example through participation in assessments and enquiries.
    - Analyse whether the problem is one of legislative design or implementation, or both.
    - Find out and assess how the problem has previously been addressed.
- Deciding whether government action is the appropriate course of action:
    - Consider whether there is an unacceptable hazard or risk that requires action.
    - Consider whether government has the capacity to intervene and address the risk successfully.
    - Consider costs to government and affected parties of the intervention, and any potential unintended impacts.
- Identifying a range of viable options to address the problem:
    - Consider both legislative and non-legislative options and explore a mix of different options.

- Decide whether maintaining the status quo or strengthening enforcement of the existing legislation will suffice and use this as a reference point for decision-making.
- Consider a mix of different options.
- Ensure that legislation is aligned with the intended regulatory strategy.

Box 13. Elements of a legal framework for standard-setting

One of the most flexible and simple regulatory mechanisms available to governments is setting standards. Standards are norms or measures designed to ensure quality, safety and reliability. In public health, standards are ordinarily set in relation to a system, a service, the safety and composition of therapeutic goods or a health provider's characteristics or competency. Standards may be set as a component of another mechanism, for example as a requirement for registration or as a prerequisite to obtaining an import permit or license.

In legislation, standards can be applied to a class of entities, goods or activities with sanctions for failing to comply. Governments can also impose standards by way of policy without legislative authority. For example, a public health authority could determine that it is only going to purchase health services from providers that meet certain standards.

The basic elements of a legal framework for standard-setting include:

Standards: The legislation will either prescribe standards or empower an authority to set standards by notice or subordinate legislation, or approve standards developed by a technical body. Standards are often technical and complex and may require specialist expertise. .

Administering authority: An authority will need to be given a mandate to administer the standards.

Offences and penalties: The legislation may contain offences and penalties for failing to comply with the standards.

Compliance plan or certification: Regulated entities may be required to demonstrate their compliance. Two common mechanisms are:

(1) compliance plans, which set out how they will implement systems to ensure standards are met; and

(2) certification from a third party that systems, practices or products meet the required standards.

Sampling and testing: If the standards relate to the composition of a product, such as food or medicines, the scheme will need to give the authority power to sample and test the products, on a random or selective basis.

Monitoring and investigation powers: The authority may require monitoring and investigation powers to carry out inspections and ensure compliance with the standards.

Enforcement powers: The authority will need to be given enforcement powers. This may include the power to issue infringement notices, particularly where there are lower-level breaches of the standards.

Public disclosure: The authority should be able or required to disclose incidences of non-compliance with the standards. Public disclosure can be a powerful deterrent to breaches of standards.

- Considering whether the problem is better addressed at the regional or international level:
  - Identify existing legal instruments and consider whether relying on, or modifying, these is sufficient.
  - Decide whether these mechanisms need to be incorporated into domestic legislation.
  - Consider whether new instruments or mechanisms are viable options.

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- Developing a stakeholder consultation strategy:
    - Vary consultations based on the size and nature of the initiative and the groups it is most likely to affect.
    - Include consultation across other relevant government agencies and affected stakeholder groups.
    - Use consultation methods that are inclusive and match the particular stakeholder groups' needs.
    - Ensure there are opportunities for active, free and meaningful participation, with an emphasis on groups that are socially marginalized and risk being excluded from mainstream efforts.
    - Ensure relevant documents are available in formats that are clear and accessible, particularly for target populations (e.g. migrants and others who do not speak the national language, indigenous people, people with disability) who may need translations or other modified formats.

Box 14. Regulatory cooperation and convergence for medicines and workforce in the Western Pacific Region

The *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* was endorsed by the WHO Regional Committee for the Western Pacific in 2017. It guides Member States to strengthen regulatory systems for medicines and the health workforce through a stepwise approach and to consider participating and utilizing global and regional convergence and cooperation platforms to support this process. It emphasizes the need for cooperation among Member States as an approach to extend regulatory reach and enable them to implement the full range of regulatory functions. It also encourages cooperation among Member States to enhance compatibility, and improve compliance and enforcement of regulatory processes.

2.2.2 Potential actions to overcome obstacles and get to a decision

Legal frameworks for health can be improved to better overcome obstacles and get to a decision. Technical challenges should be addressed using the formal processes required, gathering evidence and using these to illuminate and resolve the issue. Political challenges involve a range of interests and stakeholders, whose authentic involvement may be a powerful factor in shaping people's knowledge and attitudes towards the law, and therefore its legitimacy and efficacy. The process should be fair – and seen to be fair – by those affected. Strengthening legal frameworks for health will often be incremental and require ways of identifying windows for change and building political will and support to achieve particular goals.

Member States may consider the following, as appropriate to their context:

- Seeking political opportunities to influence and persuade those in positions of leadership and power:
    - Draw attention to the need for public health law reform based on international instruments and commitments.
    - Advocate public health considerations in trade negotiations and agreements.

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Box 15. Trade law and public health in the Pacific

There is an international trend towards increasing numbers of bilateral and regional trade agreements, and the Pacific island countries are no exception, becoming involved in a number of trade agreements with other countries. These hold significant benefits and can lead to higher living standards and better health. However, trade agreements can also present risks to health unless the health implications are taken into account in their design and negotiation.

Samoa agreed to fully apply most World Trade Organization provisions immediately following accession (with a few exceptions). As a condition of accession, the country agreed to remove its ban on the importation and domestic distribution of turkey tails (a high-fat meat product) within 12 months and replace the ban with less trade-restrictive measures including a domestic ban on the sale of these products and a 300% import duty. During the two-year period following accession, a nationwide programme to promote healthier diet and lifestyle choices was to be implemented, after which the ban on sales would be lifted and the import duty reduced to 100% or replaced by other taxes or regulatory measures compliant with the World Trade Organization.

Source: Legge D, Gleeson D, Snowdon W, Thow AM. Trade agreements and non-communicable diseases in the Pacific islands; 2013.

- Navigating the formal processes and approvals for legislative review:
    - Clearly understand the stakeholders, approvals and processes required for the introduction of legislation.
    - Specify the required approvals, timelines and steps in a plan and timetable for legislative review.
    - Be familiar with the information needs of cabinet or other high-level bodies responsible for approvals and ensure they are accurately and well informed.
    - Follow established rules in relation to drafting of legislation and liaise with relevant agencies of government.
- Navigating the informal systems that affect the passage of legislative review:
    - Undertake stakeholder analysis with potentially interested and affected individuals and groups.
    - Be aware of, and engage, as appropriate, with groups and interests that may oppose particular reforms based on factors such as ideological, economic, religious, political or financial interests, while protecting against vested interests that may conflict with public health objectives.
    - Understand the concerns of particular audiences and use relevant arguments and evidence when addressing these concerns including public health, rights-based or economic arguments.
    - Inform and mobilize the media and the public on relevant issues, including identifying appropriate champions and building networks and coalitions.
    - Draw on regional and international evidence, strategies, mechanisms and instruments to support advocacy efforts.
- Considering incremental steps to the development and passage of law based on capacity to introduce and implement change, and a judgement of social acceptance and political feasibility.
- Considering related health agendas and take advantage of the access to stakeholders to build support for these other changes as well.

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Box 16. Constitutional provisions for participation in legislative review process in Vanuatu

Section 29 of the Vanuatu Constitution establishes the National Council of Chiefs, which is made up of custom chiefs elected by their peers, who sit on the District Council of Chiefs. The National Council of Chiefs has a general competence to discuss all matters relating to custom and tradition and may make recommendations for the preservation and promotion of ni-Vanuatu culture and languages. It may be consulted on any question, particularly any question relating to tradition and custom, in connection with any bill before Parliament.

2.2.3 Potential actions to design the law

Legal frameworks for health can be improved to better design laws. The proposed law should translate the underlying policy and expectations, with drafting instructions providing sufficient detail for the drafter to have a clear sense of what the legislation is intended to achieve, what interventions are required, how the law aligns with existing legal frameworks, and anticipated impacts. Moreover, the legal instrument should be developed from the outset with implementation in mind, including responsibilities for coordination, monitoring and enforcement, and clarity of offences and penalties for non-compliance, including use of revenues from fines. Planning should start early, including resource requirements and the development of new skills (and potentially new agencies or divisions), and address educational needs, attitudes and behaviours of the staff to be involved.

Member States may consider the following, as appropriate to their context:

- Developing drafting instructions prior to drafting the law:
    - Include sufficient detail for the drafter to have a full sense of what the law is intended to achieve, but not in the form of an actual bill.
    - Use clear ordinary language.
    - Explain why the law is needed, what it intends to achieve, and how it will achieve this.

- Drafting law that translates the policy intention into an enforceable and effective legal instrument:
    - Research the existing law and the likely effect of the new law on it.
    - Prepare required amendments to other legal instruments during the drafting process.
    - Ensure the law is legally effective, complies with constitutional issues and is consistent with the rest of the jurisdiction’s legal frameworks.
    - Provide for other subsidiary legal instruments including regulations, rules and delegations to be developed as appropriate.
    - Ensure that the proposed legislative scheme is implementable and practical.
    - Provide for appropriate enforcement mechanisms, including penalties, to ensure compliance.

- Drafting legislation in an organized way with simple and clear language:
    - Organize legislation in a coherent and logical manner keeping a range of readers, not all of whom will have relevant expertise, in mind.
    - Be direct and use the shortest sentences that convey the intended meaning without using unnecessary or complicated words or qualifications.
    - Exclude language and material that has no legal effect.
    - Be consistent in the use of language – that is, not using the same word(s) to convey different meanings or different word(s) to convey the same meaning.

Box 17. Opportunities and risks from legal transplantation

Legal transplantation – importing the law from one country or one tradition to another – is a way of learning and incorporating best practice from other legal regimes. In doing so, it is essential that the transplanted law be adapted to local social, political and cultural realities and broader legal frameworks. In capacity-poor jurisdictions, a new legal instrument may be drafted with the technical assistance of donors without the consultation process that would usually be the norm because of time and resource constraints, and can result in cut-and-paste laws that are not fit for purpose. Due consideration should be given to what is appropriate and can be accommodated in each context, including its fit with administrative capability and available staffing, expertise and funding for implementation.

Sources: Palacio A, Sage CM, Woolcock MJV, editors. The World Bank legal review: law, equity, and development. Volume 2. Washington (DC): World Bank; 2006; Footer M. Technical assistance and trade law reform post-Doha: a brave new world. In: Hatchard J, Perry-Kessaris A, Slinn P, editors. Law and development: facing complexity in the 21st century. London: Cavendish; 2003.

2.2.4 Potential actions to implement the law

Legal frameworks for health can be improved to better implement laws. There are two relatively distinct phases of implementation: the initial phase when a new legislative regime is introduced; and the ongoing administration of the law.[Error! Bookmark not defined.] As emphasized in the prior section, legal frameworks should be designed in a manner that is implementable and enforceable. The ongoing administration of the law is a matter for authorities charged with this responsibility. These authorities, such as regulatory bodies, often work within an envelope of resources, which falls short of their needs. This means decisions and choices have to be made as to how best to meet the demands and expectations of their role.

Member States may consider the following, as appropriate to their context:

- Planning and managing the implementation phase in a proactive manner, including where necessary:
    - Amend relevant policy and planning document to reflect changes in legal frameworks.
    - Revise organizational structures and staffing and undertake necessary professional education, recruit and, where necessary, manage retrenchments in a fair and transparent manner.
    - Develop change management strategies for relevant staff including necessary training, mentoring and development.
    - Consider possible implications for current contractual obligations and assets and liabilities including infrastructure and intellectual property.
    - Amend relevant information, reporting systems and delegations to reflect the changes.
    - Budget for one-off and recurrent costs associated with the new legislative regime, its introduction and staffing consequences.
    - Develop and implement communication strategies to ensure all necessary stakeholders are aware of relevant changes.

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Box 18. Regulating for food safety in Viet Nam

In 2017, the National Assembly in Viet Nam reviewed the implementation of policies and the Law on Food Safety from 2011 to 2016. The review considered technical guidance from WHO and other partners and outlined a series of recommendations for improvements in the legal framework for food safety. As a result of the review, the Vietnam Food Administration under the Ministry of Health in early 2018 was given the task of revising the Law on Food Safety 2010.

In Viet Nam, the Law on Food Safety provides the legal basis for the national food safety system and defines the institutional arrangements for food control. The roles and responsibilities for food safety are divided between three ministries and their subordinate departments and agencies. With multiple regulatory agencies involved, the risk of overlaps and gaps in the enforcement of legal requirements is significant.

With the involvement of food safety regulators from all three ministries, the Law is now being revised with the purpose of overcoming overlaps and gaps in the management of food safety risks. This initiative is part of the Government's effort to strengthen the overall national food safety system.

- Administering regulation in a manner that supports achievement of policy objectives while minimizing burdens and costs to all parties:
    - Define desired regulatory outcomes.
    - Identify and document historical, current and emerging risks in relation to regulatory outcomes.
    - Assess risks to inform the design of regulatory activities, allocation of resources and selection of enforcement strategies.

Box 19. Resourcing and recognition of regulatory functions for medicines

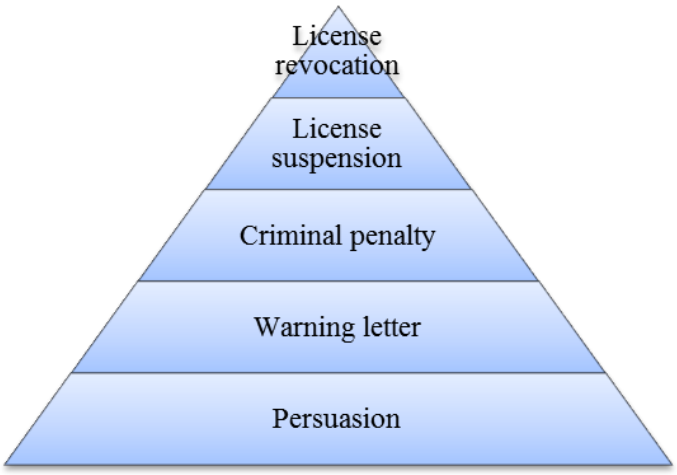
International experience suggests that regulation is only as strong as the political support and allocated resources. Government budgetary support is the financing method employed in most countries; others have a combination of fees and government allocations. Where drug regulatory authorities are financed through a government budget, the fees they charge are almost always much lower than the real costs of the regulatory function. The fees charged vary widely across countries, being much lower in developing countries. This can constrain the ability of the regulatory authority to meet its mandate. Australia is the only country in the Region that is almost entirely self-financed through cost recovery fees and levies. For 2017–2018, the sum of application and evaluation fees for new generic medicines was $A 89 900.[3]

Source: Ratanawijitrasin S, Wondemagegnehu E. Effective drug regulation: a multicountry study. Geneva: World Health Organization; 2002 (http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf).

- Undertaking regulatory activities in a manner that is responsive to the context and conduct of those being regulated:
    - Restrict entry into markets and industries where regulatory requirements are not met.
    - Take a systematic approach to monitoring compliance and enable targeted and proactive response.
    - Employ a range of strategies to manage non-compliance that are proportionate to the risks presented by the non-compliance (see Fig. 3).
    - Develop systems to respond to adverse events to protect the community from harm, including event notification, assessment, response and evaluation.

[3] US$ 67 000, based on the exchange rate as of 20 June 2018 (indexation increase will be applied to fees for 2018–2019)

Fig. 3. Regulatory pyramid of sanctions



Source: Adapted from Ayres I, Braithwaite J. Responsive regulation: transcending the deregulation debate. New York. Oxford University Press; 1992.

Box 20. WHO Nutrient Profile Model for the Western Pacific Region

Nutrient profiling is a method of classifying foods based on nutritional composition, such as amounts of energy (kcal), saturated fats, sugar and/or sodium. The *WHO Nutrient Profile Model for the Western Pacific Region* was developed by WHO, through extensive consultation with Member States, as a tool to identify whether a given food item (e.g. fruit juice) should be prohibited from being marketed to children because it exceeds an established threshold of a nutritive element (e.g. more than 5 grams of sugar per 100 grams of product), aligned with WHO nutritional recommendations (e.g. *Guideline: Sugar Intake for Adults and Children* (2015)). The model also calls for marketing restrictions on items in certain categories (e.g., confectionaries, energy drinks), while allowing for the marketing of traditional items associated with celebratory events (e.g., moon cakes during lunar new year), even if the item would otherwise fail the test. Where countries develop legal frameworks to restrict food marketing to children, a tool of this kind facilitates consistent enforcement.

- Considering social norms and forces as they relate to the achievement of regulatory outcomes:
    - Take account of existing norms and practices and leverage them, where appropriate, to achieve regulatory goals.
    - Develop strategic communications campaigns to influence norms and attitudes.
    - Identify and use social and cultural institutions, including for example traditional leaders and community groups, where appropriate, to facilitate better regulatory outcomes.
- Using big data and technology, with appropriate safeguards, to support regulatory activities, including design, targeting and enforcement.
- Ensuring transparency and accountability in the administration of regulation:
    - Maintain and secure all documentation in relation to regulatory decisions.
    - Develop and implement conflict of interest policies and procedures.
    - Establish processes to handle disputes or disagreements.
    - Monitor complaints and maintain internal review and improvement systems.

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Box 21. Regulatory Powers (Standardisation Reform) Act 2014 (Australia)

The Australian Regulatory Powers Act provides for a standard suite of provisions in relation to monitoring and investigation powers, as well as enforcement provisions through the use of civil penalties, infringement notices, enforceable undertakings and injunctions. It is anticipated that implementing the Regulatory Powers Act will support the Government's regulatory reform agenda as it intends to simplify and streamline regulatory powers across the statute book. This will provide regulatory agencies with the opportunity to use more uniform powers and increase legal certainty for businesses and individuals who are subject to those powers.

2.2.5 Potential actions to monitor and evaluate legal frameworks

Legal frameworks for health can be improved to better monitor and evaluate their effectiveness. Reliable evidence is needed to inform strategy development. Policy and legal interventions will never be perfect and policy-makers need to be able to adapt and respond. Policy-makers need to know what effects law and policy are having and, as far as possible, why and how. Monitoring and evaluation activities should not be limited to the legal intervention itself, but extended to other aspects of the policy development process, and its implementation and enforcement.

Member States may consider the following, as appropriate to their context:

- Identifying priorities for monitoring and evaluation and developing sound evaluation plans.
- Including evaluation as part of the identification and development phase:
    - Identify implementation barriers.
    - Determine whether a proposed strategy will work or not.
    - Specify the outcomes to be monitored and evaluated.
- Collecting and managing data necessary for monitoring and evaluation work:
    - Share information between sectors and countries to the mutual benefit of all.
    - Promote the public availability of information and data at all stages of the process to ensure informed community participation.
- Developing expertise to undertake monitoring and evaluation work:
    - Engage academic and research institutions.
    - Identify pressing policy issues for evaluation and research.
    - Ensure that external experts have proven subject matter/content knowledge and experience.
    - Ensure that all relevant ethical and privacy clearances are obtained before undertaking research.
- Making evaluation and research findings accessible through virtual and other channels that are readily accessible to health professionals, policy-makers and the public.
- Including persons most directly affected by legislation as much as possible in the monitoring and evaluation of its effects, to ensure the subjects' perspective is prominent in assessing the impact of the legislation.

Box 22. Policy surveillance

Policy surveillance is the ongoing, systematic collection, analysis and dissemination of information about laws and other policies of health importance. The rationale for policy surveillance is that if law matters to health, public health officers, policy-makers, researchers and the general population need basic information about what the law requires and where it applies. Policy surveillance can serve a number of basic country needs. It answers the consistent demand of countries for information about what other countries are doing in a particular area, and provides access to policy models that can help countries devise their own versions. Surveillance allows the identification of trends which can influence lawmakers to take action. It creates data for evaluation and research, and it supports diffusion of knowledge and legal competency.

Source: Burris S, Ashe M, Levin D, Penn M, Larkin M. A transdisciplinary approach to public health law: the emerging practice of legal epidemiology. Annual Review Public Health. 2016;37:135–48.

2.3 Who is involved?

Countries have different priorities for enhancing the capacities of various stakeholders involved in strengthening legal frameworks for health. Policy-makers and regulators are essential players in developing and implementing laws for health. Parliamentarians are critical with their powers to enact law, approve budgets and provide oversight. The integral role of health providers and communities demand transdisciplinary approaches to public health law can help break down disciplinary, cultural and resource barriers.

2.3.1 Potential actions to build the capacity of policy-makers

Legal frameworks for health can be strengthened through enhanced capacities of policy-makers. Policy-makers are central to the development, implementation and evaluation of health policy, including through law, from defining the problem and setting the scope and objectives of legal review, to monitoring implementation, evaluating the effectiveness of the legal framework and drawing on related research.

Member States may consider the following, as appropriate to their context:

- Developing the capacity to define problems and develop viable options to address them:
    - Develop an appreciation of legal and non-legal strategies to advance UHC and the SDGs.
    - Develop and ensure access to relevant evidence and understand the impact of legal intervention.
    - Draw as needed upon legal expertise in relevant areas of practice, including specializations such as legislative drafting.
- Planning and coordinating formal legal review processes, including approvals and stakeholder management and implementation strategies.
- Building the skills and knowledge for communicating with different categories of stakeholders:
    - Provide advice and use effective communication strategies to engage parliamentarians and other decision-makers.
    - Strengthen relationships across ministries, and build the capacity to articulate the centrality of health to social and economic development and to other sectoral priorities.
    - Build expertise in health diplomacy and the political process to influence and shape global and regional initiatives that have on impact on health.

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- Consult, research and seek informed advice on the impacts the law could have and the steps needed to ensure it benefits its intended communities.
- Train on the arguments for economic development through trade including international, regional and bilateral trade agreements and their potential impact on health.
- Raise awareness of entry points that provide opportunities to influence legal development and be able to navigate the political and economic forces that can be obstacles to, or support legal changes.

Box 23. International Legal Training Program at the McCabe Centre for Law & Cancer

The McCabe Centre for Law & Cancer (Melbourne, Australia), WHO Collaborating Centre for Law and Noncommunicable Diseases since 2018, conducts a biannual International Legal Training Program aimed at strengthening national capacities in the effective use of law for the prevention and control of NCDs. Covering a wide range of topics (including global governance; post-2015 sustainable development agenda; global NCD agenda; legal issues in tobacco control, alcohol control and promotion of healthy diets; WHO FCTC; international trade and investment law; intellectual property law; and law enforcement in low-resource settings), the curriculum includes classroom training and development of individual priority projects for each participant. In collaboration with WHO, the Program invites government lawyers, NCD focal points, and others well-placed to drive action on NCDs in low- and middle-income countries.

2.3.2 Potential actions to build the capacity of regulators

Legal frameworks can be strengthened through enhanced capacities of regulators. Whereas effective regulatory administration supports achievement of key policy objectives while minimizing the burden and compliance cost for regulated entities, well-functioning regulators should: have a clear understanding of the regulatory outcomes being sought, apply a risk-based approach to regulatory administration, effectively engage with stakeholders to share and collect information, use information as a source of intelligence to guide regulatory activity, be transparent in their approach, be accountable for their actions and decisions, and monitor and report on their performance and the effectiveness of the regulatory regime.

Member States may consider the following, as appropriate to their context:

- Developing guidance for regulators to improve understanding of relevant legal frameworks, powers and constraints within which they operate.
- Using information and evidence to inform regulatory approaches:
    - Develop systems and capacity to manage and analyse data.
    - Develop an understanding of regulatory theory and different approaches and strategies.
- Fostering productive relationships with relevant stakeholders including the regulated entities, as well as other regulators within the country and regionally and internationally.
- Securing adequate financial support for the regulatory system, along with the recognition that it is an essential component of the health system.

2.3.3 Potential actions to engage parliamentarians

Legal frameworks can be strengthened through enhanced capacities of parliamentarians. In addition to passing legislation, approving budgets and providing oversight, parliamentarians foster multisectoral collaboration, encourage participation of their constituencies and ensure alignment of national implementation with international commitments. Engagement with parliamentarians represents a whole-of-government approach to strengthening legal frameworks for health.

Member States may consider the following, as appropriate to their context:

- Raising awareness for parliamentarians on their central role in advancing UHC and achieving health in the SDGs:
    - Develop policy briefs and other advocacy materials targeting parliamentarians.
    - Organize policy dialogues to inform parliamentarians about priority health issues.
    - Identify champions for health among parliamentarians.
- Establishing strategic platforms for engagement between government and parliament:
    - Map budget cycles, parliamentary schedules and the electoral calendar to assist in identifying entry points and timing.
    - Engage with standing health committees and other committees relating to health, such as population and development, gender and equality, environment, labour, agriculture, education, finance, and trade.
    - Maintain lines of communications with parliamentarian secretariat staff to ensure immediate access and follow-up address health issues.
    - Support participation of parliamentarians in domestic and regional health fora.
- Providing technical assistance to parliamentarians in advancing action on health
    - Offer public support and visibility to parliamentarians who champion public health priorities.
    - Provide access to evidence and knowledge to support policy development, including the development of law.

Box 24. Asia Pacific Parliamentarian Forum on Global Health

The Asia-Pacific Parliamentarian Forum on Global Health is a platform for parliamentarians to exchange ideas, build political will, strengthen capacities and foster collaboration in driving sustainable action for health. Launched in 2015 by the Republic of Korea, with support from WHO, the Forum is open to 30 countries across the Asia-Pacific region. The Forum aims to enhance the role of parliamentarians in achieving health in the SDGs. Engagement with parliamentarians through the Forum represents an important part of WHO's support to Member States in strengthening legal frameworks through a whole-of-government approach.

2.3.4 Potential actions to empower and ensure the participation of communities

Legal frameworks can be strengthened through enhanced capacities of communities. The active involvement of communities, as represented by civil society, is essential to shaping the substance, legitimacy and acceptability of law. As users of the law, communities can themselves be agents and advocates of change. It is important to ensure their "legal literacy", particularly among disadvantaged groups.

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Member States may consider the following, as appropriate to their context:

- Ensuring the participation of communities in developing or amending health-related law:
    - Identify and reduce barriers to the free, active and meaningful participation of communities in legislative review processes.
    - Use the law to set requirements for the participation of civil society and communities in legislative review.
    - Engage communities and civil society in the implementation of the law and regulatory strategies.
    - Build communities' knowledge of their rights, legal entitlements and obligations, and the avenues for asserting them.
    - Facilitate the organization of community groups to strengthen the community voice and ensure that law and policy respond to community needs.
    - Identify the most vulnerable of the populations affected by the law and ensure their voices are heard.
- Identifying potential champions, such as community leaders, media and celebrities, who are well positioned and willing to support the changes proposed and their purposes.
- Engaging academic institutions in monitoring, evaluation and the research of the law and public health
    - Identify pressing policy issues that need to be subjects of evaluation and research.
    - Support and commission work on, for instance, the monitoring of laws, comparative analysis and empirical research.
    - Draw on findings of evaluation and research and incorporate these into the strengthening of legal frameworks.
    - Support the development of courses and professional development programmes on policy, law, health ethics and public health.
    - Engage academic institutions in the continuing professional development of the public health workforce.

Box 25. Engaging health users and civil society in transforming legislation

Established in the 1970s by people with disabilities themselves, the Fiji Disabled Persons Federation actively advocates for Fijians who have a disability, so that they can participate on an equal basis as other Fijians. At the national level, the Federation works with government and key actors to ensure the voice of people with disabilities is heard. This voice is one collected through active engagement of its members in many communities across Fiji. By engaging community members with disability and their families directly, the Federation can legitimately gather the key priorities and needs of people with disability to ensure government have relevant information for developing laws and policies.

The United Nations Convention on the Rights of Persons with Disabilities was signed by Fiji in 2010 and ratified in 2017. Before ratification, and ongoing today, the engagement of the Fiji Disabled Persons Federation has been essential in encouraging and supporting the Government of Fiji to understand and implement its obligations with respect to persons with disabilities as described in the Convention. The tireless activism from civil society such as the Federation not only contributed to ratification of this groundbreaking treaty on human rights, and particularly those rights associated with persons with disabilities and their families, but also contributed to Fiji's Rights of Persons with Disabilities Bill 2016. The Bill will help the Government to ensure people with disabilities have access to services like health care, and promote, protect and fulfil their rights on an equal basis. The engagement of disabled persons organizations is essential to support governments to develop effective legislation and policy, and support their implementation. In many countries in the Western Pacific Region, civil society actors like disabled persons organizations work from the community level to the national level, as government counterparts to help inform legislation and provide feedback to its implementation.

2.3.5 Potential actions to coordinate with health providers

Legal frameworks can be strengthened through enhanced capacities of health providers. Service providers and professional associations have multifaceted roles in relation to strengthening legal frameworks. They are the subject of regulation, but they are also an important source of information on problems and issues as well as being able to assist in generating solutions and navigating legislative change. Professional associations are well positioned to explain proposed changes to their members and other stakeholders, to provide constructive criticism and suggestions, and to help build consensus.

Member States may consider the following, as appropriate to their context:

- Engaging with service providers and professional associations throughout the process of developing, implementing and evaluating legal frameworks:
    - Gather views and information and develop options during the identification and development phase of legal review.
    - Ensure those represented by providers and associations are aware of how legal reforms will affect them and can contribute meaningfully to the process.
    - Take into consideration the feedback and its significance for the content and framing of legal design.
    - Involve service providers in ongoing monitoring and evaluation with the aim of improving and strengthening legal frameworks.

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3. RECOMMENDATIONS

Member States and WHO have complementary roles and commitments in the strengthening legal frameworks for health.

3.1 Recommendations for Member States

As appropriate to national needs and capacities, Member States may consider taking the following actions towards strengthening their legal frameworks for health:

- Undertake review of legal frameworks for health in aligning their national health strategies with broader efforts to advance UHC and achieve health in the SDGs, and taking into consideration:
- Set priorities for action areas and develop a programme for the strengthening of legal frameworks for health.
- Improve processes in the development, implementation, and evaluation of legal frameworks for health.
- Enhance the capacities of stakeholders involved in strengthening legal frameworks within and beyond the health sector.
- Cooperate with other countries to ensure the consideration of health in developing international legal instruments, such as agreements on trade and environment.
- Enable action on cross-border health risks and issues through legal frameworks.

3.2 Recommendations for WHO

Upon request, WHO may support Member States in strengthening their legal frameworks for health, as follows:

- Raise awareness on the importance of law for health and advocate for strengthening legal frameworks to advance universal health coverage and achieve health in the Sustainable Development Goals.
- Enhance access to evidence and knowledge to support countries in their efforts to review existing legal frameworks for health and determine priorities for action.
- Provide technical assistance to countries in their efforts to improve processes and enhance capacities for strengthening legal frameworks for health:
- Facilitate dialogue and cooperation between Member States to address cross-border health issues, foster regional collaboration opportunities; and engage in joint advocacy and action to shape international agendas.
- Mobilize legal expertise for health.

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GLOSSARY

Term	Definition
Capacity-building	Capacity-building is the development of knowledge, skills, commitment, structures, institutions, systems and leadership to enable effective and healthy public policies. (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Civil society organization	Civil society organizations are non-state, not-for-profit, voluntary organizations formed by people from the community, but excluding political parties and commercial firms. This includes a wide range of organizations, networks, associations, groups and movements independent from government. They sometimes unite to advance common interests through collective action. Some definitions also include certain businesses (e.g. media, private schools, for-profit associations), however by definition, all civil society organizations are not affiliated with government and would be expected to have mandates to benefit society and those in need. (Adapted from WHO. (n.d.). Glossary of globalization, trade and health terms. Retrieved from: http://www.who.int/trade/glossary/en/)
Community	A community is a specific group of people, often living in a defined geographical area, who share a common culture and are arranged in a social structure according to relationships. Members of a community gain their personal and social identity by sharing common beliefs, values and norms. (Adapted from WHO, (n.d.). The WHO Health Promotion Glossary. Retrieved from: http://www.who.int/healthpromotion/about/HPG/en/)
Disadvantaged groups	Disadvantaged, marginalized and vulnerable groups are groups of people who, due to factors outside their control, do not have the same opportunities as the general population and are at a higher risk of poverty and social exclusion. Depending on the context, these may include unemployed people, refugees, indigenous peoples or those from ethnic minorities, internally displaced people and migrants, the homeless, those struggling with substance abuse, people with mental illness and disabilities, isolated older people and children. (Adapted from WHO. (n.d.). Health impact assessment (HIA), glossary of terms used. Retrieved from: http://www.who.int/hia/about/glos/en/)
Discrimination	Discrimination in health is any negative judgement about a person or group made on the basis of ethnicity, sex, language, religion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation, civil, political, social or other status or opinion that limits their access to health care or the underlying social determinants of health. Discrimination can mean poorly targeted health programmes or restricted access to services. Discrimination means that those with equal need are not treated equally. Overcoming discrimination demands objective, reasonable criteria intended to rectify inequities in health. (Adapted from WHO. (2015). Health and human rights. Retrieved from: http://www.who.int/mediacentre/factsheets/fs323/en/)
Disability	Disability is a complex phenomenon, reflecting the interaction between features of a person's body and features of the society in which he or she lives. It is an umbrella term, which includes impairments, activity limitations and barriers to their full and effective participation in society on an equal basis with others. Overcoming the limitations faced by people with disabilities requires interventions to remove these barriers. (Adapted from WHO. (2011). World report on disability. Retrieved from: http://www.who.int/disabilities/world_report/2011/report/en/)

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Governance	Governance is the exercise of economic, political and administrative authority to manage a country's affairs at all levels. It comprises the mechanisms, processes and institutions through which citizens and groups articulate their interests, exercise their legal rights, meet their obligations and mediate their differences. Good governance characteristics and principles include: consensus-orientation, participation, rule of law, effectiveness and efficiency, accountability, transparency, responsiveness, equity and inclusiveness. (Adapted from UNESCAP. (n.d.). What is good governance? Retrieved from: http://www.unescap.org/sites/default/files/good-governance.pdf)
Health diplomacy	Health diplomacy brings together the disciplines of public health, international affairs, management, law and economics, and focuses on negotiations that shape and manage the policy environment for health. The relationship between health, foreign policy and trade is at the cutting edge of global health diplomacy. (Adapted from WHO. (n.d.). Global health diplomacy. Retrieved from: http://www.who.int/trade/diplomacy/en/)
Health impact assessment	Health impact assessment (HIA) is a means of assessing the health impacts of policies, plans and projects in diverse economic sectors using quantitative, qualitative and participatory techniques. HIA helps decision-makers make choices about alternatives and improvements to prevent disease/injury and to actively promote health. (Adapted from WHO. (n.d.). Health impact assessment. Retrieved from: http://www.who.int/hia/en/)
Health inequity	Health inequities are differences in health outcomes that are unnecessary and avoidable, and therefore unfair and unjust. (Adapted from: WHO Regional Office for the Western Pacific (n.d.). Health topics: Equity. Retrieved from: http://www.wpro.who.int/topics/equity_health/en/)
Health sector	A wide variety of actors and organizations that is held politically and administratively accountable for the health of the population at various levels. (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Health service	Health services are any services (i.e. not limited to medical or clinical services) that contribute to improved health or to the diagnosis, treatment and rehabilitation of sick people. (Adapted from WHO. (n.d.). Health systems: health systems strengthening glossary. Retrieved from: http://www.who.int/healthsystems/hss_glossary/en/)
Health system	Health systems encompass: (i) All the activities whose primary purpose is to promote, restore and/or maintain health; and (ii) the people, institutions and resources and policies intended to improve the health of the population and protect people from the cost and burden of ill health through activities planned and provided to improve health. (Adapted from WHO. (n.d.). Health systems: health systems strengthening glossary. Retrieved from: http://www.who.int/healthsystems/hss_glossary/en/)
Health workforce	Health workers are "all people engaged in actions whose primary intent is to enhance health". (Adapted from WHO. (2006). World health report. Working together for health. Retrieved from: http://www.who.int/whr/2006/en/)
Intersectoral action	Intersectoral action refers to the coordinated efforts of two or more government sectors, including across different levels of governance (national and subnational). Whole-of-government, health in all policies (HiAP) and healthy public policies are similar terms used in the literature. (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Multisectoral/	A whole-of-government or multisectoral approach refers to the coordinated

intersectoral/ whole-of-government approach	efforts between two or more government sectors. This can include such partnerships as information-sharing arrangements or joint programmes. Such coordination and integration is often centred on overarching societal goals rather than the specific objectives of one sector. (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Multi-stakeholder/ whole-of-society approach	A whole-of-society or multi-stakeholder approach refers to coordinated efforts by multiple stakeholders within and outside of government (including the private sector, civil society or communities). (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Nongovernmental organizations	Nongovernmental organizations are organizations not affiliated with government. The term is used to describe non-profit making, non-violent organizations that seek to influence the policy of governments and international organizations and/or to complement government services (such as health and education). They usually have a formal structure, offer services to people other than their members, and are, in most cases, registered with national authorities. Nongovernmental organizations vary greatly in their size, scope of activity and goals. They may operate nationally, or internationally, or they may be small community-based organizations (CBOs) that aim to mobilize, organize or empower their members and others, usually in a local area. (Adapted from WHO. (2004). A glossary of terms for community health care and services for older persons. Retrieved from: http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf)
Participation	All people and groups are entitled to active, free and meaningful participation in, contribution to, and enjoyment of civil, economic, social, cultural and political development in which human rights and fundamental freedoms can be realized (UNDG, 2002). Human rights law recognizes the participation of the population in all health-related decision-making at the community, national and international levels (CESCR, 2000). Participation is one of the human rights principles that needs to be considered when applying a human rights-based approach to health. Adequate and sustainable financial and technical support, including investment in empowerment of rights-holders, is essential to enable meaningful participation. (Adapted from UN Committee on Economic, Social and Cultural Rights. (2000). General Comment 14 on the right to the highest attainable standard of health. Retrieved from: www.refworld.org/pdfid/4538838d0.pdf. UNDG. (2002). UN Statement of Common Understanding on Human Rights-Based Approaches to Development Cooperation and Programming. Retrieved from: http://hrbaportal.org/the-human-rights-based-approach-to-development-cooperation-towards-a-common-understanding-among-un-agencies)
People-centred care	Care that is focused and organized around the health needs and expectations of people and communities rather than on diseases. Whereas patient-centred care is understood as focusing on the individual seeking care (the patient), people-centred care encompasses these clinical encounters and also includes attention to the health of people in their communities and their crucial role in shaping health policy and health services. (Adapted from WHO. (n.d.). Health systems: health systems strengthening glossary. Retrieved from: http://www.who.int/healthsystems/hss_glossary/en/)
Social determinants of health	Social determinants of health refer to the conditions in which people are born, grow, live, work and age, including the health system. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels. (Adapted from WHO. (2008). Closing the gaps. Final report of the WHO Commission on Social Determinants of Health. Retrieved from: http://www.who.int/social_determinants/thecommission/finalreport/en/)
Stakeholders	As used in this action agenda, the term encompasses a broad scope of different

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beyond government	actors, organizations and partners, such as non-state, non-government and civil society actors, professional and faith-based organizations, politicians and parliamentarians, academic and research organizations, foundations and businesses. A stakeholder is a person or group who has an interest or concern in a process of issue. (Adapted from WHO. (2015). Health in All Policies training manual. Retrieved from: http://who.int/social_determinants/publications/health-policies-manual/en/)
Sustainable development	Development that meets the needs and aspirations of the present without compromising the ability of future generations to meet their own needs. (Adapted from World Commission on Environment and Development. (1987). Our Common future. Appendix to document A/42/427 on Development and International Co-operation: Environment. Retrieved from http://www.un-documents.net/wced-ocf.htm)
Universal health coverage	Universal health coverage means that all people and communities receive the health services they need. This includes health promotion, treatment, rehabilitation and palliation of sufficient quality to be effective while at the same time ensuring such care does not cause financial hardship. (Adapted from WHO Regional Office for the Western Pacific. (2016). Universal health coverage: moving towards better health. Action framework for the Western Pacific Region. Retrieved from: http://iris.wpro.who.int/handle/10665.1/13371)
Whole-of-government approach	See multi-stakeholder approach
Whole-of-society approach	See multisectoral approach

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APPENDICES

Appendix 1. Summary of common legislative strategies for health, challenges and emerging issues, and promising practices

Objectives	Common Strategies	Challenges & Emerging Issues	Promising Practices	*SDGs*
Constitute Health System Governance and Leadership				
Health sector governance	• Establishment of agencies and legal mandates • Definition of legal requirements and processes • Definition and protection of rights	• Coherence across health system • Enabling intersectoral action	• Administrative infrastructure to support implementation, participation and a Health in All Policies (HiAP) approach • Collaboration in legislation and regulation development	3
Health information	• Reporting requirements e.g. mandatory sharing of surveillance information • Privacy and confidentiality regime, including sanctions • Mandatory labelling • Incentives e.g. reimbursements • Licensing of research and information actors • Information sharing agreements • Establishing centralized repositories of information e.g. National Health Facility Registry • Authorised body for dissemination of information • Establish clear procedures for information sharing and feedback across sectors	• Adequate safeguards • Appropriate reporting mechanism • Enforcement • Accuracy of information • Health literacy	• Regulation of care coordination and management • Integration of medical records • Legislation governing control of health information e.g. health records , data collection, record keeping, confidentiality, retention and access • Mandatory collection and reporting of data for public health e.g. designation of ‘reportable diseases’ • Mandatory measuring and reporting of quality indicators e.g. mortality rates • Adequate safeguards to protect patient privacy and confidentiality • Regulatory system for research authorization and access to research information, including provisions for informed consent • Penalties for violating security of health information	3

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Ensuring Access to Affordable, Safe and Quality Health Services				
Access to quality medicines	• Establishment of regulatory authority • Establishment of a quality assurance system • Regulation of marketing, production, storage, dispensation and distribution of pharmaceuticals and medical devices • Licensing and Inspection of medicines • Power to recall substandard medicines • Transparency and enforcement of standards • Quality assurance mechanism • Public procurement legislation • Regulation of special categories of medicines such as antimicrobials • Utilize TRIPS-Plus provisions • Establish principle of universal health coverage in law	• Understanding current legal environment • Scope of innovation in legal frameworks • Constraints under international law • Harmonization and collaboration in international law • Conflicts of interest • Rationalization of regulatory regimes • Weak enforcement	• Regulatory harmonization e.g. EAC medicines regulatory harmonization project model for the continent-wide African Medicines Regulatory • Implementation of FENSA • Flexible licensing for priority and emergency medicines • Use of TRIPS-Plus and advocate for the inclusion of public health safeguards in other investment and trade treaties e.g. Thailand • Incorporating equity, sustainability and human rights principles in national medicines policies • Collaboration on medicines procurement e.g. Pacific Medicines Pool • Pharmaceutical sector regulation • Pharmaceutical and medical technologies regulation e.g. Cambodia and establishment of inter-ministerial committee to tackle counterfeit and sub-standard medicines	3

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Access to quality services	• Health work registration and licensing • Accreditation of providers and training institutions • Complaints and investigation system to support registration, accreditation and licensing • Anti-discrimination legislation (employee and service delivery) • Mandate for strategic planning and decision-making • Accountability and mandated operational transparency of designated authority • Patient confidentiality system • Informed consent and bodily autonomy of patients • Occupational health and safety regulations • Mandatory reporting • Financing, including social health insurance	• Limited and inequitable distribution of resources • Structure of a health system e.g. degree of decentralization or fragmentation • Weak regulatory systems and inadequate enforcement • Changing environment and patient demands • Poor coordination and integration, • Overuse, underuse or misuse of services and resources • Migration of healthcare workers	• Health Insurance Schemes • Subsidies for vulnerable populations e.g. extension of insurance to children under 12 • Global patient safety and quality guidelines • Non-discrimination in service delivery • Coordination and collaboration, including cross-regionally e.g. cross-accreditation of health workers in Fiji and Vanuatu • Monitoring and regulation of health workers, facilities and education institutions e.g. Philippines Commission on Higher Education • Enforcement of accreditation and licensing regimes e.g. Australia's self-funded multi-practitioner regulation under one legislative framework	3

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Adequate & sustainable financing	• Subsidies • Defining membership and benefits under Social Health Insurance • Taxation for public health • Earmarking of budget line for health • Regulation of revenue collection • Regulation and reporting of pooled funds • Regulation of private health insurance • Regulation of providers • Public procurement legislation • Pricing regulation, including transparency on services and goods pricing • Audits by external providers • Establishing a governing board (or other authority) to oversee public health insurance with appropriate safeguards	• Capacity – management, administration and financing • Understanding current health care organization and priorities • Fragmentation of funding • Efficient use of donor funding • Corruption	• Periodic legislative reform • Administrative infrastructure to facilitate public and stakeholder participation • International standards integration • Strengthening regulatory institutions • Enhancing social accountability • Clarifying legal entitlements and obligations • Legislation protecting vulnerable populations	3

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Mental health	• Defining membership and benefits under social insurance scheme to include mental health • Integration of mental health with social care • Legislation regulating voluntary and compulsory treatment that conforms to human rights standards • Quality assurance guidance and oversight for mental health institutions and services • Right to access legal representation	• Evidence based legislation e.g. punitive incarceration does not meet modern medicine best practice • Ensuring legislation incorporates a rights based approach e.g. the right to dignified care • Mental health coverage in health benefits package • Access to justice for mental health care patients • Elimination of legislation that facilitates negative health outcomes e.g. use of isolation rooms (including in prisons)	• Legislation controlling dangerous substances e.g. agricultural poisons used in suicide attempts • Anti-discrimination legislation and protections for persons with mental health conditions • Automatic periodic review period for any detention associated with a mental health condition that is reasonable and timely • Enshrine presumption of self-determination in law • Mental health legislation that incorporates access to justice principles i.e. a legal process with qualified decision-maker in any instance where a person is being deprived of their liberty • Mandatory requirement to inform a potential patient or patient or their legal rights • Legislation that protects patients' rights	3
Preventing discrimination and stigma	• Anti-discrimination legislation • Parental protection legislation • Defining entitlement to maternal and child health services • Defining protected categories for vulnerable persons e.g. persons with HIV from discrimination • Human rights legislation • Embed principles of non-discrimination across policy areas and law reform	• Enforcement of anti-discrimination provisions • Social context that contributes to discrimination and stigma • Removal of systematic discrimination in laws e.g. differential treatment for women and men or minorities • Audit of new legislation for potentially discriminatory consequences • Harmonization with international instruments e.g. ICCPR	• Non-discrimination in the financial protection e.g. insurers cannot deem childbirth as a pre-existing condition • Non-discrimination incorporated in the delivery of health services and health benefits packages	3,5

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Preventing and Managing Public Health Risk				
Clean water, sanitation and hygiene	• Water management duties powers and responsibilities to relevant ministry or local governments • Accreditation of water facilities • Regulation of wastewater • Regulation of water pollutants • Legislation protecting vulnerable populations • Mandatory health impact assessments for new buildings and facilities • Mandatory requirements for provision of equitable sanitation facilities • Regulation and coordination of non-state actors delivering WASH support	• Lack of adequate infrastructure • Lack of integration with vertical programme management • Disruption during emergencies • Gender inequity • Water scarcity	• Agreements between relevant government entities and partners e.g. Memorandum of Understanding between water, health, education and finance ministries in Ethiopia • Coordinated funding agreements e.g. DfiD/Jubilee Trust collaboration with WASH stakeholders in Brazil • Incorporation of a human rights based approach to water • Mandatory public reporting of water quality • Mandatory rainwater collection and conservation	3,6

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Food safety and security	• Food safety regulations and standards in line with international recommendations such as Codex Alimentarius • Food safety guidelines and codes of practice • Define roles and responsibilities of stakeholders in the food system • Food safety standard • Codes of conduct for handling of food • Enforcement of food safety legal requirements • Establish powers to regulatory authority to oversee food safety • Mechanisms to monitor and evaluate performance of the food safety system	• Information underpinning evidence for legal interventions • Legal and policy information on food • Evolving food environment Emerging food safety issues (e.g. climate change, new technologies) • Rationalization with international trade law and agreements • Enforcement of food safety regulations • Regulatory impact assessment • Deteriorating trust in food safety systems	• Standards for food fortification and/or thresholds for sugars, fats and sodium in processed food • Development of model legal instruments (in particular in Pacific island countries and areas) • Adoption of risk-based regulatory frameworks to the management of food safety • Implementation of a food chain approach to the regulation of food safety and security • Establish partnerships across sectors, stakeholders and national borders • Strengthen leadership and common priorities for food safety and security	2,3

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Management of communicable diseases	• Establishment of a body to manage and coordinate communicable disease initiative • Grant powers to a body to utilise resources in an emergency e.g. access to laboratory equipment • Standard setting of service delivery, facilities • Monitoring of service delivery • Establish principle of universal access to prevention, diagnostics and treatment for communicable diseases • Establish principle of non-discrimination in law • Health workforce accreditation, certification, licensing and/or registration system • Mandatory reporting of key health information • Mandatory reporting of notifiable diseases • Establishment of regulatory body to oversee healthcare entities • Regulation of medicines to tackle antimicrobial resistance • Legal framework for intellectual property (recognizing TRIPS flexibilities) • Regulation of trade and supply of medicines • Transparency and accountability mechanisms in law • Regulation of blood products under a regulatory body with authority and responsibility to ensure safe blood supply and delivery • Public procurement legislation • Mandate roles and	• Protection of vulnerable populations • Legislation that creates barriers for vulnerable populations e.g. legal barriers for migrants to access services • Protection of rights of patients in law • Protection from stigma and discrimination through legal safeguards • Inadequate or weak drug and medical technologies, health care provider and informal care provider regulation • Lack of coordination and partnerships • Weak public procurement systems • Weak enforcement and legislative frameworks • Global legal environment (including presence of TRIPS)	• Drug and technologies regulation, • Harmonization of drug and technologies regulation • Social protection systems • Designating the scope of health benefits • Coordination and integration of social and health services • Establishment of principle of universal access and protections for vulnerable populations in law • Public procurement legislation • Accreditation of health providers and health support facilities • Mandatory reporting of health data and notifiable diseases • Enforcement of public health legislation • Anti-discrimination legislation • Regulation of private health providers • International and regional collaboration e.g. WHO pre-qualification mechanisms, in particular for generic medicine manufacturers • Legal framework development technical support • Earmarking of budget line or other sourcing of funds for immunization, surveillance and monitoring • Legal framework for vaccine introduction • Incentives for healthcare workers and patients to take up immunization • Legislation empowering patients e.g. developing a patient's charter • Supportive legal framework for harm reduction for people who inject drugs. • Implementation of IHR.	3

Public health emergencies	• Public health legislation and regulation that incorporates principles of equity and non-discrimination • Mandatory reporting of notifiable conditions from all healthcare service providers and health data • Public procurement legislation • Hazardous products regulation • Implementation of IHR • Occupational health and safety • Establishment of an authority with powers for prevention, planning, coordination, communication, financing and expenditure allocation • Environmental legislation and regulation (including building codes) • Define membership and benefits package in emergencies	• Implementation of IHR • Recommendations under PIP Framework • Public health legislation and regulation Incorporating principles of equity and non-discrimination • Protections for vulnerable populations • Coordination and collaboration between preparedness for zoonotic, natural disaster, chemical disaster and other non-human-to-human infection cases • Need to restrict individual's right for public health (e.g. quarantine, isolation)	• Standard setting for health care providers and service providers during an emergency • Regional agreements between service providers during an emergency • Agreements for information sharing • Establishment of infection control protocols and guidelines • Quality control and assurance for service providers • Strengthen policy and legal frameworks for food safety • Designation of power to a person responsible for coordinating responses • Establishment of a body to implement preparedness framework • Legal framework that supports investment in preparedness including earmarking of budget line for preparedness • Designate emergency powers e.g. ability to enter into emergency contracts • Registration of national health facilities to support coordination	3

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Vector abatement	• Assign duties and powers to relevant health authorities • Public nuisance laws • Food hygiene standards • Public procurement legislation and guidelines • Implementation of IHR • Legislation or interagency agreements assigning roles and responsibilities Regulation healthcare providers (formal and informal) • Establishment of multisector committees or taskforces to oversee vector control	• Mandatory reporting of health data • Establishment of preparedness funding • Private and public relationship management and coordination • Integration of preparation and preparedness resources • Public health regulation • Immigration law as a barrier to effective vector control • Environmental law that supports vector control e.g. illegal logging • Enforcement of public health regulation	• Environmental regulation to reduce vector breeding sites e.g. building codes • Mandatory reporting of health data • Public-private partnerships • Legislative frameworks to oversee public-private interaction • Accreditation of private and non-state actors also working to combat vectors	3
Monitoring and surveillance of public health threats	• Mandatory reporting health data • Assign duties and powers to monitor public health treats • Data security regime (confidentiality and privacy) • Implementation of IHR • Creation of notifiable disease categories • Assign duties and powers to a body for strategic planning and guidelines development	• Legislation to protect against discrimination and stigma, incorporate equity • Enforcement of health data reporting • Private health sector regulation • Legal and policy coherence for monitoring and surveillance • Public health law and regulation (monitoring and evaluation) • Evidence based legal developments	• Confidentiality and privacy laws • Mandatory reporting of health data • Interagency agreements on information sharing • Accreditation of health providers (ability to monitor and evaluate) • Transparency in reporting e.g. Republic of Korea • Earmark budget line for ongoing monitoring and surveillance • Mandatory data audits • Environmental legislation (building codes and regulation) • Implementation of IHR	3

Reduction in harmful use of alcohol	• Offences and penalties for driving under the influence (DUI) • Legislation and regulation on the sale and consumption of alcohol including age-restrictions, time and locations • Licensing of alcohol vendors • Legislation regulating compulsory and/or voluntary treatment for those with substance abuse • Taxation of alcohol • Regulation of alcohol marketing • Codes of conduct for industry (sale and marketing) • Product regulation • Regulation of information environment – labelling • Importation standards and controls on illegal importation • Removal of subsidies for alcohol manufacturers, distributors or agricultural produce	• Illegal, semi- or quasi-legal production and sale of alcoholic beverages • Rationalization with international trade • Enforcement of regulation with proper training and resources • Under-regulated platforms e.g. online marketing • Cultural norms associated with alcohol use and breaking the law e.g. ‘fake IDs’ • Gaps in current legislation • Evidence-based development of legislation • Taxation that negatively incentivises behaviour e.g. incentivise the production of illicit alcohol or illegal cross-border movement of alcohol • Regulation of illicit and informal alcohol manufacturers	• Entitlement to measure blood alcohol levels by law enforcement e.g. compulsory random breath-testing in NZ • Licensing of drivers linked with DUIs, offences and penalties • Age-restrictions on sale and consumption of alcohol • Licensing and inspection of alcohol venders • Regulation of alcohol marketing • Environmental legislation e.g. prohibition of consumption of alcoholic beverages in public spaces in the Philippines or in the vicinity of schools • Restrictions on the sale of alcohol to intoxicated persons	3

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Tobacco control	• Tobacco taxation • Regulation of tobacco marketing • Product regulation (including ENDS) • Strategic litigation against tobacco companies • Packaging and labelling regulation • Environmental regulations e.g. public smoking ban • Legislation and regulation of sale and consumption of tobacco products • Regulation of vendors and vending methods for tobacco • Implementation of FCTC • Offences and penalties for actors violating restrictions • Regulation mandating transparency of political activities by industry actors	• Legal capacity and support (including from NSAs) • Enforcement of tobacco regulation and control • Rationalization with trade and intellectual property law • Defending tobacco control policies and legislation from industry challenges and influence	• Budget line earmarking tobacco revenue for tobacco control measures • Tobacco taxation • Packaging and labelling regulation • Regulation on sale and consumption of tobacco products • Environmental laws	3

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Preventing Health Through Action on Social Determinants of Health				
Reduction in obesity	• Food and beverage taxation • Food marketing, advertising, sponsorship and promotion regulation • Nutrition labelling and warning systems • Environmental law e.g. regulation of school environments (regulation of unhealthy products and promote healthy behaviours) • Harmonization with international standards e.g. Codex Alimentarius • Regulation of sale and consumption of unhealthy products • Parental leave protections to facilitate breast feeding	• Evidence based development of legislation • Enforcement, monitoring and surveillance of food and other regulation • Human rights based approach to food regulation • Rationalization with trade and intellectual property regimes • Financial measures – subsidies of agricultural products • Conflicts of interest with industry operators • Use of inadequate voluntary codes	• Regulations on sales of sugar-sweetened beverages • Marketing regulations • Establish thresholds for sugars, fats and sodium in processed food • Food labelling • Food fortification standards • Social protection schemes e.g. food stamps, discounts • Consumer protection legislation	3

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Reduction of road traffic injuries	• Legislation and regulation of driving e.g. speed restrictions, DUIs • Licensing system for drivers linked to insurance and compliance with driving regulations • Offences and penalties for driving violations • Vehicle and driver registration and license system • Road safety legislation e.g. Highway Codes using international road standards • Worker safety legislation e.g. limits on hours commercial drivers can work • Product regulation for vehicles • Mandatory insurance requirement or pooled risk scheme	• Fragmented approach to legislation to combat injuries • Loopholes in legislation • Consistent enforcement of legislation e.g. drink-driving • Balancing personal liberties against the public good e.g. mandatory breathalysing	• Routine drink-driver testing e.g. New Zealand • Motor vehicle manufacturing and/or import standards • Guaranteed access to emergency care post-accident • Indirect regulation e.g. civil liability system to determine liability and assign fault • Voluntary harmonization of highway code and signs at the international level • Mandatory road safety audits for planning and design of new infrastructure (administrative law and governance)	3

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Appendix 2. Examples of laws relevant to health that may lie outside the health portfolio

Area of regulation	Comment
Occupational health and safety	These laws usually oblige employers to create a safe working environment for employees. There may be an insurance scheme that compensates workers injured at work. Poor working conditions may give rise to hazards. A lack of breaks or excessively long shifts have obvious health consequences and risks.
Agriculture and livestock breeding and slaughtering	Agriculture laws govern legal issues affecting farming and production of primary products. Laws on livestock production cover the conditions under which food-producing animals are raised, while slaughtering laws regulate the conditions under which food animals are slaughtered. Recent outbreaks of zoonotic diseases show the importance of managing the contact between animals and people.
Consumer protection and product safety	Laws that regulate consumer protection and product safety have obvious health implications. Rapidly emerging new and microtechnologies are examples of areas with potential health consequences that are still unknown. Consumer protection agencies are attempting to predict these and address this issue.
Injury and accident and motor car and traffic laws	Laws in this area have had demonstrable impact on public health and safety. Examples include the mandatory requirement to wear seat belts, as well as the imposition of speed limits and blood alcohol limits on drivers.
Construction laws, particularly about space requirements, waste management and other matters affecting health	Many building laws have requirements about space in domestic dwellings. Laws also regulate distance from the next house, waste management arrangements and other requirements with health implications. Sometimes such laws are jointly administered by both the minister responsible for the construction industry and the Minister for Health.
Planning laws	Planning laws can have an impact on decisions about funding programmes, planning of buildings and community settings with significant impacts on health.
Migration laws and laws about refugees	The treatment of refugees has health consequences for refugee populations and for those who work with them and ultimately for the communities in which they are housed.
Anti-discrimination laws	Laws that protect persons from discrimination, including prohibition of discrimination on any ground (including based on race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, disability, health status (including HIV/AIDS), sexual orientation, and civil, political, social or other status)
Coronial services	Many countries have granted powers to coroners to make recommendations to protect public health arising from coronial investigations.
Laws establishing subnational levels of government	These laws often specify areas of function and lawmaking. When subnational governments are given health functions, it becomes important to understand the configuration of the health system and where to place resources and efforts aimed at the use of law for health system strengthening.

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Area of regulation	Comment
Certain criminal laws relevant to health	Some countries choose to criminalize activities that lead to adverse health consequences for affected populations.
Taxation laws	Taxation laws have enormous potential to affect health outcomes. This is particularly the case with NCDs. Tax laws can encourage or discourage exercise or the consumption of unhealthy products, and they can affect activities such as the purchase and use of cars and the availability of sports grounds in community settings. Tax laws can also provide a significant income stream to fund health promotion activities and sponsorships.
Laws creating system accountability	Laws establishing and empowering tribunals, courts, offices such as ombudsperson, health commissioners, human rights commissioners and other independent agencies can often have ramifications for health.
Trade laws and laws about ratification of treaties	Laws in this area govern a country's approach to international bodies such as the World Trade Organization and management of bilateral and multilateral trade relationships. The health perspective in such negotiations can have a significant impact. A country can influence treaty contents such as flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), making sure that the health perspective is considered.

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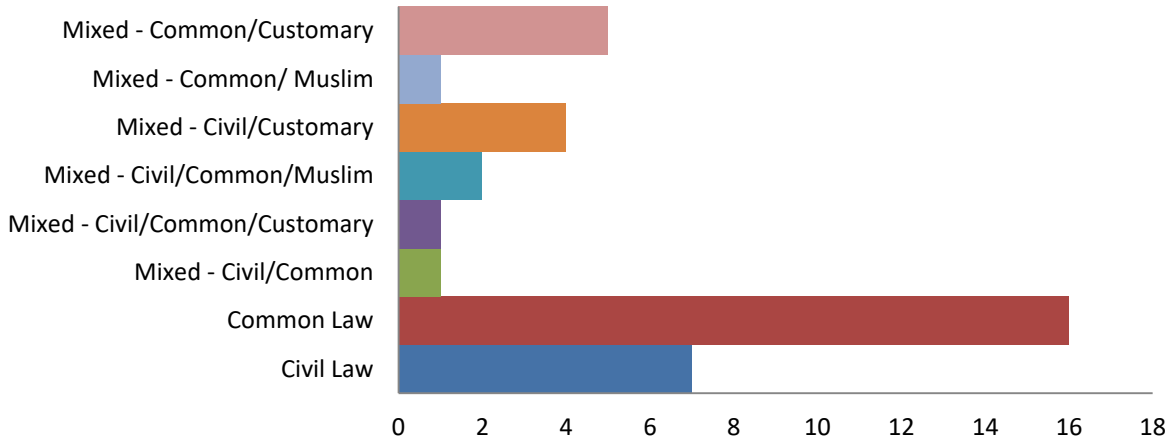
Appendix 3. Legal systems of Member States in the Western Pacific Region

Distribution of Legal Systems in the Western Pacific Region[4]



Common law	Political entities whose law, for the most part, is technically based on English common law concepts and methods which assign a preeminent position to case-law.
Civil law	Political entities that for the most part give precedence to written law and opt for a systematic codification of their general law.
Customary law	Customary law systems vary and are usually rooted in wisdom born of concrete daily experience or more intellectually based on great spiritual or philosophical traditions.
Muslim law	An autonomous legal system which is of a religious nature and predominantly based on the Koran.

Source: University of Ottawa, JuriGlobe – World Legal Systems (www.juriglobe.ca)

Member State	**Legal System**
Australia	Common law
Brunei Darussalam	Mixed – Muslim law/common law/customary law
Cambodia	Civil law
China	Mixed – civil law/customary law
Cook Islands	Common law
Fiji	Common law
Japan	Mixed – civil law/customary law
Kiribati	Common law
Lao People's Democratic Republic	Civil law
Malaysia	Mixed - Muslim law/common law/customary law
Marshall Islands	Common law
Micronesia (Federated States of)	Mixed – common Law/customary law
Mongolia	Mixed – customary law/civil law
Nauru	Common law
New Zealand	Common law
Niue	Common law
Palau	Common law

[4] See also Appendix 2.

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Papua New Guinea	Mixed – customary law/common law
Philippines	Mixed – common law/civil law
Republic of Korea	Mixed – civil law/customary law
Samoa	Mixed – common law/ customary law
Singapore	Mixed – common law/ Muslim law
Solomon Islands	Mixed – common law/customary law
Tokelau	Common law
Tonga	Common law
Tuvalu	Common law
Vanuatu	Mixed – civil law/customary law/common law
Viet Nam	Civil law
Member States with Responsible Areas	
Hong Kong SAR (China)	Mixed – common law/customary law
Macao SAR (China)	Civil law
French Polynesia, New Caledonia, Wallis & Futuna (France)	Civil law
Pitcairn Islands (United Kingdom)	Common law
American Samoa, Guam, Commonwealth of Northern Mariana Islands (USA)	Common law

Appendix 4. Detailed situational analysis and mapping by action areas

Health system governance and leadership:[5] Legal frameworks play an important role in defining a health mandate and establishing the health system in all countries. Overarching health system legislation is receiving increasing attention in transitional economies as part of broad economic and legal reforms, with a number of countries pursuing overarching law reforms with a view to clearly articulating roles and responsibilities in the health system (see Box 4). It is a feature of Pacific island legislation that the responsible Minister is generally granted strong powers for the implementation, administration and enforcement. This is narrowed in some countries because of existence of health boards and other mechanisms. Health boards can be a way of taking an inter-sectoral approach and engaging sectors outside health in health matters. This has been done in the Republic of Korea, Fiji and Papua New Guinea, but the extent to which these can be leveraged depends on the extent to which such boards are supported and engage the senior officers and other participants. The Republic of Korea Health and Medical Services Policy Deliberation Committee has achieved a high level of engagement because its Chairperson is the Prime Minister and Vice Chair the Minister for Health Welfare and Family Affairs. In the Lao People's Democratic Republic, broad powers are granted to the Ministry of Health which include research, planning, regulating administration and issuance of authorization to practice. Most countries have some kind of mandate for disease control which is often extended to health protection and even health promotion. A broader system wide mandate is less common.

Protection of rights:[6] As States Parties to the Constitution of the World Health Organization, Member States are committed to the right to health:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

Further, all WHO Member States have committed to at least one international convention enshrining the right to health, and the majority to several. In the Western Pacific Region, recent years have seen major strides in countries' efforts to advance rights. Table A3.1 gives an overview of the ratification by country of four major human rights treaties, all of which recognize the right to health. These encompass economic, social and cultural rights (1966), the elimination of discrimination against women (1979), the rights of the child (1989) and the rights of persons with disabilities (2006)

[5] See also Appendix 1.
[6] See also Appendices 1 and 3.

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Table A3.1. Member State ratification or accession of selected international treaties

Country	International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966	Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), 1979	Convention on the Rights of the Child (CRC), 1989	Convention on the Rights of Persons with Disabilities, 2006
Australia	✓	✓	✓	✓
Brunei Darussalam		✓	✓	✓
Cambodia	✓	✓	✓	✓
China	✓	✓	✓	✓
Cook Islands	✓	✓	✓	✓
Fiji		✓	✓	✓
Japan	✓	✓	✓	✓
Kiribati		✓	✓	✓
Lao People's Democratic Republic	✓	✓	✓	✓
Malaysia		✓	✓	✓
Micronesia (Federated States of)		✓	✓	✓
Marshall Islands	✓	✓	✓	✓
Mongolia	✓	✓	✓	✓
Nauru		✓	✓	✓
Niue	✓	✓	✓	
New Zealand	✓	✓	✓	✓
Palau	✓*	✓*	✓	✓
Papua New Guinea	✓	✓	✓	✓
Philippines	✓	✓	✓	✓
Republic of Korea	✓	✓	✓	✓
Samoa		✓	✓	✓
Singapore		✓*	✓*	✓
Solomon Islands	✓	✓	✓	✓*
Tokelau*	✓	✓		
Tonga			✓	✓*
Tuvalu		✓	✓	✓
Vanuatu		✓	✓	✓
Viet Nam	✓	✓	✓	✓
* *signature only*				

Explicit recognition of health rights in national constitutions or related laws provides a strong basis for protecting, promoting and fulfilling the right to the highest attainable standard of health for all. Some countries have included health as a constitutional right; others as a directive principle. Countries generally provide broader human rights protections without a specific mention of health but there are some interesting examples of specific reference to health. The Constitution of the Lao People's Democratic Republic provides that the State and Society attend to building and improving disease prevention systems and providing healthcare to all people, creating access to health care, especially women and children, poor people and people in remote areas, to ensure peoples good health. It also provides that the state promotes private sector investment in public health services in accordance with

the laws and regulations. The Marshall Islands Constitution recognizes the right of the people to health care and the obligation to take every step reasonable and necessary to provide these services.

The protection of rights within public health legislation is an area in which opportunities for reform have generally not be taken up. For many countries, there is no provision for the application of Siracusa principles or few obligations restricting the use of broad coercive powers to manage communicable disease. Examples of such restrictions include a principle to use a proportional response to the public health threat and to use the least restrictive option to manage the threat. Such measures are absent in the relevant law of Brunei Darussalam, Cambodia, Fiji, Nauru, Niue, Kiribati, the Lao People's Democratic Republic, Malaysia, the Marshall Islands, Palau, Papua New Guinea, Solomon Islands, Singapore, the Republic of Korea, Tokelau, Tuvalu and Vanuatu. Many countries granted extensive powers to their Minister, departmental head or medical authority to address the outbreak of communicable disease. These included few, if any restraints and protections for those affected.

Access to affordable, safe and quality health services:[7] Regulations for the public and private provision of health services depend on the country's health system configuration. They may include assignment of particular responsibilities, standard setting, licensing and registration, the location of health services, consistency with planning requirements, conditions on partnerships, contracting arrangements and private sector conditions. The movement of people and products, particularly medicines, across national borders, adds another layer of complexity to regulation. Generally speaking, advanced economies have more mature regulatory systems. The good performance of regulatory systems relies on the presence of adequately trained and experienced regulators, supporting legal and regulatory infrastructure, and specialized technicians to perform regulatory functions. As with the regulation of medicines, for many countries, particularly smaller countries national regulators may not be best placed to perform all the regulatory functions across the product life cycle; other options should be considered that pool resources and expertise such as through regional or multilateral regulatory processes. Regulatory systems for traditional medicines are well established in certain countries such as China, Japan, the Republic of Korea and Singapore, and are a more recent or yet to be developed in others.

[7] See also Appendix 4.

Annex

Table A3.2. Legal provisions and market exit activities

	Legal provisions for recalls and withdrawals	List of recalled and withdrawn products publicly available
Australia	✓	✓
Brunei Darussalam	✓	
Cambodia	✓	
China	✓	✓
Cook Islands		
Fiji	✓	
Hong Kong SAR (China)	✓	✓
Japan	✓	✓
Kiribati		
Lao People's Democratic Republic	✓	✓
Macao SAR (China)		
Malaysia	✓	✓
Marshall Islands		
Micronesia (Federated States of)		
Mongolia	✓	
Nauru		
New Zealand	✓	/
Niue		
Palau		
Papua New Guinea	✓	
Philippines	✓	✓
Republic of Korea	✓	✓
Samoa		
Singapore	✓	✓
Solomon Islands		
Tonga		
Tuvalu		
Vanuatu		
Viet Nam	✓	✓

Annex

Table A3.3. Member States of the Western Pacific Region and number of regulated health professions[##]

Member States	Number of regulated professions	Member States	Number of regulated professions
Australia*	14**	Mongolia*	5
American Samoa*	12	Nauru	3
Brunei Darussalam	22	New Zealand*	16**
Cambodia	5	Commonwealth of the North Mariana Islands*	23
China*	7	Palau*	13
Cook Islands*	20	Papua New Guinea	19
Fiji*	8	Philippines*	12
Guam*	9	Republic of Korea*	24
Hong Kong SAR (China)*	13	Samoa*	27
Japan*	16	Singapore*	11
Kiribati	15	Solomon Islands	4
Lao People's Democratic Republic	4	Tonga	6
Malaysia*	23	Tuvalu	5
Marshall Islands*	13	Vanuatu	9
Micronesia (Federated States of)	4	Viet Nam*	5

Notes: ## Based on review of the Member State legislations; * indicates Member States that have regulation on traditional and complementary medicine practitioners; **includes 22 occupation groups

Management of public health risk:[8] Generally, legal frameworks are in place for the management of communicable diseases which rely on the local system for notifiable diseases. Nearly every country in the Region has a system for identifying and notifying diagnosis of specified communicable diseases to a health authority with accompanying powers to address a possible outbreak. The systems, the notifiable diseases and the authorities to whom they are reported and the available powers differ, but use of this approach is almost universal. A surprising number of these frameworks require not just doctors and nurses to notify, but heads of households and even employers in some cases. Examples include Kiribati, Malaysia, Nauru, Niue, Papua New Guinea, the Republic of Korea, Solomon Islands, Singapore, Tokelau, Tuvalu and Vanuatu all have duties on lay people to report when a person contracts or may have contracted a notifiable disease.

Public health thinking, diagnostic techniques, confidentiality in medical information have all considerably advanced from such approaches, but where the law has not been regularly reviewed, such requirements remain. Both in the Pacific and in Asia, the approach is heavy in its use of command and control mechanisms, without provisions limiting the breadth of such powers and protecting the rights of those affected by laws. In many cases, lists of notifiable diseases are outdated and systems not in place to effectively operationalize them. Many countries still used nuisance as the legislative mechanism to manage low level public health risk. Despite this, innovation was to be found among regional statutory responses to public health risk. Japan requires review of definitions and categories of diseases every five years considering the progress of pharmaceuticals and the development of international exchange. Tonga enables the issuance of a public health order to require a person to do something that is reasonably necessary to remove, reduce or contain a public health risk or the adverse effects of a public health risk or prevent a risk to public health from recurring

[8] See also Appendix 1.

which is appropriate in the circumstances having regard to the nature and seriousness of the risk at the time the order is made.

Few countries have taken the opportunity to align powers to manage communicable disease to powers to manage other health risks, particularly in a multi hazard incident. Without such an alignment of powers, for example in an outbreak of avian flu, a country may be trying to utilize different powers in different laws with different triggers and empowering different officer across health, agriculture, food safety and quarantine. In this important area, some countries have innovated and their ideas may serve as models for the consideration of others. The Republic of Korea's Infectious Disease Control Committee is empowered to formulate a master plan and crisis control measures including a response system and roles of each agency at emergency scenes, a determination and decision-making system of emergencies and schemes for stockpiling and supplying medical supplies.

Countries are increasingly relying on legal frameworks to address noncommunicable diseases (NCDs), including measures such as excise taxes, restrictions on marketing, restrictions on commercial availability, restrictions on public consumption, and labelling requirements, which target products associated with NCD risk factors, including tobacco, alcohol, and unhealthy foods. All Member States in the Western Pacific are Parties to the WHO Framework Convention on Tobacco Control, which took effect in 2015 as the world's first global health treaty negotiated under the auspices of the WHO and commits Parties to implement a wide range of supply and demand reduction measures, many through law. Further, in 2013, Pacific health ministers adopted the Tobacco-Free Pacific Goal by 2025 with an adult tobacco use prevalence of less than 5% in each country in the Pacific. Hong Kong SAR (China), New Zealand and Singapore continue to stand as global leaders in reducing tobacco use, while Australia was the world's first country to implement plain packaging of tobacco products and successfully defended challenges to the measure from the tobacco industry at the national and international levels. Indeed, whereas tobacco industry interference has been cited by Member States as one of the biggest impediments to effective tobacco control, and countries also report on resistance from other industries against product regulation, policymakers must take strong, proactive steps to protect the development, implementation, and evaluation of legal frameworks from undue influence based on vested corporate interests. China is taking innovative approaches with legal reform at the city level, particularly with respect to smoke-free zones.

Beyond tobacco control, Samoa has established SPAGHL: Samoan Parliamentary Advocacy Group on Health Living, a platform for stakeholders to engage with parliamentarians in strengthening their role in NCD prevention and control. Australia started the first health promotion foundation, followed by Mongolia, Tonga and Malaysia, which has since pioneered effective cross-sectoral governance arrangements and funds various community initiatives on health promotion. The Lao People's Democratic Republic, Samoa, Solomon Islands, Vanuatu and Viet Nam are all working towards autonomous infrastructure and financing for the promotion of health and prevention of disease. The Philippines has successfully implemented increased taxes on tobacco, alcohol, and sugar-sweetened beverages, with revenues allocated to supporting national programmes for universal health coverage. The Republic of Korea has successfully banned marketing of specific types of food to children and is a leader in cancer surveillance, screening and referral systems. Countries are also strengthening legal frameworks to address other health issues through the life course, including child and maternal health, reproductive health, disabilities and rehabilitation, mental health, road traffic safety, injuries and violence prevention, workers' health, environmental health, and healthy ageing.[9]

Action on social determinants of health: Many countries are choosing to adopt a health-in-all-policies approach to policy development, implementation and agenda setting. For example, in 2013, ASEAN leadership called on all sectors to accelerate the adoption of Health in All Policies in tackling unhealthy lifestyles including risk behaviours for NCDs. However, this shift to centring health in policy development has not often been integrated into legislative mechanisms, for example, only a

[9] See also Appendices 5–8.

few countries in the region have mandated that health impact assessments be carried out on large infrastructure projects. Planning requirements are more common, but some countries also used mechanisms such as a declaration on NCDs with a power to formulate and implement orders and guidelines. The Korean Framework Act on Health and Medical Services requires State and Local Governments to implement projects of lifelong healthcare for citizens which take into account health characteristics of each life cycle and major harmful factors to health. Countries with a health board or some form of inter-sectoral committee in their health legislation Fiji, Japan, New Zealand, Papua New Guinea, Singapore, and the Republic of Korea.

Laws can also create mandates for the active and meaningful participation of affected communities and other stakeholders, for example by legislating/enshrining their participation. For example, some countries have laws about consultation and participation which set out who is to be consulted and how this should be done. In the Republic of Korea, state and local governments must collect the opinions of nationals, including interested persons, in formulating and implementing policies on health and medical services which exert significant influence on the life of nationals, including the rights and duties of nationals. In the New Zealand Public Health and Disability Act, before determining the New Zealand health strategy or the New Zealand disability strategy, or amending or replacing either of them, the relevant Minister must consult any organizations and individuals that the Minister considers appropriate. The Papua New Guinea Organic Law on Provincial Governments and Local-level Governments requires consultation of Provincial Governments in formulation of new national law affecting provinces.

Annex

Administration and Allocation of Health Mandate						
Country	**Does the Minister have allocated powers and responsibilities relevant to a health mandate or overarching health system responsibility?**	**Does the Department Head have allocated powers and responsibilities relevant to a health mandate or overarching health system responsibility?**	**Does the Government or Department have allocated powers and responsibilities relevant to a health mandate or overarching health system responsibility under its Public Health Law?**	**Is there a health board, or equivalent ? (Yes, No, Partially)**	**Does the health board, or equivalent, (i) advise, or (ii) have policy-making powers?**	**Does the Minister, departmental head or Health Board (or equivalent) have any intersectoral powers and/or responsibilities? (Yes, Some, No, Unknown)**
Australia	No	No	No	No	N/A	Yes
Brunei Darussalam	Partially	Partially	Partially	No	N/A	No
Cambodia	No	No	Yes	No	N/A	No
China	No	No	Yes	No	N/A	Yes
Cook Islands	No	No	No	No	N/A	No
Fiji	Yes	Yes	No	Yes	Policy-making powers	No
Japan	Yes	Unknown	Yes	Yes	Advisory	Some
Kiribati	No	No	No	No	N/A	No
Lao People's Democratic Republic	Yes	No	Yes	No	N/A	Unknown
Malaysia	No	No	No	No	N/A	No
Marshall Islands	No	Yes	No	No	N/A	No
Micronesia (Federated States of)	No	Yes	Yes	No	N/A	Unknown
Mongolia	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]
Nauru	No	No	No	No	N/A	No
New Zealand	Yes	No	No	Yes	Yes	No

Annex

Niue	No	Yes	No	No	N/A	Yes
Palau	No	Yes	Yes	No	N/A	No
Papua New Guinea	Yes	Yes	Yes	Yes	No	Yes
Philippines	Yes	No	No	No	N/A	No
Republic of Korea	No	No	Yes	Yes	No	Yes
Samoa	Yes	Yes	Yes	No	N/A	Yes
Singapore	Partial	Partial	Partial	Yes	Yes	No
Solomon Islands	Partially	No	No	Partially*	Advisory	No
Tokelau	No	No	No	No	N/A	No
Tonga	No	Yes	No			
Tuvalu	No	No	No	No	N/A	No
Vanuatu	Yes	No	Yes	No	N/A	No
Viet Nam	No	No	Yes	No	N/A	Yes

* Power exists to create a health boards and committees

Annex

Protection of Rights						
Country	**Protection of rights^**	**Are Siracusa principles applied directly into legislation?**	**(a) Proportional response**	**(b) Least restrictive option**	**(c) Time limited orders**	**(d) Rights of appeal**
Australia	No	N/A	N/A	N/A	N/A	Yes
Brunei Darussalam	No	No	No	No	No	No*
Cambodia	Yes	No	No	No	No	No*
China	Yes	No	No	No	No	No*
Cook Islands	No	No	No	No	No	Yes
Fiji	Yes	No	No	No	No	Some
Japan	Partially#	Some	No	No	Yes	Yes
Kiribati	Partially#	No	No	No	No	No*
Lao People's Democratic Republic	Yes	No	No	No	No	No*
Malaysia	Partially#	No	No	No	No	No*
Marshall Islands	Yes	No	No	No	No	No*
Micronesia (Federated States of)	Yes	Some	No	Yes	Yes	Yes
Mongolia	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]
Nauru	Partially#	No	No	No	No	No*
New Zealand	Yes	Yes	Yes	Yes	Yes	Yes
Niue	Yes	No	No	No	No	No*
Palau	Yes	No	No	No	No	No*
Papua New Guinea	Yes	No	No	No	No	No*
Philippines	Yes	No	No	No	No	No*
Republic of Korea	Yes	No	No	No	No	Yes
Samoa	Partially#	No	No	No	No	No*
Singapore	Yes	No	No	No	No	No*
Solomon Islands	Partially#	No	No	No	No	No*
Tokelau	Yes	No	No	No	No	No*
Tonga	No	Some	Yes	No	Yes	No*
Tuvalu	Partially#	No	No	No	No	No*
Vanuatu	Partially#	No	No	No	No	No*
Viet Nam	Yes	No	No	No	No	No*

^Are human rights or a specific right to health or healthcare protected (Constitution or Public Health Act).
Reference to human rights more broadly or related human rights, for example, right to life
* No explicit right of appeal or specialised system of appeals but assume a form of judicial review is available as part of the wider legal system

Annex

Data and Information Collection for Surveillance Epidemiology and Research				
Country	**Are there provisions for data collection?**	**Are there provisions to protect confidentiality of data?**	**Are there specific provisions for data warehousing?**	**Are there provisions for regional information sharing?**
Australia	Yes	Yes	No	Yes
Brunei Darussalam	Yes	Yes[1]	No	No
Cambodia	N/A[7]	N/A[7]	N/A[7]	N/A[7]
China	Yes	Yes	No	No
Cook Islands	Yes	No	No	No
Fiji	Yes[1]	No	No	No
Japan	Yes	Yes[1]	No	No
Kiribati	Yes	No	No	No
Lao People's Democratic Republic	Yes	Yes[1]	No	No[2]
Malaysia	Yes	N/A[7]	N/A[7]	N/A[7]
Marshall Islands	No	No	No	No
Micronesia (Federated States of)	Yes	N/A[7]	N/A[7]	N/A[7]
Mongolia	N/A[7]	N/A[7]	N/A[7]	N/A[7]
Nauru	Yes	No	No	No
New Zealand	Yes	Yes	No	No
Niue	Yes[3]	No	No	No
Palau	No	No	No	No
Papua New Guinea	Yes	No	No	No
Philippines	Yes	No	No	No
Republic of Korea	Yes	Yes	Yes	No
Samoa	Yes[3]	No	No	No
Singapore	Yes	Yes	Partial	Yes
Solomon Islands	Yes	No	No	No
Tokelau	No	No	No	No
Tonga	Yes	Yes	No	No
Tuvalu	Yes[3]	No	No	No
Vanuatu	Yes[3]	No	No	No
Viet Nam	Yes	Yes	Yes	No

1 - Some confidentiality provisions e.g. doctor-patient confidentiality obligation; 2 - May be permitted ; 3 - Obligation to report rather than a duty to collect; 7 - Unknown e.g. regulations not discoverable or not available in English; 8 - in development

Annex

Management of Communicable Diseases					
Country	**Is there a notifiable diseases list?**	**Can the notifiable diseases be quickly amended list in the face of an emergency involving a new communicable disease threat?**	**Does the notifiable diseases list include SARS and H1N1?**	**Are there powers to respond to an outbreak of communicable disease?**	**Does the Health Act recognize the need for powers to align with national emergency powers?**
Australia	N/A[6]	N/A[6]	N/A[6]	Yes	Yes
Brunei Darussalam	Yes	Yes	Both	Yes	XX
Cambodia	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]
China	Yes	No	Both	Yes	Yes
Cook Islands	Yes	No	Influenza	Yes	No
Fiji	Yes	Yes[4]	Influenza	Yes	No
Japan	Yes	Yes[4]	Both	Yes	Yes
Kiribati	Yes	Yes	Neither	Yes	No
Lao People's Democratic Republic	No	No	Neither	Yes	No
Malaysia	Yes	No	Both	Yes	No
Marshall Islands	No	N/A	N/A	Yes	X
Micronesia (Federated States of)	N/A[7]	N/A[7]	N/A[7]	Yes	Yes
Mongolia	N/A[7]	N/A[7]	N/A[7]	N/A[7]	N/A[7]
Nauru	Yes	No	Both	Yes[5]	No
New Zealand	Yes	No	Both	Yes	No
Niue	Yes	Yes[4]	Neither	Yes	No
Palau	No	No	Neither	No	No
Papua New Guinea	Yes	No	Neither	Yes	No
Philippines	No	No	Neither	Partial	No
Republic of Korea	Yes	Yes	Both	Yes	Yes
Samoa	Yes	No	Influenza	Yes	No
Singapore	Yes	Yes	Both	Yes	Yes
Solomon Islands	Yes	Yes	No	Yes	No
Tokelau	No	N/A	N/A	Yes[5]	No
Tonga	Yes	N/A[7]	N/A[7]	Yes	Yes
Tuvalu	No	N/A	N/A	Yes[5]	No
Vanuatu	Yes	Yes	No	Yes[5]	No
Viet Nam	Yes	Yes	Both	Yes	Yes

4 - Additional step required; 5 – Limited; 6 - Power devolved to State Level; 7 - Unknown e.g. regulations not discoverable

Annex

Management of Noncommunicable Diseases			
Country	**Is there a requirement for health planning (for NCDs) under public health legislation?**	**Is there a requirement to produce health impact statements within public health legislation?**	**Are there any other provisions in the public health act relevant to NCD management?**
Australia	Yes	Yes, partially	Yes, partially
Brunei Darussalam	No	No	No
Cambodia	No[9]	No[6]	No
China	No	No[6]	Yes[7]
Cook Islands	Yes	No[6]	No
Fiji	No	No[6]	No
Japan	Yes	No	Yes
Kiribati	No[9]	No[6]	No
Lao People's Democratic Republic	Yes	No[6]	Yes
Malaysia	Yes	No[6]	No
Marshall Islands	Yes, partially.	No[6]	Yes
Micronesia (Federated States of)	Yes, partially.	No[6]	Yes
Mongolia	Yes, partially.	No[6]	No
Nauru	Yes, partially.	No	No
New Zealand	Yes	Yes, partially	Yes
Niue	Yes, partially.	No[6]	No
Palau	No	No	No[7]
Papua New Guinea	Yes, partially.	No[6]	Yes
Philippines	Yes	No[6]	Yes
Republic of Korea	Yes	Yes, partially	No[7]
Samoa	Yes	No[6]	No[7]
Singapore	Yes	No	Yes
Solomon Islands	No	No[6]	Yes
Tokelau	No	No	No
Tonga	No	No[6]	Yes
Tuvalu	No	No[6]	No
Vanuatu	Yes, partially.	No[6]	Yes
Viet Nam	Yes	No[6]	No[7]

6 - Environmental impact assessment with a health related component or other community impact assessment required; 7 - But some specific legislation around risk factors or specific NCDs e.g. mental health; 8 - Legislation in development; 9 - Not in primary legislation

Annex

Appendix 5. Summary of medicines regulatory authorities in the Western Pacific Region

	National regulatory authority	Pharmaceutical legislation	Registered products			
			Medicines	Vaccines and biologicals	Traditional and complementary medicines	Medical devices
Australia	Therapeutic Goods Administration	National Health Act 1953	✓	✓	✓	✓
Brunei Darussalam	Medicines Control Authority, Ministry of Health	Medicines Order 2007, Medicines Regulation 2010	✓	✓		✓
Cambodia	Department of Food and Drugs, Ministry of Health	Law on the Management of Pharmaceuticals 2007	✓	✓	✓	✓
China	China Food and Drug Administration	Pharmaceutical Administration Law	✓	✓	✓	✓
Fiji	Fiji Pharmaceutical and Biomedical Services, Ministry of Health	Medical Products Act 2011				
Hong Kong SAR (China)	Department of Health	Pharmacy and Poisons Ordinance, Chinese Medicine Ordinance	✓	✓	✓	✓
Japan	Pharmaceuticals and Medical Devices Agency	Pharmaceutical Affairs Law 1960 (revised in 2013)	✓	✓	✓	✓
Lao People's Democratic Republic	Food and Drug Department, Ministry of Health	Law on Drug and Medical Products 2011, Regulation governing drug registration 2003	✓	✓	✓	✓
Macao SAR (China)	Drug Office		✓	✓	✓	✓
Malaysia	National Pharmaceutical Regulatory Agency	Poisons Act 1952, Sale of Drugs Act, Control of Drugs and Cosmetics Regulations	✓	✓	✓	✓
Mongolia	Drug Regulatory Unit – Center for Health Development, Ministry of Health coordinating regulatory functions across different agencies	Drug Law 1998 (revised in 2010)	✓	✓	✓	
New Zealand	Medicines and Medical Devices Safety Authority	Medicines Act 1981, Medicines Regulation 1984	✓	✓		✓
Papua New Guinea	Pharmaceutical Services Standard, National Department of Health	Medicines and Cosmetic Act 1999, Regulation 2001				
Philippines	Food and Drug Administration	Generics Act 1988, Universally Accessible Cheaper and Quality Medicines Act 2008, Food and Drug Administration Act 2009, Philippines Pharmacy Act 2016	✓	✓	✓	✓
Republic of Korea	Ministry of Food and Drug Safety	Pharmaceutical Affairs Act	✓	✓	✓	✓
Singapore	Health Sciences Authority	Health Products Act, Medicines Act	✓	✓	✓ (required for Chinese Proprietary Medicines only)	✓
Viet Nam	Drug Administration of Viet Nam	Pharmacy Law No. 34/2005/QH11, Decision 10/2007/QD-BTM	✓	✓	✓	✓

Annex

Appendix 6. Summary of tobacco control progress in Member States via MPOWER

In 2008, to accelerate implementation by countries of key demand reduction interventions called for under the WHO Framework Convention on Tobacco Control, WHO devised the MPOWER package: M (monitoring use), P (protecting against second-hand smoke), O (offering cessation assistance), W (warning of tobacco harms via labelling), E (enforcing bans on marketing), R (raising tobacco taxes). MPOWER illustrates the need for a comprehensive approach to tobacco control. Law is an important tool to ensure implementation of many MPOWER measures, particularly smoke-free zones, warning labels, marketing bans, and tobacco taxation. Whereas all Member States in the Western Pacific are Parties to the WHO FCTC and thus legally bound to implement their obligations under the treaty, the table shows the progressive nature of how countries develop their legal frameworks over time and according to national priorities and capacities.

2014 INDICATOR AND COMPLIANCE

COUNTRY	ADULT DAILY SMOKING PREVALENCE (2013)	M MONITORING	P SMOKE-FREE POLICIES (LINES REPRESENT LEVEL OF COMPLIANCE)	O CESSATION PROGRAMMES	W WARNINGS: HEALTH WARNINGS	W WARNINGS: MASS MEDIA	E ADVERTISING BANS (LINES REPRESENT LEVEL OF COMPLIANCE)	R TAXATION
Australia	14%		IIIIIIII				...	57%
Brunei Darussalam	13%		IIIIIII				IIIIIIIIII	62%
Cambodia	20%		—				IIIII	22%
China	22%		IIII				IIIIII	44%
Cook Islands	...		IIIII				IIIIIIIII	61%
Fiji	18%		IIIIII				IIIIIIIII	44%
Japan	18%		—				—	64%
Kiribati	46%		IIIIIIII				IIIIIII	89%
Lao People's Democratic Republic	29%		IIIII				IIIIIII	17%
Malaysia	18%		—				IIIIIIII	55%
Marshall Islands	...		IIIIIII				IIIIIIIII	59%
Micronesia (Federated States of)	...		IIIIIII				—	63%
Mongolia	23%		IIIIIIII				IIIIIII	42%
Nauru	40%		IIIII				IIIIIII	...
New Zealand	16%		...				...	77%
Niue	12%		—				—	70%
Palau	...		IIIIIIII				IIIIIIIII	67%
Papua New Guinea	...		III				IIIII	36%
Philippines	21%		IIIII		⊙		IIIIIII	74%
Republic of Korea	26%		IIIIIII				...	62%
Samoa	24%		IIIIII				IIIIIIIII	55%
Singapore	13%		...☆				...	66%
Solomon Islands	...		II		⊙		IIIIIIII	29%
Tonga	26%		IIIIIII				IIIIIIII	72%
Tuvalu	...		IIIIII				IIIIIIIII	3%
Vanuatu	...		—				IIIII	52%
Viet Nam	19%		IIII				IIIIIIII	42%

Annex

MONITORING: PREVALENCE DATA

	No known data or no recent data or data that are not both recent and representative
	Recent and representative data for either adults or youth
	Recent and representative data for both adults and youth
	Recent, representative and periodic data for both adults and youth

CESSATION PROGRAMMES: TREATMENT OF TOBACCO DEPENDENCE

	Data not reported
	None
	NRT and/or some cessation services (neither cost-covered)
	NRT and/or some cessation services (at least one of which is cost-covered)
	National quit line, and both NRT and some cessation services cost-covered

MASS MEDIA: ANTI-TOBACCO CAMPAIGNS

	Data not reported
	No national campaign conducted between July 2012 and June 2014 with duration of at least three weeks
	National campaign conducted with 1–4 appropriate characteristics
	National campaign conducted with 5–6 appropriate characteristics, or with 7 characteristics excluding airing on television and/or radio
	National campaign conducted with at least seven appropriate characteristics including airing on television and/or radio

TAXATION: SHARE OF TOTAL TAXES IN THE RETAIL PRICE OF THE MOST WIDELY SOLD BRAND OF CIGARETTES

	Data not reported
	≤ 25% of retail price is tax
	26–50% of retail price is tax
	51–75% of retail price is tax
	>75% of retail price is tax

SMOKE-FREE POLICIES: POLICIES ON SMOKE-FREE ENVIRONMENTS

	Data not reported/not categorized
	Up to two public places completely smoke-free
	Three to five public places completely smoke-free
	Six to seven public places completely smoke-free
	All public places completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation)

HEALTH WARNINGS: HEALTH WARNINGS ON CIGARETTE PACKAGES

	Data not reported
	No warnings or small warnings
	Medium size warnings missing some appropriate characteristics OR large warnings missing many appropriate characteristics
	Medium size warnings with all appropriate characteristics OR large warnings missing some appropriate characteristics
	Large warnings with all appropriate characteristics

ADVERTISING BANS: BANS ON ADVERTISING, PROMOTION AND SPONSORSHIP

	Data not reported
	Complete absence of ban, or ban that does not cover national television, radio and print media
	Ban on national television, radio and print media only
	Ban on national television, radio and print media as well as on some but not all other forms of direct and/or indirect advertising
	Ban on all forms of direct and indirect advertising

COMPLIANCE: COMPLIANCE WITH BANS ON ADVERTISING, PROMOTION AND SPONSORSHIP, AND ADHERENCE TO SMOKE-FREE POLICY

IIIIIIIII IIIIIIII IIIIIII	Complete compliance (8/10 to 10/10)
IIIIIII IIIIII IIIII IIII III	Moderate compliance (3/10 to 7/10)
II I	Minimal compliance (0/10 to 2/10)

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Appendix 7. Using law to implement policies protecting children from the harmful impact of food marketing in the Western Pacific Region

Legal action	A green cell implies that some type of legislation (legally enforceable measure) is in place. Refer to A, B and C below the table for further classification/explanation.
Voluntary action	A yellow cell implies that some type of voluntary action is in place. This might include voluntary pledges, voluntary initiatives by the government, self-regulations or voluntary industry codes.
No action	A red cell implies that no action is taken.
No information	A blank cell implies that no information is available.

Member States and areas	COLUMN 1	COLUMN 2		COLUMN 3	COLUMN 4	COLUMN 5
	International Code of Marketing of Breast-milk Substitutes	Marketing of foods for infants and young children **covered up to 36 months**		Marketing of foods and non-alcoholic beverages to children	Nutrition labelling (especially nutrient declaration)	Front-of-pack labelling
		Milk products	Complementary foods			
American Samoa						
Australia						
Brunei Darussalam						
Cambodia	B	(24)				
China	C	(4)				
Commonwealth of the Northern Mariana Islands						
Cook Islands						
Federated States of Micronesia						
Fiji	A	(6)	(24)			
French Polynesia						
Guam						
Hong Kong SAR (China)						
Japan						

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Kiribati						
Lao People's Democratic Republic	C	(24)	(24)			
Macao SAR (China)						
Malaysia						
Marshall Islands						
Mongolia	B	(24)	(24)			
Nauru						
New Caledonia						
New Zealand		(12)				
Niue						
Palau	A	(36)	(12)			
Papua New Guinea	C					
Philippines	A	(36)	(24)			
Pitcairn Islands						
Republic of Korea	C					
Samoa						
Singapore						
Solomon Islands	C					
Tokelau						
Tonga						
Tuvalu						
Vanuatu						
Viet Nam	A	(24)	(24)			
Wallis and Fortuna						

Source: Protecting children from the harmful impact of food marketing. Manila: WHO Regional Office for the Western Pacific; 2017.

Notes:

- Column 1: national adaptation of International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions. Data obtained from WHO/UNICEF/IBFAN status report on regulatory measures and IBFAN status report 2016 on voluntary measures. Only legislation are marked green, under three categories: A. Full provisions in law. B. Many provisions in law. C. Few provisions in law.

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- Column 2: national implementation of World Health Assembly resolution WHA69.9 welcoming the Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, aged 6–36 months. Data obtained from 2016 status report on Code implementation, or through consultations with Member States. Reference to age group in any policy noted in months of age.
- Column 3: national implementation of WHO Set of Recommendations on the Marketing of Foods and Non-alcoholic Beverages to Children. Only legislation are marked green.
- Column 4: national implementation of policies on nutrient declaration aligned with Codex Alimentarius guidelines (CAC-CL2-1985, last update 2016); accurate labelling is essential to enforce marketing restrictions based on amounts of nutrient content (e.g., salt, sugar, and/or fats)
- Column 5: national implementation of policies on front-of-pack labelling; in addition to nutrient declaration, FOP labelling informs consumers of potential concerns arising from a food product's nutrient content (e.g., high amounts of salt, sugar, and/or fats).

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Appendix 8. Strengthening an international mandate: evolution of the International Code of Marketing of Breast-milk Substitutes and through subsequent resolutions by the World Health Assembly

Year	Resolution	Selected Highlights and Features
1981	WHA34.22	• Code adopted by Health Assembly (118 in favour, 1 no, 3 abstentions). • Stressed that adoption and adherence to the Code is a minimum requirement. • Urged Member States to implement the Code into national legislation, regulations and other suitable measures.
1982	WHA35.26	• Recognized that commercial promotion of breastmilk substitutes contributes to an increase in artificial feeding and calls for renewed attention to implement and monitor the Code at national and international levels.
1984	WHA37.30	• Requested that WHO Director-General work with Member States to implement and monitor the Code and to examine the promotion and use of foods unsuitable for infant and young child feeding.
1986	WHA39.28	• Urged Member States to ensure that small amounts of breastmilk substitutes needed for minority of infants are made available through normal procurement channels and not through free or subsidized supplies. • Directed attention of Member States to: - Any food or drink given before complementary feeding is nutritionally required may interfere with breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period. - Practice of providing infants with follow up milks is not necessary.
1988	WHA41.11	• Requested the WHO Director-General to provide legal and technical assistance to Member States in drafting or implementing the Code into national measures.
1990	WHA43.3	• Urged Member States to ensure that principles and aim of Code are given full expression in national health and nutrition policy and action.
1992	WHA45.34	• Urged Member States to: - Encourage and support all public and private health facilities providing maternity services so that they become “baby-friendly”. - Take measures appropriate to national circumstances aimed at ending donation or low-priced sale of supplies of breastmilk substitutes to health-care facilities providing maternity services. - Draw upon experiences of other Member States in giving effect to Code.
1993	WHA46.7	• Urged Member States by year 2000 to: - Reduce substantially prevalence of starvation and widespread chronic hunger; undernutrition, especially among children, women and old people; iron deficiency anaemia; foodborne diseases; and social and other impediments to optimal breast-feeding; and to remedy inadequate sanitation and poor hygiene. - Contain and reduce the rate at which prevalence of diet-related diseases and of conditions related to them is rising.

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1994	WHA47.50	• Urged countries to foster appropriate complementary feedings practices from age of about six months. • Reiterated earlier calls in 1986, 1990 and 1992 to end free or low cost supplies and extends ban to all parts of health care system (effectively superseding provisions of Article 6.6 of the Code).
1996	WHA49.15	• Called on Member States to ensure that: - Complementary foods are not marketed for or used to undermine exclusive and sustained breastfeeding. - Financial support to health professionals does not create conflicts of interests. - Code monitoring is carried out in independent, transparent manner free from commercial interest.
2001	WHA54.2	• Moved global recommendation of exclusive breastfeeding from four months to six months. • Emphasized that, to meet evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods, while breastfeeding continues for up to two years or beyond.
2002	WHA55.25	• Endorsed Global Strategy on Infant and Young Child Feeding (GSforIYCF). • Recognized that infant and young child mortality can be reduced with nutritionally adequate and safe complementary feeding through introduction of safe and adequate amounts of indigenous foodstuffs and local foods. • Recognized role of optimal infant feeding in reducing risk of obesity. • Alerted that micronutrient interventions should not undermine exclusive breastfeeding. • Member States urged to ensure that introduction of micronutrient interventions and marketing of nutrient supplements do not replace or undermine support for sustainable practice of exclusive breastfeeding and complementary feeding.
2005	WHA58.32	• Asked Member States to: - Ensure that nutrition and health claims for breastmilk substitutes are not permitted unless national or regional legislation specifically allow this. - Be aware of risks of intrinsic contamination of powdered infant formulas and to ensure this information be conveyed through label warnings. - Ensure that financial support and other incentives for programmers and health professionals working in infant and young child health do not create conflicts of interest.
2006	WHA59.11	• Asked Member States to make sure response to HIV pandemic does not include non-Code compliant donations of breastmilk substitutes or promotion thereof.
2006	WHA59.21	• Welcomed 2005 Innocenti Declaration. • Asked WHO to mobilize technical support for Code implementation and monitoring.
2007	WHA60.23	• Requested WHO Director-General to promote responsible marketing including development of set of recommendations on the marketing of foods and non-alcoholic beverages to children in order to reduce impact of foods high in saturated fats, trans-fatty acids, free sugars, or salt, in dialogue with all relevant stakeholders, including private-sector partners, while ensuring avoidance of

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		potential conflict of interest.
2008	WHA61.20	• Urged Member States to scale up efforts to monitor and enforce national measures and to avoid conflicts of interest. • Investigated safe use of donor milk through human milk banks for vulnerable infants, mindful of national laws, cultural and religious beliefs.
2010	WHA63.23	• Recognized that promotion of breast-milk substitutes and some commercial foods for infants and young children undermines progress in optimal infant and young child feeding. • Expressed deep concern over persistent reports of violations of the Code by some infant food manufacturers and distributors. • Urged Member States to: - Develop and strengthen legislative and regulatory measures to control marketing of breastmilk substitutes to give effect to Code and resolutions. - End all forms of inappropriate promotion of foods for infants and young children and to ensure that health and nutrition claims not be permitted on these foods. - Ensure that required breastmilk substitutes in emergency responses are purchased and distributed according to strict criteria.
2012	WHA65.6	• Requested the WHO Director-General to provide clarification and guidance on the inappropriate promotion of foods for infants and young children cited in resolution WHA63.23, taking into consideration the ongoing work of the Codex Alimentarius Commission (CAC).
2014	WHA67(9)	• Requested WHO Director-General to provide clarification and guidance by end of 2015 on meaning of “ending inappropriate promotion of food for infants and young children” as cited in resolution WHA63.23 on infant and young child nutrition.
2016	WHA69.9	• Welcomed technical guidance on ending inappropriate promotion of foods for infants and young children (up to 36 months) • Urged Member States to continue to implement International Code of Marketing of Breast-milk Substitutes and WHO recommendations on marketing of foods and non-alcoholic beverages to children

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Appendix 9. Details of assessment criteria and legislation coverage for major risk factors of road safety among countries in the Western Pacific Region

	Speed		Drink-driving		Child restraints		Helmets			Seat belts	
	Urban speed limit ≤50km/h	Local authorities can reduce speed limits as required	BAC limit of ≤0.05g/dl for the general population	BAC limit of ≤0.05g/dl for young or novice drivers	Requirement for use of child restraints is based on age, weight, height or combination of these factors	Restriction of children under a certain age or height from sitting in the front seat	Protective helmets must be worn by all drivers and passengers, on all roads, on bikes of all engine types	Law specifies helmet must be properly fastened	Law specifies a national or international quality standard	Applies to drivers and front-seat passengers	Applies to rear-seat passengers
Australia	50km/h	Yes	0.049	0.00	Age	Yes	Yes	Yes	Yes	Yes	Yes
Cambodia	40km/h	No	0.05	0.05	Age	No	Drivers only	No	No	Yes	No
Cook Islands	40km/h	No	0.08	0.08	No	No	Yes	No	Yes	No	No
China	?	Yes	0.02	0.02	No	No	Yes	No	Yes	Yes	Yes
Fiji	No	No	0.08	0.00	No	No	No	No	No	No	No
Japan	60km/h	Yes	0.03	0.03	Age	No	Yes	Yes	Yes	Yes	Yes
Kiribati	40km/h	No	0.08	0.08	Age	No	No	No	No	Yes	Yes
Korea	80km/h	Yes	0.05	0.05	No	No	Yes	No	Yes	Yes	Yes
Lao PDR	40km/h	No	0.05	0.05	No	No	Yes	No	No	Yes	No
Malaysia	90km/h	Yes	0.08	0.08	No	No	Yes	Yes	Yes	Yes	No
Marshall Islands	40km/h	Yes	No	No	No	No	Yes	No	No	No	No
Micronesia	No	No	No	No	No	No	No	No	No	No	No
Mongolia	60km/h	No	0.04	0.04	No	No	Yes	No	No	Yes	Yes
New Zealand	50km/h	Yes	0.05	0.00	Age	Yes	Yes	Yes	Yes	Yes	Yes
Palau	No	No	0.1	0.1	No	No	Yes	Yes	No	No	No
Papua New Guinea	60km/h	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
Philippines	40km/h	Yes	0.05	0.05	No	Yes	Yes	No	Yes	Yes	Yes
Samoa	56km/h	No	0.08	0.08	No	No	Yes	Yes	No	Yes	No
Singapore	70km/h	No	0.08	0.08	Weight/ height	No	Yes	Yes	Yes	Yes	Yes
Solomon Islands	No	Yes	No	No	No	No	Yes	Yes	Yes	No	No
Tonga	50km/h	No	0.03	0.03	No	No	Yes	Yes	Yes	No	No
Vanuatu	No	No	No	No	No	No	Yes	No	Yes	No	No
Viet Nam	50km/h	No	0.00-0.05	0.00-0.05	No	No	Yes	Yes	Yes	Yes	No

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Appendix 10. Sustainable Development Goals: rule of law mapping

Sustainable Development Goals/ rule of law principles	Goal 3 - Ensure healthy lives and promote well-being for all at all ages	Goal 5 - Achieve gender equality and empower all women and girls	Goal 8 - Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	Goal 10 - Reduce inequality within and among countries	Goal 11- Make cities and human settlements inclusive, safe, resilient and sustainable	Goal 12 - Ensure sustainable consumption and production patterns	Goal 13 - Take urgent action to combat climate change and its impacts*	Goal 14 - Conserve and sustainably use the oceans, seas and marine resources for sustainable development	Goal 15 - Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	Goal 16 - Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels	Goal 17 - Strengthen the means of implementation and revitalize the global partnership for sustainable development
Public promulgation		5.1.1	8.8.2	10.5						16.3	
Equal enforcement		5.6c 5.1.1	8.7 8.8	10.5						16.3 16.10.b	
Independent adjudication										16.3 16.1	
Consistent with human rights norms and standards		5.1.1 5.6a 5.6c	8.8	10.3		12.8c			15.6	16.3	
Ensure adherence	3.9b	5.6c	8.7 8.8	10.5 10.7.A.1	11.b	12.4 12.4.1	13.3a	14.5 14.6 14.7		16.3 16.10.b	
Supremacy of law	3.9.a				11.b	12.4	13.3a	14.5 14.7		16.3	17.1

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Equality before the Law		5.6.A.2		10.3						16.3	
Accountability	3.9b	5.6c		10.5				14.7.C.1		16.3	
Fairness (in application)		5.6a 5.6c 5.6.A.2		10.3						16.3	17.1
Separation of powers										16.3	
Participation in decision-making				10.6 10.6.1		12.8c		14.4		16.3	
Legal certainty								14.6 (World Trade Organization obligations)		16.3 16.9 16.1	
Avoidance of arbitrariness										16.3	
Procedural and legal transparency								14.7.C.1		16.3 16.9 16.1 16.10.b	17.1
Law as a tool											
Lawmaking		5.6a 5.6c	8.8.2	10.5		12.8c		14.4 14.6 14.7.B.1	15.8.1		
Realization of international law	3.9a (Health) 3.9b (Trade) 3.9D.1 (Health)	5.6a (Human rights) 5.6c (Human rights)	8.8 (Labour)	10.3 (Human rights) 10.7A (Trade)	11.b (Environment)	12.4 (Environment)	13.3a (Environment)	14.5 (Environment) 14.7 (Environment)	15.6 (Human rights)	16.10.b (Human rights)	