Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce
Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce
## ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>AEFI</td>
<td>adverse event following immunization</td>
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<tr>
<td>AHPRA</td>
<td>Australian Health Practitioner Regulation Agency</td>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<tr>
<td>APEC</td>
<td>Asia-Pacific Economic Cooperation</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>CPD</td>
<td>continuing professional development</td>
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<tr>
<td>CPP</td>
<td>certificate of pharmaceutical products</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
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<tr>
<td>GUNTM</td>
<td>Global University Network of Traditional Medicine</td>
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<tr>
<td>HPCA</td>
<td>Health Practitioners Competence Assurance, New Zealand</td>
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<tr>
<td>HPDT</td>
<td>Health Practitioners Disciplinary Tribunal, New Zealand</td>
</tr>
<tr>
<td>IAMRA</td>
<td>International Association of Medical Regulatory Authorities</td>
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<tr>
<td>ICDRA</td>
<td>International Conference of Drug Regulatory Authorities</td>
</tr>
<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>IGBA</td>
<td>International Generic and Biosimilar Medicines Association</td>
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<tr>
<td>IPRF</td>
<td>International Pharmaceutical Regulators Forum</td>
</tr>
<tr>
<td>IRCH</td>
<td>International Regulatory Cooperation for Herbal Medicines</td>
</tr>
<tr>
<td>IGDRP</td>
<td>WHO-International Generic Drug Regulators’ Pilot</td>
</tr>
<tr>
<td>MRA</td>
<td>mutual recognition agreement</td>
</tr>
<tr>
<td>PIC/S</td>
<td>Pharmaceutical Inspection Co-operation Scheme</td>
</tr>
<tr>
<td>PQF</td>
<td>Pacific Qualifications Framework</td>
</tr>
<tr>
<td>SSFFC</td>
<td>substandard, spurious, falsely labelled, falsified and counterfeit</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration, Australia</td>
</tr>
<tr>
<td>UHC</td>
<td>universal health coverage</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
The Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce guides Member States on actions to strengthen regulatory systems for medicines and the health workforce. These actions – both at the national level and across national borders – can be implemented most effectively through the cooperative efforts of Member States and by their participation in and the use of global, regional and bilateral convergence and cooperation platforms. Implementation of these actions can help ensure the quality and safety of medicines and the health workforce, which are fundamental to the achievement of universal health coverage.

**Situational analysis**

Medicines and the health workforce are the most important elements of a well-functioning health system, and they account for the largest share of health system expenditures. The regulatory landscape for medicines and the health workforce is varied across the Western Pacific Region. While some Member States have highly functional regulatory systems, others have relatively weak systems or no formal regulations. In many countries, while legislative frameworks for regulations exist, their implementation and enforcement remain uneven, particularly in relation to traditional medicine.

The introduction of therapeutic products and new technologies and services, as well as the increasing mobility of people and products, increases the need for effective regulatory systems in the Region. While some regulatory systems have evolved to address these changes, others are seriously constrained by resources, leading to an uneven level of regulation and a variability of standards across the Region. This exposes populations in these countries to higher risks of substandard and poor-quality products and unqualified practitioners.

All countries need to strengthen their regulatory systems in order to progress more rapidly towards universal health coverage. However, some countries cannot efficiently and effectively perform all the necessary regulatory functions, particularly in relation to medicines. Alignment with existing international standards and best practices can help strengthen national regulatory systems in those countries that are facing challenges. Further, the convergence of regulatory systems is increasingly important in the context of rapidly changing and globalizing markets for medicines and the health workforce.
Regulatory convergence and cooperation have enabled countries to strengthen their regulatory systems through information sharing; collaboration on setting standards, processes and guidelines; and opportunities for capacity-building and mutual recognition of regulatory functions. Notably, however, there are barriers for participation in existing convergence mechanisms that often leave less-developed countries behind.

**Regulation of medicines**

Regulatory systems across countries vary widely in terms of the range of regulatory functions performed and the level of capacity. Overall, marketing authorization and inspections of good manufacturing practices are relatively stronger, while pharmacovigilance and market surveillance are relatively weaker. In countries where marketing authorization is weak or non-existent, pharmacovigilance and market surveillance need to be strengthened to protect the population from harmful products.

The number of convergence and cooperation initiatives for the regulation of medicines has been increasing, with potential duplication in some areas. Mostly, only more-developed countries are able to participate in standard-setting initiatives. The Western Pacific Region has among the most advanced national regulatory systems for medicines and medical products in the world, which provides an opportunity for other regions and countries with less-mature regulatory systems to rely on the Western Pacific for training and capacity-building.

**Regulation of the health workforce**

Regulatory systems across Member States in the Region vary widely in terms of health workforce regulatory arrangements and functions. Patients and communities do not receive the same level of protection nor the same standard of care across all countries. At a time of increased workforce mobility, there is a need for both strong national systems and similar basic standards across countries. Strengthening health workforce regulation requires approaches that will cover the course of the professional practice from requirements for entry into practice and on to in-practice monitoring and finally processes for exit from practice.

Limited technical capacity and financial resources pose challenges for efforts to strengthen health workforce regulation. Depending on the health system context, Member States need to invest in building the capacity of regulatory authorities and regulators to ensure the availability of professionals or practitioners who have adequate knowledge, skills, experience and competence to make informed decisions based on professional standards, codes and ethical principles. Regulatory strengthening, convergence and cooperation mechanisms provide an opportunity to improve the regulation of health workers in countries and in the Region.
The role of regulatory convergence and cooperation in strengthening national regulatory systems

Member States have recognized the need to strengthen national regulatory systems, but many face challenges including both the difficulties in prioritizing the development of regulatory functions relevant to their needs and the lack of domestic resources to invest in the development of regulatory systems and infrastructure.

Regulatory convergence and cooperation have the potential to address these challenges and support a stepwise approach to strengthen regulatory systems in countries. This can be achieved through the use of common standards, as well as learning from more experienced countries about how to implement standards and use opportunities for training, capacity-building and information sharing to facilitate evidence-based and informed policy- and decision-making. Forms of cooperation, such as referencing and reliance on more experienced countries, could eliminate repetitive procedures and help countries realign their resources to support the strengthening of other regulatory functions that are most relevant to their needs. Regulatory convergence and cooperation can also help raise the level of regulation across the Region to address common public health concerns.

RECOMMENDATIONS FOR MEMBER STATES

a. Strengthen national regulatory authorities for medicines and the health workforce, as appropriate, including by:
   — Setting priorities for regulatory system strengthening based on the country-specific context and public health needs, including identification of a core set of regulatory functions to be performed.
   — Applying a self-evaluation tool on regulatory system performance.
   — Formulating plans to address the capacity gaps and other weaknesses in regulatory system performance.
   — Developing the required technical, statutory and administrative competencies of regulatory authorities to effectively implement and administer the relevant regulatory functions.
   — Drawing on standards and practices of other countries to accelerate strengthening of weak national regulatory systems.

b. Engage in global, regional and subregional networks of national regulatory authorities for medicines and the health workforce, as appropriate, including by:
   — Recognizing the importance of convergence and collaboration in reducing duplication and pooling regulatory capacity to promote greater access to quality and safe medicines and the health workforce.
   — Collaborating on developing policies that lay the foundation for regulatory strengthening and convergence and increasing cooperation, which should include
efforts to promote the standardization of quality assurance by implementing internationally accepted, contemporary regulatory approaches that cover medicines and the health workforce.

— Identifying opportunities for convergence efforts to help strengthen national regulatory systems, especially where substantial gaps exist, such as technically complex and resource-intensive regulatory functions.

— Promoting various forms of convergence including information sharing, cooperation, collaboration, reliance, and mutual recognition and work sharing, depending on the country context and needs.

c. **Put in place systems, incentives and policies to collect, report, analyse and use reliable and impartial regulatory data, including a means to enhance transparency, accountability and the performance of regulatory systems.**

d. **Improve the quality of data and strengthen policies to address information gaps on the scale, composition and direction of movements of health workers.**

**RECOMMENDATIONS FOR WHO**

a. **Continue to support Member States to strengthen their national regulatory systems, as appropriate, including by:**

— Raising awareness of the importance of effective regulatory systems to improve quality and safety within the health system, thereby protecting public health and advancing universal health coverage.

— Engaging in policy advocacy and dialogue to support legislative reform and regulatory systems strengthening, including engagement with lawmakers to galvanize political commitment and action.

— Supporting Member States in applying self-evaluation tools and using the results to inform policies and actions to strengthen regulatory system performance.

— Providing technical support to implement institutional development plans in national regulatory authorities, thereby strengthening capacity on core regulatory functions.

b. **Strengthen and coordinate global, regional and subregional networks of national regulatory authorities, as appropriate, including by:**

— Promoting greater participation by Member States in existing or evolving networks for convergence.

— Facilitating the dissemination of information, best practices and experiences across the convergence and cooperation initiatives.

— Assisting in the development of appropriate regulatory standards and guidelines.

— Advocating for prioritization of initiatives that will support strengthening of regulatory systems in less-resourced countries.
1. INTRODUCTION

Universal health coverage (UHC) – defined as all people having access to quality health services without suffering the financial hardship associated with paying for care – is the overarching vision for health sector development.¹ The Western Pacific regional action framework, Universal Health Coverage: Moving Towards Better Health, endorsed by the Regional Committee for the Western Pacific in October 2015,² describes ways to advance UHC by strengthening the performance of health systems. Quality is a key attribute of a good health system and central to the achievement of UHC.

Governments regulate health services and systems to improve service quality and safety and, thereby, improve health outcomes, ensure equitable access, protect public health, promote social cohesion and increase economic efficiency.³ Effective regulation is also important for strengthening accountability in the health system and setting incentives for appropriate behaviour.

Medicines and the health workforce are two critical factors, which if properly regulated, are essential to improving health system performance and, thereby, to advancing UHC.³ Competent national regulatory authorities are the foundation necessary to ensure effective regulation across the life course of a product or provider, from pre-market to in-market and post-market phases. The extent to which governments rely on regulation and their specific approach may vary from country to country. However, all governments need to

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strike a balance between the need to ensure the quality and safety of health services and protect the population on one hand, while avoiding unnecessary or excessive restraints on the other. Further, given the limitation of resources, governments cannot directly regulate all relevant aspects of the markets for medicines and the health workforce. Governments therefore need to make informed decisions about when, where, what, who and how to regulate in order to effectively manage risk.

While competent national authorities are essential in all countries, health workers and medical products travel across borders. As the regulatory environment becomes increasingly complex, transnational, and influenced by trade and globalization, effective regulation cannot be achieved by individual countries acting on their own. Countries need to consider regulatory convergence and cooperation to ensure the safety and quality of medicines and the health workforce.

A range of existing regional and global initiatives seeks to facilitate regulatory convergence. These initiatives can also strengthen national regulatory systems in relation to medicines and the health workforce. Conversely, strengthening of national regulatory systems can also enable better regulatory convergence. The challenge for countries is to determine in what areas convergence is desirable and with whom, and how to accomplish it most effectively in their context in order to strengthen regulatory outcomes and promote and protect public health. This Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce aims to guide Member States in their efforts to strengthen regulation in medicines and the health workforce, including identifying potential areas for convergence and factors that can facilitate the achievement of good regulatory outcomes and thereby advance UHC.

REGIONAL ACTION AGENDA OVERVIEW

This Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce introduces an analytical framework for regulatory strengthening and convergence based on regulatory functions and applies this approach in relation to medicines and the health workforce, respectively. For each area of regulatory activity, the Regional Action Agenda: (1) describes the current regulatory environment in the Region; (2) identifies issues and challenges for regulatory systems; and (3) identifies trends in relation to regulatory convergence, as well as existing regional and global initiatives. It goes on to provide guidance on priorities and opportunities for regulatory systems strengthening and convergence and the implications for implementation, with recommendations for the World Health Organization (WHO) and Member States on the way forward.
Regulatory systems strengthening
It includes all efforts directed to improve the discharge of relevant regulatory functions across the life course of products or practitioners, as well as attributes of appropriate regulatory governance.

Regulatory convergence
It refers to all means and processes by which regulatory regimes across countries or regions become similar, aligned or compatible to achieve a common outcome. It encompasses the full regulatory cycle and encompasses a wide range of mechanisms from legally binding instruments through to informal information exchange.

Medicines
They include therapeutic products, vaccines, biologicals and traditional medicines.

Health workforce
It refers to individuals who have the acquired knowledge base, decision-making skills and competencies to be engaged in actions whose primary intent is to enhance health.
2. SITUATIONAL ANALYSIS

The 37 countries and areas in the WHO Western Pacific Region vary widely in stages of development, as well as demographic, socioeconomic and geographic characteristics. They are grouped into geographic as well as trade and political affiliations, such as the Association of Southeast Asian Nations (ASEAN), the Greater Mekong countries, and the Pacific island countries and areas. This diversity is also reflected in the patterns of convergence of national regulatory systems. Countries in the Region regulate a wide range of products, including medicines, vaccines, biologicals, traditional medicines, cosmetics, and diagnostics and other health technologies, as well as a wide range of health professions.

The regulatory landscape for medicines and the health workforce across the Region is complex and often mirrors the variability in the structure and organization of the health systems. Member States have various regimes and capacities, ranging from highly functional regulatory authorities to relatively weak formal systems. In addition, the wide use of traditional medicine in the Region poses equally complex regulatory challenges. While a few Member States in the Region have established regulatory systems for traditional medicine practitioners and products, other Member States are in the process of doing so.

In many countries, while legislative frameworks for regulations exist, their implementation and enforcement remains weak. Markets for medicines and health workers have evolved rapidly, with little or no planning. As a result, significant differences in practice standards exist, which impact the delivery of safe, effective and reliable health services. Weak regulation and/or enforcement puts people at risk, and exposes the health system to higher costs. At a regional level, the existing divergence in regulatory system capacity threatens coordinated policy action, interoperability, and national and regional health security.
In an era of globalization, characterized by the increasing mobility of people and products, the strengthening of regulations and convergence has become important. In the case of medicines, regulatory functions, including research and development, clinical trials, manufacturing, packaging, and distribution and supply, may take place in different locations across countries. The finished products entering into international trade require marketing authorization, registration, continuing quality assurance and decisions to recall or withdraw, all of which lie within the jurisdiction of individual countries. Weaknesses at points along the regulatory cycle can compromise efficiency and the consistent application of quality and safety standards.

Similarly, in the case of health workers, regional and domestic labour markets are interlinked. The drivers of health workforce mobility include incentives and supporting mechanisms, the growth in demand for health services, rising educational attainment, increases in the number and share of health workers, and a wide variation in economic opportunities across the skills continuum in Member States. The ability of foreign-qualified health workers to be employed and contribute to economic growth will depend on their ability to put their credentials, such as education, skills, languages, and professional experience, to good use. Evidence points to various challenges at the individual, labour market and system levels that may limit fair gainful employment and weaken economic mobility prospects for health workers. The nature and stringency of health workforce regulations in Member States influence admissions, workforce integration and labour market outcomes. In a dynamic labour market, Member States with weaker capacity to enforce the regulatory framework may find themselves at a disadvantage.

Significant divergence is also seen in regulatory standards and systems capacity for traditional medicines in Member States across the Region as well as in the level of development of traditional medicine and the regulatory status of traditional medicine products and practitioners, which hinders cooperation. The rapid increase in the mobility of traditional medicine products and practitioners poses public health challenges in many Member States in the Region.

Whatever the specific national context, efforts to ensure the quality and safety of medicines and health workers, including in relation to traditional medicine, should include the establishment of regulatory systems with clear standards and processes that can maintain public trust, respond to population health needs and protect well-being. Strengthened commitment to ensure accountability between regulatory bodies and health services can promote accountability, transparency, responsiveness to change, consistency of approach, and integration and coordination between regulatory bodies.
• The maturity of regulatory systems for medicines and the health workforce is quite uneven across the Region.

• There is a need for regulatory systems strengthening in all countries to advance UHC.

• Some countries cannot efficiently and effectively perform all regulatory functions, particularly in relation to medicines.

• Adoption of existing international reference standards and best practices can help strengthen national regulatory systems in particular countries.

• Convergence of regulatory systems is increasingly important in the context of rapidly changing and globalizing markets for medicines and the health workforce.

• The trend of increasing regional cooperation and expanding markets is paving the way towards increased regulatory cooperation and convergence.
3. ANALYTICAL FRAMEWORK

The analysis in this Regional Action Agenda is organized principally by the regulatory functions that need to be performed across the life course of a product or practitioner – from entry into the market or practice, to continuing quality assurance, and exit from the market or practice. This framing enables guidance on when, where and how to focus regulation, including identification of associated risks and opportunities for regulatory convergence across countries. The analysis also addresses issues of regulatory governance that need to underpin the implementation and enforcement of any regulatory approach. Fig. 1 summarizes the analytical framework and the subsequent sections describe its elements.

3.1 REGULATORY FUNCTIONS

While regulatory functions are common to most regulators, the specific functions in a given country and their implementation will vary, depending on the areas of regulatory activity. Mapping the respective regulatory functions helps in identifying risks and the appropriate entry points and benchmarks for managing or mitigating such risks. At these points, governments and regulators need to set standards and requirements depending on country context and assessment of the associated risks.
**FIG. 1.** Analytical framework for regulatory strengthening, convergence and cooperation

**TABLE 1.** Description of regulatory functions

<table>
<thead>
<tr>
<th>Entry</th>
<th>• Regulators are responsible for managing entry into a market or practice. By setting and managing entry requirements, regulators can minimize risks to quality and safety and protect the public interest.</th>
</tr>
</thead>
</table>
| Continuing quality assurance | • Once in practice or in market, regulators need to continually monitor compliance. A risk-based programme of compliance review enables targeting of higher-priority risks and improved efficiency and responsiveness.  
• Regulators need a range of options that are proportionate to the risks in responding to non-compliance. |
| Exit                    | • Regulators need to further monitor and review measures taken in response to non-compliance as well as the regulatory systems themselves. |
3.2 REGULATORY GOVERNANCE

While approaches to regulation vary, including the extent to which they converge with other jurisdictions, regulation in all countries must be administered by competent regulatory authorities in order to achieve the relevant policy objectives. The qualities of competent regulatory authorities also vary; however, some broad principles are fundamental, apply to all regulatory functions and contribute to better regulatory outcomes overall. In part, they reflect principles of good governance and public administration, but have particular application in the context of regulation.

| Role clarity | • An effective regulator has clear objectives, with clear and linked functions and the mechanisms to coordinate with other relevant bodies. |
| Capability and resourcing | • Training, retention and recruitment programmes need to develop and maintain the competencies that are essential for effective regulatory administration. • The amount and source of funding for a regulator determines its organization and operations, but should not influence regulatory decisions. The regulator should be enabled to function impartially and efficiently. |
| Trust, accountability and transparency | • Regulatory decisions and functions need to be conducted with the utmost integrity to ensure confidence in the regulatory regime. It is important to encourage investment and have an environment that enables inclusive growth built on trust. • Regulators are generally accountable to three groups of stakeholders: i) ministers and the legislature; ii) regulated entities; and iii) the public. • Regulators must be aware of the impacts of their actions and decisions. |


3.3 REGULATORY APPROACHES AND IMPLEMENTATION

In most Member States, the challenge lies in moving from “what to regulate” to “how to regulate”. A strong regulatory system should include a “full-cycle” approach that commences with production and continues throughout the life course of the product or practitioner. Common regulatory approaches include statutory regulation, co-regulation and voluntary regulation. The choice between these approaches depends on the local circumstances, culture and context.
**TABLE 3. Summary of regulatory approaches**

<table>
<thead>
<tr>
<th>Regulatory Approach</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Statutory</strong></td>
<td>A regulatory body is established under statute and given powers to register and regulate.</td>
</tr>
<tr>
<td><strong>Co-regulation</strong></td>
<td>Government enters into a partnership arrangement with a body or an entity to regulate.</td>
</tr>
<tr>
<td><strong>Voluntary self-regulation</strong></td>
<td>Voluntary regulation has no statutory force.</td>
</tr>
</tbody>
</table>

Ultimately, what regulators do in enforcing regulation can be as important as the regulation itself. Taking a risk-based approach to regulation (that is, identifying, managing and communicating risk, in relation to the achievement of relevant objectives) can help maximize the efficient use of limited resources and enable a more proactive rather than reactive approach. It also helps improve the responsiveness of regulation strategies to the regulatory environment and to the conduct of the regulated in deciding whether a more or less interventionist response is needed. One type of responsive regulation is “pyramidal responsiveness” which promotes persuasion and/or capacity-building strategies before increasing the levels of punishment.

### 3.4 REGULATORY CONVERGENCE MECHANISMS

The analysis of issues and risks and, therefore, of when and where regulatory convergence is desirable is based on regulatory functions. Regulatory convergence goes beyond the development of uniform standards and processes to take into account how regulatory regimes work in practice. Indeed, internationally, the trend has moved away from an emphasis on complete harmonization of regulation towards more flexible mechanisms and processes. This follows a recognition that frictions from regulatory divergence often result from enforcement and implementation as opposed to regulations and standards themselves.

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The benefits and risks of regulatory convergence are context-specific and should be assessed as part of a broader policy development cycle. However, they tend to involve a few common themes. Regulatory convergence can reduce transaction and administrative costs for businesses and government and improve access to goods and services. It can extend the reach of regulation beyond national borders, thereby reducing cross-jurisdictional leakage and improving regulatory effectiveness. It can also increase critical mass in relation to particular regulatory functions or assist in overcoming capacity limitations. However, it also has risks, including reduced policy autonomy and capacity for local decision-making, participation and accountability. It can also increase costs, including in relation to coordination, implementation and enforcement.

The analysis considers the different forms and mechanisms for regulatory convergence through which regulatory convergence can be achieved. These mechanisms range from formal and legally binding to informal arrangements. For example, convergence may take the form of joint institutions, uniform and binding standards across jurisdictions, negotiated agreements, non-binding guidelines, or facilitation of discussion. These forms have different benefits and risks, including in relation to various regulatory functions and particular country contexts. Further, while convergence can be undertaken for each regulatory function separately, it is also important to consider regulatory convergence as a whole or the implications of convergence in one particular function or other functions within a particular area of regulatory activity.
4. REGULATION OF MEDICINES

Medicines regulation aims to ensure equitable access to medicines that are of a required quality, safety and efficacy. This requires enforcement of stringent standards on the development, production, supply and disposal of medicines in order to mitigate risks and deal with problems or adverse events in a timely, effective and appropriate manner while appropriately sanctioning non-compliance. Regulations help in timely detection and elimination of substandard and falsified drugs, thereby ensuring integrity of the supply chain. In addition, the capacity of the health system to respond to public health emergencies and other public health needs depends on a flexible or adaptive national regulatory authority that can support innovation and access to new medical products.

To achieve these regulatory outcomes, regulatory authorities must be able to implement a range of regulatory functions, including registration, regulatory inspection, quality assurance, post-marketing surveillance and pharmacovigilance (Table 4). Strong and competent governance is required to carry out these functions in a manner that is consistent, objective, free from conflict of interest and undue influence, and that can protect public welfare and safety and gain public trust.
4. REGULATION OF MEDICINES

**TABLE 4.** Categorization of regulatory functions for medicines

<table>
<thead>
<tr>
<th>Entry</th>
<th>Continuing quality assurance</th>
<th>Exit</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Licencing of establishment&lt;br&gt;• Clinical trial oversight</td>
<td>• Quality assurance in production and good manufacturing practice inspection&lt;br&gt;• Market surveillance on quality</td>
<td>• Recall&lt;br&gt;• Withdrawal</td>
</tr>
</tbody>
</table>
| • Marketing authorization or registration | • Quality-control testing<br>• Pharmacovigilance<br>• Quality assurance in storage, distribution and good storage practice, and good distribution practice inspection | |}

**4.1 REGIONAL OVERVIEW**

Although it is difficult to categorically assign levels of maturity to regulatory authorities, it is widely acknowledged that national regulatory systems are more advanced in Australia, Japan, New Zealand, the Republic of Korea and Singapore. China, Malaysia, the Philippines and Viet Nam have regulatory systems in place but are dealing with the challenges of expanding pharmaceutical products and health sector market, as well as the increasing demands of the population. Consequently, the capacity and resources needed to enforce the range of regulatory functions are constrained. At the other end of the spectrum, Cambodia and the Lao People’s Democratic Republic are in the initial stages of building their regulatory systems, and regulatory systems are largely informal or non-existent in the Pacific island countries and areas. In the field of vaccines, five producing countries – Australia, China, Japan, the Republic of Korea and Viet Nam – are considered to have functional national regulatory authorities for vaccine regulation, based on an assessment using WHO criteria (Table 5).

The range and extent of the performance of regulatory functions also depends on whether countries are engaged in the production, export or import of medicines, or some combination of these (Table 6). Countries such as Australia, China, Japan, Malaysia, the Philippines, the Republic of Korea, Singapore and Viet Nam have sizeable pharmaceutical industries composed of multinational and local producers. Several of these countries, such as China, Japan and Singapore, are major players in the global pharmaceuticals value chain.
<table>
<thead>
<tr>
<th>Country and area</th>
<th>National regulatory authority</th>
<th>Pharmaceutical legislation</th>
<th>Registered products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Therapeutic Goods Administration</td>
<td><em>Therapeutic Goods Act 1989; Therapeutic Goods Regulations 1990; Therapeutic Goods (Medical Devices) Regulations 2002</em></td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>Medicines Control Authority, Ministry of Health</td>
<td>Medicines Order 2007, Medicines Regulation 2010</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Department of Drugs and Food, Ministry of Health</td>
<td>Law on the Management of Pharmaceuticals 2007</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>China</td>
<td>China Food and Drug Administration</td>
<td>Pharmaceutical Administration Law</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Fiji</td>
<td>Fiji Pharmaceutical and Biomedical Services, Ministry of Health</td>
<td>Medical Products Act 2011</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Hong Kong SAR (China)</td>
<td>Department of Health</td>
<td>Pharmacy and Poisons Ordinance, Chinese Medicine Ordinance</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Japan</td>
<td>Pharmaceuticals and Medical Devices Agency</td>
<td>Pharmaceutical Affairs Law 1960 (revised in 2013)</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>Food and Drug Department, Ministry of Health</td>
<td>Law on Drug and Medical Products 2011, Regulation governing drug registration 2003</td>
<td>✓ ✓ ✓ ✓</td>
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<tr>
<td>Malaysia</td>
<td>National Pharmaceutical Regulation Agency</td>
<td>Poisons Act 1952, Sale of Drugs Act, Control of Drugs and Cosmetics Regulations</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Country and area</td>
<td>National regulatory authority</td>
<td>Pharmaceutical legislation</td>
<td>Registered products</td>
</tr>
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</tr>
<tr>
<td>Papua New Guinea</td>
<td>Pharmaceutical Services Standard, National Department of Health</td>
<td>Food and Drug Administration, Ministry of Food and Drug Safety, Health Sciences Authority</td>
<td>Medical devices, Vaccines &amp; biologicals, Medicines, Traditional medicines, Medical devices</td>
</tr>
<tr>
<td>Philippines</td>
<td>Ministry of Food and Drug Safety, Health Sciences Authority</td>
<td>Pharmacetical Affairs Act, Health Products Act, Drug Administration of Viet Nam</td>
<td>Medical devices, Vaccines &amp; biologicals, Medicines, Traditional medicines, Medical devices</td>
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<td>Republic of Korea</td>
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<td>Singapore</td>
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</tr>
<tr>
<td>Viet Nam</td>
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<td>Medical devices, Vaccines &amp; biologicals, Medicines, Traditional medicines, Medical devices</td>
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</tbody>
</table>
### Table 6. Key pharmaceutical activities of countries in the Western Pacific Region*

<table>
<thead>
<tr>
<th>Country an area</th>
<th>Local production</th>
<th>Importation</th>
<th>Exportation</th>
<th>Generics</th>
<th>Vaccines &amp; biologicals</th>
<th>Local companies with research and development capacity for innovation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>ü</td>
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<td>Lao People’s Democratic Republic</td>
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<td>New Zealand</td>
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<td>Republic of Korea</td>
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<td>ü</td>
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<td>ü</td>
<td>ü</td>
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<td>ü</td>
<td>ü</td>
<td>ü</td>
<td>ü</td>
<td>ü</td>
</tr>
</tbody>
</table>

*No local production capacity in the Pacific island countries except Fiji, which has one manufacturing facility in the country.
Countries that produce, export and import medicines and vaccines perform the full range of regulatory functions, from pre-market (including research and development) and market entry, to continuing quality assurance and imposition of decisions and sanctions for market exit. However, most countries in the Region primarily import medicines and vaccines and thus regulate only market entry, market surveillance and control, and pharmacovigilance. Notably, in Pacific island countries and areas, even market entry regulations and market control are not established. Most activity in these countries focuses on importation, through their procurement systems.

Similarly, in the field of vaccines, the extent of regulations is based on the categorization of the country’s pharmaceutical activity, that is, producing, procuring and non-procuring. Producing countries cover the whole range of regulations from pre-market to production and market exit. Procuring countries and non-procuring countries cover regulatory functions from registration to market exit. Five countries in the Region, namely Australia, China, Japan, the Republic of Korea and Viet Nam, are vaccine-producing countries. Brunei Darussalam, Malaysia, New Zealand, the Philippines and Singapore procure vaccines through independent bidding or other mechanisms. The remaining countries procure them through the United Nations System.

Similarly, the varying level of development of the regulatory system and the regulatory status of traditional medicines across Member States depends on factors such as the historical and cultural context, the overall governance of regulations for medicines and medical products, regulatory capacities, infrastructure, and financial resources.

The regulatory system for traditional medicines is well established in China, Hong Kong SAR (China), Japan, Macao SAR (China), the Republic of Korea and Singapore. Mongolia and Viet Nam also have a long history of development of regulations on traditional medicines and have tried to overcome many challenges in implementing them. Cambodia and the Lao People’s Democratic Republic have developed regulations on traditional medicines and face many challenges in implementing them. Member States such as Australia, Malaysia and the Philippines recently developed regulatory systems for traditional medicines, while New Zealand is in the process of developing a system. Regulation of traditional medicines is at a very early stage in the Pacific island countries and areas, although a few, including Fiji and Papua New Guinea, have initiated the process. Despite such substantial variation in the level of development of the regulatory systems, countries face common challenges in ensuring quality, safety and effectiveness of traditional medicines.
Risk-based approaches to the regulation of medicines

The Therapeutic Goods Administration (TGA) of Australia operates on the principle that regulation is only used where absolutely needed and only to the extent needed to protect and advance public health. The level of regulation and the regulation and compliance efforts are commensurate with the risks posed by particular therapeutic products. The products are evaluated based on evidence of their risks and benefits and the corresponding regulations are based on the level of such risks.

Japan also applies a risk-based approach to regulations. Its regulations of medical products are based on the management of potential risks of drug-related events based on information collected throughout the life cycle of the drug, from development to post-marketing. Risk-management guidance is used to support the manufacturing and the marketing-authorization holder in developing risk-minimization plans for the reduction of treatment-related risks in addition to conventional pharmacovigilance plans. Another unique feature of Japan’s regulations is the provision of the “restrictive approval clause” which applies to medicines used in emergencies to prevent the spread of diseases that may have a major effect on public health. It also applies to drugs for diseases for which the drug concerned is the only method of treatment and which are marketed overseas.

4.1.1 Regulatory governance

Institutional arrangements – National regulatory authorities derive their mandate, scope of operations and governance mechanisms from national laws. National regulatory authorities established within ministries of health perform the full extent of the regulatory functions in most countries, except China and the Republic of Korea. Full enforcement of regulations needs legislative, administrative and judicial actions and therefore extends beyond health ministries, to customs, trade, police, the judiciary, local governments, health providers, industry and professional bodies. These stakeholders are involved in various capacities in the definition, implementation, compliance, enforcement and prosecution of offences related to the regulation of medicinal products.

Capability and resourcing – WHO estimates that at least three out of every 10 national regulatory authorities in the world are not fit for purpose, largely due to limited resources and low recognition of their crucial role in their national health systems. Even better-established national regulatory authorities, such as those in high-income countries, face resource challenges and administrative backlogs due to continuous trade expansion and the emergence of innovative products that require new regulatory know-how and

approaches. An assessment confirmed that 14 countries (Australia, Brunei Darussalam, Cambodia, China, Japan, the Lao People’s Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Philippines, the Republic of Korea, Singapore and Viet Nam) have laws mandating national regulatory authorities to regulate medical products. Many developing countries struggle with weak legislation or regulation, understaffing and funding shortfalls.

A large gap remains in regulatory capacity and expertise from one country to another. Experience shows that regulatory capacity develops in phases and over time. Factors such as the level of development and legal basis of the pharmaceutical sector, appropriate regulations, and the availability of trained staff, infrastructure and financial resources influence the size and sophistication of the regulatory authority and its ability to carry out various regulatory functions. The ability of national regulators to perform all the regulatory functions across the product life cycle is often limited, especially in resource-constrained settings with limited staff. International experience suggests that regulation is often only as strong as the available resources. Government budgetary support is the financing method employed in most countries; others have a combination of fees and government budget. Australia is the only country in the Region that is almost entirely self-financed through fees. 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 fully implement its functions. For instance, in principle, evaluation for the registration of medicines should have the same rigour, based on consistent criteria and standards, across countries. Countries such as Australia, China, Japan and Singapore charge a minimum of US$ 5000 and up to US$ 231 000 to register new chemical entities, while Malaysia and the Philippines charge only around US$ 800–1000. For generic medicines, Australia charges up to 88 000 Australian dollars, while Malaysia and the Philippines charge between US$ 200–700. The Lao People’s Democratic Republic charges US$ 50 for local generics and US$ 100 for imported medicines.

Increases in international trade and the technological complexity of manufacturing and product specifications have created additional challenges for national regulatory authorities and manufacturers, particularly in developing countries. Newer products, such as new chemical entities and biosimilars, are being rapidly registered, but only the more advanced regulatory authorities, such as those in Australia, Japan, the Republic of Korea and Singapore, have the capacity to assess these products.

13. HO–WPRO, Cross-country analysis of fees on medicines registration and inspection, unpublished data.
Trust, accountability and transparency – Decision-making in the pharmaceutical sector needs a high degree of transparency and public accountability to prevent substandard, counterfeit, harmful and ineffective medicines from entering local and international markets. Making regulatory procedures and decisions public is an important way to gain public trust. A number of regulatory authorities in the Western Pacific Region have established websites that inform the public about their mandate, standard operating procedures, decision-making processes, and updates and alerts on the quality and safety of medicines (Table 7).

Drug regulatory authorities need to be supported by administrative and legal systems that ensure their independence, such as transparent staff selection processes, clear procedures for the discharge of staff duties and mechanisms for declaration of conflicts of interest. In some countries in the Region, individuals from the pharmaceutical industry are not eligible for appointment to the drug regulatory authority within three years of their separation from the pharmaceutical industry.

<table>
<thead>
<tr>
<th>Country and area</th>
<th>National regulatory authority website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei Darussalam</td>
<td><a href="http://www.moh.gov.bn/SitePages/Pharmacy%20Services.aspx">http://www.moh.gov.bn/SitePages/Pharmacy%20Services.aspx</a></td>
</tr>
<tr>
<td>Cambodia</td>
<td><a href="https://www.ddfcambodia.com/">https://www.ddfcambodia.com/</a></td>
</tr>
<tr>
<td>China</td>
<td><a href="http://eng.sfda.gov.cn">http://eng.sfda.gov.cn</a></td>
</tr>
<tr>
<td>Fiji</td>
<td><a href="http://www.health.gov.fj/?page_id=192#15">http://www.health.gov.fj/?page_id=192#15</a></td>
</tr>
<tr>
<td>Hong Kong SAR (China)</td>
<td><a href="http://www.drugoffice.gov.hk/eps/do/en/level.html">http://www.drugoffice.gov.hk/eps/do/en/level.html</a></td>
</tr>
<tr>
<td>Japan</td>
<td><a href="https://www.pmda.go.jp/english/">https://www.pmda.go.jp/english/</a></td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td><a href="http://www.fdd.gov.la/">http://www.fdd.gov.la/</a></td>
</tr>
<tr>
<td>Malaysia</td>
<td><a href="http://npra.moh.gov.my/">http://npra.moh.gov.my/</a></td>
</tr>
<tr>
<td>New Zealand</td>
<td><a href="http://www.medsafe.govt.nz/">http://www.medsafe.govt.nz/</a></td>
</tr>
<tr>
<td>Philippines</td>
<td><a href="http://www.fda.gov.ph/">http://www.fda.gov.ph/</a></td>
</tr>
<tr>
<td>Republic of Korea</td>
<td><a href="http://www.mfds.go.kr/eng/">http://www.mfds.go.kr/eng/</a></td>
</tr>
<tr>
<td>Singapore</td>
<td><a href="http://www.hsa.gov.sg/content/hsa/en.html">http://www.hsa.gov.sg/content/hsa/en.html</a></td>
</tr>
<tr>
<td>Viet Nam</td>
<td><a href="http://www.dav.gov.vn/">http://www.dav.gov.vn/</a></td>
</tr>
</tbody>
</table>

4.2 PERFORMANCE OF REGULATORY FUNCTIONS

4.2.1 Entry functions

Marketing authorization or registration

The role of marketing authorization or registration is important in ensuring access to quality-assured and safe medicines. The effectiveness of this regulatory function will to a large extent determine the range and types of products available in a country’s jurisdiction. Almost all countries in the Western Pacific Region have legal provisions requiring the registration of medical products for approval for market access. Cambodia and the Lao People’s Democratic Republic give voluntary options for medicines to be used in the public sector. Standards and technical dossier formats for marketing authorization vary across countries. For example, Japan uses the technical guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ASEAN Member States apply the ASEAN Technical Dossier. Pacific island countries and areas do not have a system for pharmaceutical registration.

To ensure the quality of pharmaceutical products moving in international commerce, WHO has proposed that a Certificate of Pharmaceutical Products (CPP) be issued by the exporting authority, certifying that the given product is authorized to be placed in the exporting country. Most countries in the Western Pacific Region require such a certificate to be submitted for registering imported products. In addition, Japan, New Zealand and the Republic of Korea have a Summary of Product Characteristics that is accessible from the regulatory authority website, while Australia has product information that is publicly accessible.

While tools such as common technical dossiers and CPPs are already in place, countries face many challenges in drug registration including the following:

a. Non-availability of experts to review technical dossiers especially for new chemical entities and new forms of therapies. Knowledge gaps also exist, especially with respect to non-clinical and clinical trial data and other technical requirements, for regulating emerging medical products such as biotherapeutics (including biosimilars) and cell and gene therapy products, as well as in the areas of marketing authorization, pharmacovigilance and changes to approved products. Challenges with respect to traditional medicines often start from ensuring the quality and safety of raw materials, such as through identification; control over contamination by heavy metals, pesticides and microorganisms; non-compliance with good agricultural and collection practices; and lack of coordination with relevant ministries. Difficulties in evaluating the evidence, the lack of standards and limited information on products are major challenges for market authorization and registration.
b. Persistent backlogs due to the large volume of products registered.

c. Weak capacity for regulatory inspection: The most stringent part of product life-cycle management for vaccines and biological medicines is pre-market inspection to confirm good manufacturing practices (GMP), usually requiring the demonstration of lot-to-lot consistency through clinical trials. However, most countries in the Region lack the capacity for regulatory inspection (including of GMP) and laboratories needed for market authorization.

d. Gaps in laws and regulations authorizing the use of vaccines, medicines and diagnostics in public health emergencies. Slow progress in regulatory research and the development of regulatory evaluation policy and tools limits the entry of new products, especially during emergencies. For example, Viet Nam required clinical trials for medicines that have been out of circulation for five years in the country of origin. This provision limited the entry into the country of medical products such as H1N1 influenza vaccines and newer drugs for drug-resistant tuberculosis. Recognizing that this provision has restricted access, the Government revised this provision in the Pharmaceutical Law of 2016.

**Licencing of establishments**

Pharmaceutical establishments need to hold a licence issued by a regulatory authority that meets essential standards for operation and trade and that complies with relevant standards for good manufacturing (in the case of manufacturers) and storage and distribution (in the case of wholesalers, importers, distributors and retailers) practices. This also applies to traditional medicines. Inspection is fundamental to ensuring compliance with standards and, thereby, the quality, safety and efficacy of medical products during production and along the supply chain. Non-compliance should lead to withdrawal or recall of products, cancellation of licences or enforcement measures for corrective and preventive actions. All countries in the Region, except for the Pacific island countries, have laws providing for such inspections.

**Conduct and oversight of clinical trials**

Phase III and IV clinical trials on human subjects and randomized clinical trials are often conducted as part of medicines development before marketing authorization. Multi-national pharmaceutical companies extensively conduct clinical trials for medicines and vaccines in many countries in the Region, with high volumes in Cambodia, China, the Lao People’s Democratic Republic, the Philippines and Viet Nam. The global trend is to conduct multi-country trials. However, in some countries, local trials or bridging studies are mandatory to ensure the efficacy and safety of medicines in the local population.
Most countries in the Region make it mandatory to obtain approval for clinical trials for an investigational new drug from a competent authority, local ethics committee or institutional review board. Countries with more stringent regulations register clinical trials, review and approve protocols, and conduct inspections at trial sites to ensure compliance with good clinical practices. Countries with weak regulatory capacity face significant challenges in ensuring ethical and safe research, as they lack the needed infrastructure and skilled investigators.

4.2.2 Continuing quality assurance

Good manufacturing practices

Regulatory inspection to ensure compliance to good manufacturing practices (GMP) is one of the most common regulatory functions in the Region, with a number of countries, for example, Australia, China, Hong Kong SAR (China), Japan, Malaysia, New Zealand, the Philippines, the Republic of Korea, Singapore and Viet Nam, having a local manufacturing industry or hosting multinational manufacturers of medical products. Some countries rely on inspections by regulatory authorities from the country of origin.

One convergence platform for regulatory inspection is the Pharmaceutical Inspection Co-operation Scheme (PIC/S), a non-binding, informal cooperation arrangement among regulatory authorities that implement stringent standards for GMP. In the Western Pacific Region, seven countries and areas – Australia, Japan, Hong Kong SAR (China), Malaysia, New Zealand, the Republic of Korea and Singapore – are members of the scheme.

Quality-control laboratories

Quality-control laboratories play a major role in quality assurance. Manufacturers undertake quality-control testing during production, as a requirement for registration, and during market and post-market surveillance to monitor counterfeit and substandard medicines. Countries importing vaccines and blood products are increasingly adopting national regulatory authority lot-release requirements. However, quality-control laboratories require extensive investment in infrastructure and trained analysts to perform such testing. Some countries, such as Australia, Japan, the Republic of Korea and Singapore, have well-developed laboratory capacity for medical products. Quality control of biological products and blood products remains challenging. The capacity for laboratory testing of new medical products is also limited throughout the Region. A limited number of countries in the Region have the technical capacity to conduct laboratory testing for traditional medicines (Table 8).
TABLE 8

Quality-assurance systems for medical products in the Western Pacific Region

<table>
<thead>
<tr>
<th>Country and area</th>
<th>Quality monitoring</th>
<th>Pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality-control laboratory exists</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quality-control laboratory accredited</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Has reported at least once to WHO global</td>
<td></td>
</tr>
<tr>
<td></td>
<td>surveillance and monitoring system for</td>
<td></td>
</tr>
<tr>
<td></td>
<td>substandard and falsified medicines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uppsala Monitoring Centre</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>✓</td>
<td>Full Member (1968)</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td></td>
<td>Full Member (2005)</td>
</tr>
<tr>
<td>Cambodia</td>
<td>✓</td>
<td>Full Member (2012)</td>
</tr>
<tr>
<td>China</td>
<td>✓</td>
<td>Full Member (1998)</td>
</tr>
<tr>
<td>Fiji</td>
<td></td>
<td>Full Member (1999)</td>
</tr>
<tr>
<td>Hong Kong SAR (China)</td>
<td>✓</td>
<td>Full member (1972)</td>
</tr>
<tr>
<td>Japan</td>
<td>✓</td>
<td>Full Member (2015)</td>
</tr>
<tr>
<td>Lao People's Democratic</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Republic</td>
<td>ISO 17025</td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>✓</td>
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</tr>
<tr>
<td>Mongolia</td>
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<td>Associate Member</td>
</tr>
<tr>
<td>New Zealand</td>
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<td></td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>✓</td>
<td>Full Member (1968)</td>
</tr>
<tr>
<td>Philippines</td>
<td>✓</td>
<td>Associate Member</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>✓</td>
<td>Full Member (1995)</td>
</tr>
<tr>
<td>Singapore</td>
<td>✓</td>
<td>Full Member (1992)</td>
</tr>
</tbody>
</table>

* WHO PQ: WHO prequalification
**Market surveillance and control**

Continuing surveillance of products in the market can reduce the circulation of substandard and counterfeit products. The import and export of medical products and the integrity of supply chains are serious concerns in the Region, especially in countries with weak customs and border regulations. In the Greater Mekong countries for instance, borders are particularly porous and transit of medical products across these borders is a regular concern.

The increasing number of products entering the market, the proliferation of retailers in the informal sector, and unregulated advertising and marketing contribute to the entry of products in the informal market. Unlicenced distributors and sellers are prevalent in the Region, and several incidents of substandard and falsified medicines have been reported. In terms of traditional medicines, the control of promotion, marketing and advertisement activities is critical since traditional medicines are often easily accessible to consumers without guidance from qualified health professionals.

**Pharmacovigilance**

Monitoring of adverse events, especially those that are life-threatening, is important as a way to establish the safety of medical products. A well-functioning pharmacovigilance system can provide signal for recall or withdrawal of products that are unsafe. Twelve countries and areas are full members and two countries are associate members of the WHO Programme for International Drug Monitoring at Uppsala (Table 8).

Most countries in the Region rely on spontaneous reporting of adverse events, mainly from health providers and less frequently from consumers. In Australia, the TGA rely mostly on sponsors reporting which is mandated for serious adverse events. This comprises the majority of all spontaneous reports received by the TGA. In many countries, pharmacovigilance systems are not well established, resulting in very weak to absent reporting of adverse events, especially for traditional medicines. Challenges include under-reporting, delays in timely investigations, incomplete causality assessment and lack of funds. While the national regulatory authorities monitor the safety of medicines, surveillance of adverse events following immunization (AEFI) is often conducted by national immunization programmes. Weak reporting and management of AEFI have diminished trust in vaccine programmes and sometimes resulted in reluctance to adopt vaccines.
4.2.3 Exit functions

Recall and market withdrawal

Laws and regulatory statues in many countries in the Western Pacific Region support recalls (Table 9), which may be ordered by national regulatory authorities or undertaken voluntarily by pharmaceutical companies. A number of countries lack clear mechanisms or procedures for recalls or the resources needed to implement them. Many countries rely on information provided through WHO alerts of products recalled in other countries. There is currently no system for sharing information of products recalled in the Region. Temporary suspension of the use of vaccines due to serious public concerns requires regulatory action, including a systematic investigation of the quality of the given product or service.

KEY MESSAGES

- Countries across the Western Pacific Region vary widely in terms of the range of functions performed and level of capacity of their regulatory systems.

- The type of regulatory functions performed and level of sophistication depends on the development status of the country and the pharmaceutical profile or activity (that is, importing, producing and exporting, or a combination of these).

- Marketing authorization and GMP inspections are relatively stronger in the Region, while pharmacovigilance and market surveillance are relatively weaker. In countries where marketing authorization is weak or non-existent, pharmacovigilance and market surveillance need to be strengthened to protect the population from harmful products.

- No country can rigorously perform all regulatory functions all the time. Countries therefore need to follow a stepwise approach to strengthen their national regulatory authorities based on country contexts.

- The Western Pacific Region has among the most advanced national regulatory systems for medicines and medical products in the world, including those in Australia, Japan, the Republic of Korea and Singapore. There is huge potential for the less-developed countries to avail of these as resources for training and capacity-building. Regional mechanisms for knowledge flow and cross-country support for strengthening of regulatory systems should be considered.
### TABLE 9. Legal provisions and market-exit activities

<table>
<thead>
<tr>
<th>Country and area</th>
<th>Legal provisions for recalls and withdrawals</th>
<th>List of recalled and withdrawn products publicly available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Cambodia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cook Islands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fiji</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hong Kong SAR (China)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Japan</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Kiribati</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Macao SAR (China)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micronesia, (Federated States of)</td>
<td>Under development</td>
<td>Non-existent</td>
</tr>
<tr>
<td>Mongolia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nauru</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>✓</td>
<td>/</td>
</tr>
<tr>
<td>Niue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palau</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Philippines</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Samoa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singapore</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solomon Islands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonga</td>
<td>Non-existent</td>
<td>Non-existent</td>
</tr>
<tr>
<td>Tuvalu</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanuatu</td>
<td>Non-existent</td>
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<td>Viet Nam</td>
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</table>
4.3 KEY ISSUES AND CHALLENGES

Member States, especially those in earlier stages of development, face serious challenges in regulating medicines. While marketing authorization and regulatory inspections are established in many countries, persistent backlogs in registration and inspection occur. This is due to weak capacity in countries to filter the types of products needed for their population, as well as to implement risk-based approaches to regulation. Some regulatory functions, particularly monitoring, surveillance and pharmacovigilance, typically receive less attention. Monitoring of the pharmaceutical chain, including in the informal sector, is especially weak. Several aspects of drug regulation are weakly implemented. Counterfeit and substandard products and those with dubious or exaggerated claims of efficacy are often widespread in the informal sector. Although many countries are members of the Uppsala Monitoring Centre, pharmacovigilance activities are limited in the Region and almost non-existent in Pacific island countries.

The following factors make these challenges more complex:

a. The transnational nature of medicines production and the supply chain – The transnational nature of production and the supply chain for medicines requires regulations that transcend national borders. The development and production of medicines often occur and the supply of medicines often resides in countries or locations that lie outside the territories of responsibility of regulatory authorities. As a result, the process of assuring the quality, safety and efficacy of medicines cannot lie within the traditional scope of governance of a single regulatory authority.

b. Rapid evolution of regulatory science – The introduction of new products and technologies contributes to the rapid evolution of regulatory science, and this process requires countries to adjust and adopt new tools, standards and approaches to assess their safety, efficacy, quality and performance. Public health crises related to medicines have increasingly put pressure on regulatory authorities to step up quality assurance processes. As a result, quality assurance has evolved from quality requirements to assurance of safety and efficacy, and from quality control of finished products to building in quality across the product development and manufacturing process.

c. The increasing expectations by health-care providers and patients for timely access to medicines have increased pressure on national regulatory authorities for expedited review and approval. In addition, the increasing availability of information from advertising and the Internet has transformed consumer knowledge. Regulatory authorities need to provide objective and independent drug information to the public in more accessible formats.

d. The need for statutory and technical competence – The statutory frameworks and technical competence of many regulatory systems in the Region are relatively under-
developed. While countries with underdeveloped systems can learn from a range of statutory models and legal frameworks, adapting these to national contexts is much more complex. Carrying out the legal mandates effectively requires adequate financial and human resources. Performing the various regulatory functions for medicines requires a high degree of technical competence. However, most countries in the Region have not established regulatory professions and therefore lack the availability of formal education and training.

4.4 REGULATORY CONVERGENCE AND COOPERATION IN MEDICINES

4.4.1 When and where do convergence and cooperation matter?

Analysis of existing mechanisms and experience shows that convergence starts with the recognition that regulatory authorities cannot cover all the regulatory functions needed across the product life cycle, especially in the context of the international nature of medical products.

Regulatory convergence and cooperation initiatives have been increasingly adopted at the regional and global level, aiming to consistently implement technical standards over a range of regulatory functions and facilitate trade expansion among countries and across regions. Some mechanisms combine both these goals.

Member States may choose to participate in these initiatives, based on their needs and gaps in their regulatory functions that need to be addressed.

The transnationality of production and supply chains for medicines requires regulations that transcend national territories and borders. The process of assuring quality, safety and efficacy of medicines cannot lie in the traditional governance of a single regulatory authority. Regulatory convergence and cooperation also serve the interest of public health through the following dimensions:

The access dimension – Access to essential medicines and new therapies depends on the capacity of regulators to assess and inspect new products entering the market. However, many regulatory authorities lack the resources and competent experts to ensure appropriate assessment of such products. The territoriality of national regulations for medicines is considered a barrier for improving access and consistently applying standards across countries. The separation of national drug approval policies and procedures, particularly the varying regulatory regimes and capacities, prevents attainment of the commonly desired outcomes of quality, safety and efficacy. Differing drug registration requirements also impose substantial costs to governments, as they entail maintaining

enough staff, infrastructure and technology to ensure implementation of the full range of regulatory functions.

**Regulatory function dimension** – Convergence can occur across the range of regulatory functions. Analysis of experience shows that convergence matters when:

- a. there is need to ensure consistent standards for products coming from sources that are beyond the territory of the receiving countries;
- b. there is need to reduce repetitive processes that cause backlogs and burden regulators;
- c. information that lies beyond the jurisdiction of national regulators is needed for decision-making; and
- d. gaps in resources and capacity exist.

**Product dimension** – Some products, such as exports, generics and new forms of therapies (biologics, biosimilars and nanotechnologies), hold important potential, but may pose risks when not regulated. For example, quality generic drugs, also known as multi-source medicines, can help reduce health-care costs and promote access to essential medicines. However, reviewing and approving these products adds to the burden of drug regulatory authorities, often requiring them to contend with more sophisticated generics and complex global production and distribution chains. Similarly, regulating new bio-therapeutic products through their life cycle poses challenges such as the absence of clear regulatory pathways and standards for approval, weak capacity for clinical evaluation and pharmacovigilance, and lack of consensus on the nomenclature for similar bio-therapeutics. Key issues to grapple with in regulating traditional medicines include control over raw materials, diverse categorization of traditional medicines during registration pathways, standards for approval, evidence for therapeutic claims, control over marketing/advertising capacity for laboratory testing, lack of reporting and complex assessments in pharmacovigilance, and difficulties in regulating traditional medicines produced by traditional medicine practitioners. Given these challenges, the need for regulatory cooperation and convergence, including sharing of information across countries, is an important approach.17

4.4.2 How can convergence and cooperation help strengthen national regulatory systems?

Regulatory convergence and cooperation can support strengthening of national regulatory systems for medicines in the following ways:

- **Complement existing capacity of national regulatory authorities in performing the full range of national regulatory functions** – Where a country cannot fully perform a

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certain regulatory function or decides to lessen the burden of performing such a function, convergence and cooperation mechanisms can be used to complement national efforts. One particular area that benefits from cooperation and/or convergence is marketing authorization. Many regulatory authorities in the Region face persistent backlogs and delays in assessment and registration of medicines. Some also have weak capacity to assess new forms of therapies or implement restrictive requirements, including for clinical trials. These weaknesses pose barriers for timely market entry of products. Convergence efforts in such cases can enable countries to rely on registration processes in other countries, reducing the costs and burdens from repetitive regulatory requirements.

• **Fill the regulatory and legal vacuum at the supranational level** – Regulatory convergence provides a legal framework for implementing internationally accepted standards across countries. This helps eliminate differences in domestic regulations and fills the vacuum where no domestic regulations exist, increasing predictability and legal certainty and enabling the reform and modernization of national laws.\(^{18}\)

• **Improve knowledge flow and confidence in regulatory decisions** – Convergence provides an opportunity for dialogue, exchange of reliable and comparable information, and greater leveraging of the resources and work products of other regulatory agencies. It can increase trust, reduce duplication of efforts and promote informed risk-based resource allocation by authorities.\(^{19}\)

• **Enhance resilience of regulatory systems** – Convergence mechanisms facilitate a prompt and coordinated multi-country response to emerging issues, such as counterfeit and substandard medicines that cross borders, or the shortage of medicines in key areas. It expands the exchange of reliable information by strategically linking and facilitating networks so that risk-based allocation of resources by regulatory authorities can help address common work areas and challenges.

### 4.4.3 Regional and global initiatives

Strengthening and convergence initiatives that are recognized at global level include, among others:

• the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the earliest initiative for harmonization, which is well recognized for its success in implementing the Common Technical Document format, good clinical practices guidelines and capacity-building around the world;

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• WHO, which has several guidelines and initiatives to assess and certify regulatory agencies and products and for capacity-building, mainly in emerging and less-developed countries;
• the Pharmaceutical Inspection Co-operation Scheme (PIC/S), focused on the harmonization of inspection procedures and strengthening the capacity of regulatory authorities with industry participation;
• the International Pharmaceutical Regulators Forum (IPRF), which meets in conjunction with ICH for the operational aspects of implementation; and
• the International Conference of Drug Regulatory Authorities (ICDRA), with a relevant role in strengthening collaboration for medicines and medical product regulation.

Significant regional initiatives include ASEAN Pharmaceutical Harmonization, which supports implementation of the ASEAN Foreign Trade Agreement, and the Asia-Pacific Economic Cooperation – Life Sciences Innovation Forum.

Similar global and regional strengthening and convergence initiatives exist for traditional medicines. At the global level, International Regulatory Cooperation for Herbal Medicines aims to share information on regulatory requirements and standards for quality, safety and efficacy of herbal medicines. At the regional level, the ASEAN Harmonization of Traditional Medicines and Health Supplements is a mandatory convergence mechanism that currently focuses on the convergence of registration standards and claims substantiation of traditional medicines and health supplements. The Forum for the Harmonization of Herbal Medicines is another regional convergence initiative to develop common regulatory standards for herbal medicines, focusing on quality control, nomenclature and adverse-event reporting.

The Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific, initiated in 2011, has worked on: (a) strategic planning to strengthen institutional development towards meeting WHO minimum criteria for performance maturity; (b) building capacity on self-benchmarking, pharmacovigilance/AEFI, quality management systems, laboratory quality assessments, GMP, clinical trial oversight and product evaluation; (c) partnership and resource mobilization to support resource-limited national regulatory authorities; (d) a harmonized approach to strengthen the regulation of vaccines and medicines; and (e) sharing information on lessons learnt and best practices through annual meetings. Most recently, at the fifth workshop for national regulatory authorities, convened in September 2016, a task force was set up to expand the scope to include medicine regulation and the WHO Global Benchmarking Tool. It was developed in 2015 and introduced at the workshop, and provides harmonized indicators to measure regulatory systems performance for vaccine and medicines.

Additionally, two voluntary networks of national control laboratories for vaccines and biologicals in the Western Pacific Region were initiated. In 2012, China initiated the China–
Japan–Korea tripartite network to discuss new vaccine research. In 2015, the Republic of Korea initiated another national control laboratory network in the Region to exchange information on the national regulatory authority lot-release system and standardization of laboratory quality–control methods. The network on new vaccine research focuses on the regulatory science agenda for non-clinical and clinical evaluations of new vaccines in order to accelerate new product development. The latest developments in vaccines and innovative evaluation technology were presented, such as the world’s first vaccines for enterovirus 71, developed and marketed in China, and the rapid evaluation of pandemic influenza vaccine candidates. The other national control laboratory network of national regulatory authorities’ lot-release and laboratory testing policy and strategies focuses on developing national biological reference standards that are essential for laboratory quality-control testing related to lot-release or random testing during post-market surveillance. The latter network is open to countries that have recently introduced lot releases of imported vaccines and blood products, such as Malaysia and the Philippines.

Existing bilateral agreements between Australia and Canada as well as Malaysia and Singapore are other good examples of mutual recognition in regulatory activities.

*Convergence initiatives in medical products*

**International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)**

ICH is a voluntary harmonization initiative for both regulators and the pharmaceutical industry that covers registration of new medicines for human use. It aims to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration, with a view of reducing duplications of testing carried out during the research and development of new human medicines.

ICH was founded in 1990, reorganized as a non-profit legal entity under Swiss Law on 23 October 2015. The governing body is its Assembly, composed of its members, and it makes decisions on Articles of Association, Rules of Procedure, admission of new members and adoption of guidelines.

Membership:
- **Founding Regulatory Members:** European Commission; Japan’s Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency, the United States Food and Drug Administration
- **Founding Industry Members:** European Federation of Pharmaceutical Industries and Associations, Japan Pharmaceutical Manufacturers Association, Pharmaceutical Research and Manufacturers of America

**Standing Regulatory Members:** Swissmedic, Health Canada; Industry: International Generic and Biosimilar Medicines Association (IGBA), World Self-Medication Industry
Standing Observers: WHO, International Federation of Pharmaceutical Manufacturers and Associations

Observers: Regulatory authorities, Regional Harmonization Initiative, international industry pharmaceutical organizations, international organizations with an interest in pharmaceuticals

**The Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

The PIC/S is a non-binding informal cooperative arrangement between regulatory authorities for good manufacturing practices (GMP) for both human and veterinary pharmaceutical products. It harmonizes inspection procedures through development of common standards for GMP as well as capacity-building for regulatory authorities.

Membership: There are 47 members, including Australia, Hong Kong SAR (China), Japan, Malaysia, the Republic of Korea and Singapore.

**ASEAN Pharmaceutical Harmonization**

ASEAN Pharmaceutical Harmonization membership is mandatory. It covers a broad range of pharmaceutical regulations including: registration (ASEAN Common Technical Dossier); harmonization of labelling standards; harmonization of post-marketing alert system; and regulatory capacity and development. It compliments and facilitates the implementation of the ASEAN Foreign Trade Agreement by eliminating technical barriers to trade that are posed by regulations.

Membership: ASEAN member states

**Asia-Pacific Economic Cooperation (APEC) – Life Sciences Innovation Forum**

This platform is a part of the broader APEC goal on health – “healthy population is necessary to a healthy economy”. There are ongoing discussions on whether or not this will be imposed as a part of APEC commitments (discussion tabled during APEC meeting in 2017). It covers a broad range of pharmaceutical regulations, but mainly registration of pharmaceuticals and biosimilar products.

Membership: APEC Member States, industry, academia

**International Generic Drug Regulators Programme (IGDRP)**

This is a voluntary mechanism that deals with the pre-market review of generic medicines. It promotes collaboration and convergence in the area of generic drug regulation and facilitates timely authorization and availability of safe, effective and quality generic drugs. A Steering Committee is currently in place which is composed of one representative from participating regulatory authorities, with WHO as an observer and New Zealand, the Russian Federation, South Africa and the European Directorate for the Quality of Medicines and Healthcare as members.
Australia–Singapore–Switzerland–Canada Consortium
This is a voluntary cooperation initiative among the countries involved. It covers manufacturing compliance and enforcement, generic medicines, assessment reports for new medicines and a secure portal for information exchange and development of technical guidelines. Working groups have been established for the following: generic medicines, new chemical entities/benefit-risk, complementary health products, information technology architecture and pharmacovigilance.

Regulatory Cooperation Initiative (RCI)
The RCI is a work-sharing project between Health Canada and the TGA to eliminate the duplication of effort, where possible. Key areas identified as areas of focus for the project include new medicines, generic medicines, medicine manufacturing site inspections and post-market surveillance.

ASEAN Harmonization of Traditional Medicines and Health Supplements
This is a mandatory convergence mechanism that covers a broad range of regulations, including registration requirements, harmonization of GMP standards, guidelines on claims and claims substantiation, guidelines on labelling requirements, guidelines on negative lists of substances and additives and excipients, and regulatory capacity. It facilitates implementation of the ASEAN Healthcare Integration Roadmap and eliminates technical barriers to trade for traditional medicines and health supplements.

Membership: ASEAN member states

Forum for the Harmonization of Herbal Medicines
This is a voluntary technical forum among regulatory authorities, academic/research institutions and industry. It covers a broad range of technical issues, including harmonization of nomenclature of herbal medicines, compendia, standards for quality control, adverse drug reactions, development of technical guidelines and information exchange. It provides scientific guidelines for improvement or development of standards in safety, quality and efficacy of herbal medicines and reduces duplication of efforts. This mechanism was established in 2002 with support from the WHO Regional Office for the Western Pacific.

Membership: one member from regulatory authorities and the other member from academia of the following: Australia, China, Hong Kong SAR (China), Japan, the Republic of Korea, Singapore and Viet Nam.

International Regulatory Cooperation for Herbal Medicines (IRCH)
This is a voluntary network among national regulatory authorities and regional/subregional bodies. It covers areas including prevention of adulteration (laboratory testing), quality of herbal
medicines (reference standards), pharmacovigilance of herbal medicines, evidence, research, consumer/practitioner awareness and information sharing through IRCH MedNet. It promotes and facilitates the safe use of herbal medicines through sharing experience and information on regulatory requirements and standards for quality, safety and efficacy of herbal medicines among regulatory authorities. It also recommends future activities on herbal medicines to WHO and recommends relevant key issues to ICDRA. Established in 2006, it grew out of a WHO working group meeting on international regulatory cooperation for herbal medicines.

Membership: Currently 33 members, with ASEAN and seven countries from the Region: Australia, Brunei Darussalam, China, Japan, Malaysia, the Republic of Korea and Singapore.

Benefits of regulatory convergence in medicines

**Improves access to medicines** – Many regulatory authorities in the Western Pacific Region face persistent backlogs and delays in assessment and registration. Some also have weak capacity to assess new forms of therapies or implement restrictive requirements, including for clinical trials. These weaknesses pose barriers for timely market entry of products. Convergence efforts in such cases can enable countries to rely on registration processes in other countries, reducing the costs and burdens from repetitive regulatory requirements (Table 10).

**Fills regulatory and legal vacuum at the supranational level** – Regulatory convergence provides a legal framework for implementing internationally accepted standards across countries. This helps eliminate differences in domestic regulations and fill the vacuum where no regulations exist, increasing predictability and legal certainty and enabling the reform and modernization of national laws.

**Fills capacity gaps and helps strengthen national regulatory authorities** – Convergence provides an opportunity for dialogue, exchange of reliable and comparable information, and greater leveraging of the resources and work products of other regulatory agencies. It can increase trust, reduce duplication of efforts and promote informed risk-based resource allocation by authorities.

**Enhances resilience of regulatory systems** – Convergence mechanisms facilitate the prompt and coordinated multi-country response to emerging issues, such as counterfeit and substandard medicines that cross borders, or the shortage of medicines in key areas. It expands exchange of reliable information by strategically linking networks and facilitates risk-based allocation of regulatory authority resources to help address common work areas and challenges.
4. REGULATION OF MEDICINES

**KEY MESSAGES**

- Regulatory convergence in medicines and medical products is an established mechanism at the global and regional level. The two principal imperatives for convergence are: a) development, adoption and recognition of standards and technical guidelines across the range of regulatory functions; and b) trade facilitation.

- The numbers of convergence initiatives have been increasing, with potential duplication in some areas.

- In general, only more developed countries, such as Australia, Japan, the Republic of Korea and Singapore, are able to participate in standard-setting initiatives such as ICH and PIC/S. Participation in these initiatives is costly. Less-developed countries are usually not involved in these convergence mechanisms.

- Mechanisms to use global and regional convergence initiatives to facilitate knowledge flow and strengthen less-developed systems should be considered.
<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Market authorization</th>
<th>GMP inspection</th>
<th>Various aspects of regulatory convergence</th>
<th>Generic medicines</th>
<th>Medicine quality control labs</th>
<th>Regulatory frameworks &amp; benchmarking</th>
<th>Vaccine clinical trial</th>
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* PPWG: Pharmaceutical Product Working Group  ** ICMRA: International Coalition of Medicines Regulatory Authorities  ***IMDRF: International Medical Device Regulators Forum
5. REGULATION OF THE HEALTH WORKFORCE

The overarching purpose of health workforce regulation is to ensure that the public has access to health workers who have adequate knowledge, skills, experience and competence to make informed decisions based on professional standards, codes and ethical principles. Regulation can help build and maintain trust in the health system. By imposing requirements, restrictions and conditions, regulatory bodies ensure that only qualified and competent health workers are allowed to practise. Moreover, standards, codes and guidelines express expectations about professional behaviour and conduct in the interest of public safety in broad terms.

Entry-to-practice requirements are essential to ensure that individuals entering professional practice have obtained and maintain the core competencies required for safe practice. In-practice requirements aim to maintain core competencies and develop new competencies in response to demands and evolving public health needs. In-practice processes include activities undertaken to protect the public interest, such as continuing professional development, relicencing and disciplinary processes. Exit-from-practice processes help to ensure compliance with disciplinary actions as a mechanism to promote public safety. These include suspension, revocation of licence, malpractice litigation, administrative formalities through which regulators collect and share information, and other actions (Table 11).
Regional Overview

Regulatory arrangements, approaches and processes in Member States of the Region vary according to the purpose of the regulation, the statute for self-regulation or co-regulation, and the relative maturity of the regulatory system, which in turn determine the type of institutional arrangements in place, the number of regulated health professions and the extent of community involvement (Table 12).

All Member States have legislation that regulates medical doctors, dentists, nurses, midwives and, often, pharmacists. Some Member States, for example, Australia, Brunei Darussalam, Fiji, Hong Kong SAR (China), New Zealand, Samoa and Singapore, separately regulate allied health professions; and a smaller number of Member States – Australia, China, Mongolia, Japan and the Republic of Korea – regulate traditional and complementary medicine practitioners.

The number of regulated health professions is not indicative of the maturity of a regulatory system. In the interest of public safety, it is the quality of regulatory functions that is important rather than the quantity of regulated professions. It is therefore necessary to consider the trade-offs required and whether the balance is appropriate. All Member States need to establish clear criteria and transparent decision-making processes for assessing which health professions should be regulated based on their country-specific context, health system needs and resource availability. A well-designed regulatory system should not create unnecessary burdens, for example, financial and administrative; should be focused on risks to public safety, proportionate to potential benefits; and should be

### TABLE 11. Categorization of regulatory functions for health workforce

<table>
<thead>
<tr>
<th>Entry</th>
<th>Continuing quality assurance</th>
<th>Exit</th>
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<tbody>
<tr>
<td>Registration standards</td>
<td>• Continuing professional development</td>
<td>• Removal from practice</td>
</tr>
<tr>
<td>Licencing &amp; certification</td>
<td>• Complaints assessment</td>
<td>• Compliance monitoring</td>
</tr>
<tr>
<td>Competency standards</td>
<td>• Practice monitoring</td>
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<tr>
<td>Accreditation standards</td>
<td>• Continuing compliance with standards of conduct, performance and ethics</td>
<td>• Information sharing</td>
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<td>Qualification framework</td>
<td>• Relicensing</td>
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<td>• Practice restrictions</td>
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5.1 REGIONAL OVERVIEW
## TABLE 12. Number of regulated health professions in Member States of the Western Pacific Region**

<table>
<thead>
<tr>
<th>Member State</th>
<th>No. of regulated professions</th>
<th>Member State</th>
<th>No. of regulated professions</th>
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<tbody>
<tr>
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<td>16**</td>
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<td>Cambodia</td>
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<td>Commonwealth of the Northern Mariana Islands*</td>
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<tr>
<td>Marshall Islands*</td>
<td>13</td>
<td>Viet Nam*</td>
<td>5</td>
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</table>

### Based on a review of legislation in Member States
* Indicates Member States that have regulations on traditional and complementary medicine practitioners
** Includes 22 occupation groups

sufficiently flexible to work effectively for different health-care needs and approaches, and with regard to future changes.\(^{20}\)

In some Member States, such as Australia\(^{21}\) and New Zealand,\(^{22}\) risk-based regulatory regimes are increasingly being considered for regulated professions. The risk profile for each profession is typically calculated on the basis of the number, frequency, and significance of notifications and complaints made against members of the profession,

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where such data exist. In some countries, it may also include consideration of the cost of adverse events. It should also include risks associated with context (for example, non-hospital settings, degree of supervision or oversight), scopes of practice, training relevance and quality, skill retention, and clinical decision-making and treatment protocols.

As part of these discussions, consideration should be given not only to which professions need to be regulated, but also whether there are efficiencies that can be gained by reviewing the regulatory processes and how the collection of data can contribute to risk management efforts.

### 5.1.1 Regulatory governance

**Institutional arrangements**

Institutional arrangements to implement the range of regulatory functions may comprise a unit in a ministry or a separate entity with its own statutory foundation, governing body, staff and executive management. In Member States such as China, Japan and Viet Nam, health workforce regulation is the direct responsibility of the ministry or department of health. Other Member States, for example Singapore, have structures within the government or ministry of health, but also a separate board or council for licencing or registering each profession. In Malaysia, the Professional Regulation Commission confers licencing responsibilities on profession-specific regulatory boards. Other Member States, such as Australia and New Zealand, have systems that are more independent of government, but where board or council members are ministerial appointments.  

Supporting legislation is available in most Member States, although, in a few instances, periodic review of the legislation to ensure its fitness for purpose is not regularly undertaken.

Similarly, the regulatory system for traditional and complementary medicine practitioners varies across Member States, often depending on the regulatory capacity for overall health workforce and the integration of traditional and complementary medicine in national health systems. Countries and areas such as China, Japan, Hong Kong SAR (China), Macao SAR (China), Mongolia, the Republic of Korea, Singapore and Viet Nam have a long history of developing regulatory systems for traditional medicine practitioners. Australia and Malaysia have recently established regulatory systems for certain traditional and complementary medicine practitioners. In Australia, under the National Registration and Accreditation Scheme, Chinese medical practitioners, osteopaths and chiropractors are regulated. In some Pacific island countries, there are regulations on complementary medicine practitioners such as acupuncturists, chiropractors and chiropodists based on a risk-based approach, but implementation is often challenging. A few Pacific island countries, such as Samoa, have recently tried to develop a registration system for indigenous traditional medicine practitioners.

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23. WHO 2016. Health workforce regulation in the Western Pacific Region.


5. REGULATION OF THE HEALTH WORKFORCE

**Capability and resourcing**

Some Member States, including Australia, China, Hong Kong SAR (China), New Zealand and Singapore, feature strong, well-established regulatory systems characterized by the enactment of recent or recently amended legislation, the establishment of boards or councils with defined responsibilities for registration, setting and ensuring adherence to standards, and processes for complaints and disciplinary actions. In many Member States, the performance of the regulatory system is compromised by inadequately trained and experienced regulators, resulting in widespread recognition of the need for capacity-building and training.

Financing of the regulatory system appears to vary across Member States. For instance, in New Zealand, some regulatory functions are indirectly funded by the Government for public sector employees, or by the private sector if privately employed. In Australia, the regulatory system is funded almost exclusively through annual registration fees paid by the registered health practitioners, on the premise that achieving and maintaining the standards are individual responsibilities.

**Trust, accountability and transparency**

Regulators need to provide a broad range of information to regulated entities and other stakeholders. Conflicts of interest can pose a significant risk for regulators and undermine public confidence in their integrity. Across the Region, complaint, review and disciplinary processes may be administered at national or local levels. For example, in New Zealand the Health Practitioners Competence Assurance (HPCA) Act (2003) details the responsibilities of the Health Practitioners Disciplinary Tribunal (HPDT), an independent multidisciplinary tribunal that hears disciplinary complaints against health practitioners. The chairperson and deputy chairperson of the HPDT are barristers or solicitors from the High Court and a mix of laypersons and health practitioners from the concerned profession, as prescribed in the HPCA Act. In Japan, responsibility for managing complaints sits with local governments at the prefecture level.

Regulatory arrangements usually grant a significant amount of discretion to health professions to determine professional standards, codes and guidelines. However, it is imperative that standards and restrictions are set at an appropriate level that focuses on the interest of public safety rather than a profession’s self-interest. New Zealand is an example of a Member State that is improving accountability of the regulatory system by involving laypeople in decision-making at the board level of the responsible authority, in the Health Practitioners Disciplinary Tribunal, and in professional conduct committees and competence review committees. Similarly, Australia and Fiji have community representatives on their boards to represent the views of their communities.

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5.2 PERFORMANCE OF REGULATORY FUNCTIONS

5.2.1 Entry functions

Qualification and accreditation

The number of training schools and professional programmes varies significantly across Member States in the Region. Comparability of qualifications is an issue of increasing concern, in particular for Member States that either rely heavily on overseas-qualified health workers or train extensively for international markets. The absence of accreditation mechanisms perpetuates variation in education quality standards, affecting the relative transferability or applicability of qualifications.

The extent to which training providers in the Region use international benchmarks and criteria varies. In Japan, the Japan Accreditation Council for Medical Education has been constituted to strengthen and advance medical education. The Council evaluates medical education programmes, based on the World Federation for Medical Education’s Global Standards for Quality Improvement of Medical Education.27

In a few Member States, a ministry or department of education or similar entity accredits programmes and providers; in others, such as Malaysia, this is done by a qualifications agency, with input from the relevant professional regulatory board. In Hong Kong SAR (China) and the Philippines, agencies other than the body responsible for registration or licensure accredit education programmes. In Australia and New Zealand, a council or board established under a health professions regulatory act is also responsible for registration, prescribing qualifications, assessing equivalency of overseas graduates and licensure.28

In Australia, under the legislation, national boards must decide whether an accreditation function for the health profession is to be exercised by an external accreditation entity or an independent committee established by the board. Currently, 11 boards have appointed external accreditation councils and three boards have accreditation committees.

There have been recent efforts27 to develop internationally vetted core competencies delineating recommended basic, entry-level practice for health professionals. However, many national regulatory authorities lack the technical capacity, financial support and operational guidance against which to measure safe and effective practice standards.

**Registration, licencing and certification**

The responsibility for registration, licensure and setting standards may be assumed by different agencies or bodies. In some Member States, the board established under legislation is responsible for all functions; in others, the responsibility for registration or licensure and discipline may be under the board, but setting and assuring standards may be the responsibility of a professional body (Table 13).

<table>
<thead>
<tr>
<th>New Zealand</th>
<th>Singapore</th>
<th>Malaysia</th>
<th>Republic of Korea</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal framework</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration</td>
<td>Registration</td>
<td>Registration</td>
<td>Registration/</td>
<td>Registration/</td>
</tr>
<tr>
<td>Annual Practicing Certificate</td>
<td>Practicing Certificates</td>
<td>(provisional and full) Practicing Certificate</td>
<td>LICENSING</td>
<td>LICENSING</td>
</tr>
<tr>
<td>Validity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual</td>
<td>Two years</td>
<td>Annual</td>
<td>Lifelong</td>
<td>Lifelong</td>
</tr>
<tr>
<td>Responsible authority</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Council of New Zealand</td>
<td>Singapore Medical Council</td>
<td>Malaysian Medical Council</td>
<td>Ministry of Health and Welfare</td>
<td>State Council, Health Administration Department</td>
</tr>
</tbody>
</table>

Most legislation and associated regulatory documents stipulate that qualifications must be from approved courses and from an approved university, and they may identify the period of internship required before full licensure is granted.

There is variation in whether a national examination is used to qualify graduates for registration or licensure, whether this examination is linked to a curriculum, and the involvement of professional associations in setting the content or standards for the examination. In Japan, all regulated health professionals are required to pass the national
examination set by the Ministry of Health, Labour and Welfare. In Australia, the Psychology Board and the Pharmacy Board have a national examination. Cambodia has introduced a national exit examination for doctors, dentists, nurses, pharmacists and midwives, managed by an inter-ministerial body (National Examination Committee). Additional requirements may include a declaration from applicants regarding their criminal history in all countries and any history of medical conditions that may affect their ability to practise the profession, as well as proficiency in the local language, to enable them to practise safely.

Although information about registration requirements for overseas-qualified health workers is scarce, regardless of the maturity of their regulatory systems, reliance on such workers is common among countries in the Region. Recognition of prior learning and determining equivalence in regard to qualifications is increasingly important, but complex, due to the aforementioned variability in educational quality and standards (Table 14). Most Member States register health workers from overseas based on review of documented education, work and training experiences. Regulators relying primarily on such documentation review often have difficulty in determining the authenticity of these documents, particularly in light of advancements in technology.

The processes used to assess the qualifications and registration status of health workers also vary among Member States. Some Member States have prescriptive requirements, including levels and periods of supervision, for recognizing and registering overseas-qualified health workers. Other Member States may rely on material presented, including curriculum vitae, references, copies of qualifications and sometimes a medical certificate.

As people increasingly migrate across the globe, their health-seeking behaviour as it relates to traditional medicine treatments leads has led to a rapid increase in the mobility of traditional and complementary medicine practitioners. The increasing popularity of traditional and complementary medicine also contributes to this increase. However, the registration of overseas-qualified traditional and complementary medicine practitioners is difficult, since their education and regulatory system varies substantially across Member States. Furthermore, some Member States in the Region do not have a regulatory or formal education system for traditional and complementary medicine practitioners. Without an understanding of the education and regulatory system in countries where overseas-qualified health workers are trained and regulated, assessment of their qualifications can be extremely challenging.

5.2.2 Continuing quality assurance

**Renewals**

There is variability among Member States and across professions regarding requirements for renewal of registration or licensure. Some Member States, such as Australia
and New Zealand, require renewal of annual practice certificates, whereas others such as the Commonwealth of the Northern Mariana Islands, require biannual renewal. Hong Kong SAR (China) requires an annual renewal for doctors and dentists and most other regulated health professions, but triennial renewal for nurses, midwives and Chinese medicine practitioners. Still others have a longer period of renewal, which, for example, is every five years for all regulated health professions in Mongolia.

Other Member States issue lifelong licenses for some professions, such as for nurses in Solomon Islands, and all regulated health professionals in Japan. A few Member States, such as Cambodia, the Lao People’s Democratic Republic and Viet Nam, are currently reviewing the licencing requirements.

**Continuing professional development**

Member States that require periodic renewal of a registration or licence, such as Australia, Hong Kong SAR (China) and New Zealand, have regulations that also describe a demonstration of fitness to practise and/or the required continuing professional development (CPD). However, limited information is available about CPD requirements and whether these are voluntary or mandatory. In some Member States, even where a CPD requirement is stipulated by law, such as Singapore, ensuring compliance, including penalties for non-compliance, can be a challenge.\(^{30}\) Similarly, CPD for traditional medicine practitioners is usually voluntary in many Member States, and regulatory authorities have often not paid much attention to such requirements.

**Complaints and disciplinary processes**

Laws in many Member States specify complaint and disciplinary procedures. Some Member States, such as Cambodia, are revising current laws relating to complaint processes that prescribe the regulatory body to receive and investigate complaints about registrants. However, published information on the implementation of these procedures or penalties applied is limited. Existing information indicates that disciplinary matters are managed in the first instance by employers and escalated to external professional or registration bodies in cases of serious professional misconduct. Complaints may be dealt with at the local, regional, provincial or national levels, with processes differing across professions. For example, in Cambodia, Regional Midwives Councils are responsible for receiving and investigating complaints relating to the performance and behaviour of midwives in instances of breach in the standards of practice.\(^{31}\)

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### TABLE 14. Registration requirements process for overseas-qualified registered nurses in selected Member States

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Prerequisites</th>
<th>Educational qualifications</th>
<th>Recent clinical practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td></td>
<td>Must meet Nursing and Midwifery Board’s eight criteria, including that it must be an externally accredited programme equivalent to an Australian bachelor degree as a minimum and must lead to eligibility for registration in country of origin.</td>
<td>Completion of a minimum of 450 hours of practice within the past 5 years</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>Current registration/licensure in country of origin</td>
<td>Diploma in Nursing</td>
<td>3 years post-licensure experience</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Current registration/licensure in country of origin</td>
<td>Diploma in Nursing</td>
<td>3 years post-licensure experience</td>
</tr>
<tr>
<td>Fiji</td>
<td>Current registration/licensure in country of origin</td>
<td>Basic nursing qualification</td>
<td></td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>Current registration/licensure in country of origin</td>
<td>Diploma (3 years)</td>
<td>At least 3 years</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Current registration/licensure in country of origin</td>
<td>Diploma in Nursing (3 years)</td>
<td>Minimum 3 years</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Current registration/licensure in country of origin</td>
<td>Programme equivalent to a New Zealand bachelor degree (registered nurse)</td>
<td>2 years or a minimum of 2500 hours post-registration nursing practice</td>
</tr>
<tr>
<td>Philippines</td>
<td>Current registration/licensure in country of training</td>
<td>Bachelor of Science in Nursing</td>
<td>3 years post-licensure experience</td>
</tr>
<tr>
<td>Singapore</td>
<td>Current registration/licensure in country of training</td>
<td>Diploma in Nursing</td>
<td>3 years post-licensure experience</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Qualification of education and licence of the home country</td>
<td>Diploma in Nursing</td>
<td>Optional</td>
</tr>
<tr>
<td>Country</td>
<td>Licensure or applicable examinations</td>
<td>Competency assessments required</td>
<td>Verification of nursing registration</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------</td>
<td>---------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Australia</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Cambodia</td>
<td>N/A</td>
<td>Competency evaluation and fitness to practise</td>
<td>Yes</td>
</tr>
<tr>
<td>Fiji</td>
<td>Conditional registration for 6 months subject to satisfactory performance</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Lao People's Democratic Republic</td>
<td>N/A</td>
<td>Assessment requirements under development</td>
<td>Yes</td>
</tr>
<tr>
<td>Malaysia</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>N/A</td>
<td>Completion of NMBA*-approved programme or period of supervised practice</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Pass the qualifying examination</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Singapore</td>
<td>Pass SNB** registered nurse licensure exam</td>
<td>Pass 6 months clinical assessment</td>
<td>Yes</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Meet requirements set out in the Law on Medical Examination and Treatment and associated circulars and administrative orders</td>
<td>N/A</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* NMBA: Nursing and Midwifery Board of Australia – ** SNB: Singapore Nursing Board
Source: Adapted from ASEAN Joint Coordinating Committee on Nursing (AJCCN) documentation; Nursing and Midwifery Board of Australia; Nursing Council of New Zealand; Fiji Nursing Council.
In some Member States, such as China and Japan, disciplinary matters are the responsibility of government agencies that also have other, broader responsibilities. For instance, in Mongolia, the Department of Health’s Medical Ethics Committee, the State Professional Inspection Agency or National Police Agency may deal with disciplinary matters relating to medical practice. Amendments to the Health Law of Mongolia (1998) currently under consideration may help clarify disciplinary processes.

There should be clearly articulated processes for investigation of concerns and determining the appropriate action. The process should be accessible and transparent and should include lodging, assessment, investigation, health or performance assessment, immediate action, and complaints committee/panel hearings. It is important that the processes are streamlined and efficient to ensure quick and cost-effective resolution for all parties involved.

Based on the outcome of the hearings, a decision may be made to either dismiss the complaint or take necessary disciplinary action such as revocation, suspension, and/or imposition of terms, conditions and limits on the scope of practice. Practitioners should have access to an appeal process.

Public sharing of decisions on disciplinary action taken against a health worker is also an important aspect of regulation. In some Member States, this information is easily accessible to the public (Table 15). For instance, in Australia, decision on reprimands, suspensions and conditions on registration are recorded on the public register on the website of the Australian Health Practitioner Regulatory Agency (AHPRA). This Agency also maintains a register of practitioners who have had their registration cancelled. The tribunal decisions are published on the relevant tribunal website.

In safeguarding the public, the role of professional regulation should be supported and complemented by the responsibilities of employing organizations. The latter should be able to foster a work environment that allows open discussions on managing risk or harms while avoiding a culture of “shame and blame”. This may encourage a less defensive approach to professional practice, avoiding the need for health workers to protect themselves at the expense of public accountability.

Another critical issue for regulators is sharing information about how complaints are dealt with and how to access relevant information when a health worker applies for a licence from overseas. As such, making complaints data freely available and accessible is critical to prevent health workers facing disciplinary action in one jurisdiction from moving to another without appropriate actions and sanctions being imposed and regulatory bodies being advised. This sharing of information is currently limited to a small number of jurisdictions on a voluntary basis and is subject to privacy laws. In the backdrop of increasing migration, even if the laws are silent on this, regulators should consider innovative policies for data sharing in the interest of public protection.

5.2.3 Exit functions

Laws in several Member States in the Region specify disciplinary procedures for health workers. However, except in Member States with relatively mature and well-established regulatory systems, published information is limited on how compliance with disciplinary decisions is monitored, including the type of censure or penalty applied in instances of non-compliance. In a few Member States, such as Australia, the regulation agency is responsible for monitoring health practitioners whose registration has been restricted, suspended or cancelled. Monitoring and compliance functions are designed to ensure that practitioners comply with such restrictions on their registration.

An effective complaint management system should also include information for health workers about the criteria and processes for appealing decisions on disciplinary matters. The provision for appeals is usually laid out in the legislation. For instance, Singapore’s Medical Registration Act enables a medical practitioner who is aggrieved by any order of the Medical Council to appeal within 30 days of being notified of the order. Similarly, a nurse in New Zealand can appeal against the decision of the tribunal in the High Court. In Australia, the National Board decisions can be appealed to the relevant tribunal. The tribunal decisions can be appealed, but the authority that hears the appeal varies according to state and territory legislation.

There may be situations where a health worker disciplined in one jurisdiction may migrate to another and continue to practise in the same or a related profession. To avoid such instances, regulators are often obliged to provide a broad range of information to regulated entities and stakeholders in other jurisdictions, unless there is a compelling reason for the information to be withheld. The purpose is to prevent sanctioned practitioners from moving across jurisdictions to avoid the effects of disciplinary action. This is critical for public protection.

5.3 KEY ISSUES AND CHALLENGES

The regulatory system must remain relevant to the local context, taking into consideration factors such as governance arrangements, the legislative framework, the mix of available health workers and cultural preferences.

### TABLE 15. Complaints and disciplinary processes for medical practitioners in selected Member States

<table>
<thead>
<tr>
<th></th>
<th>Australia</th>
<th>Hong Kong SAR (China)</th>
<th>Malaysia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pathway for patients to lodge complaints</strong></td>
<td>Online lodgement – Australian Health Practitioner Regulation Agency (AHPRA) website</td>
<td>Online lodgement Medical Council website</td>
<td>Online lodgement Medical Council website</td>
</tr>
<tr>
<td><strong>Complaints investigation and disciplinary process</strong></td>
<td>Preliminary assessment undertaken by AHPRA and the National Board. National Board may: - take no further action, OR - health matter (refer to health panel), OR - performance &amp; conduct matter (refer to performance and professional standards panel), OR - serious cases (refer to relevant state/territory tribunal). Practitioner has a right to a hearing and to be represented. Panel may caution, reprimand, attach conditions to registration, cancel or accept an undertaking. Tribunal may do the same but may also suspend or cancel registration. &quot;Immediate action&quot; powers to suspend, attach conditions or accept an undertaking if public health and safety are at risk. Medical Council may appoint a Preliminary Investigation Committee, a Health Committee (fitness to practise), an Education and Accreditation Committee (specialists), Ethics Committee (professional conduct) or may hold an inquiry (panel of assessors appointed by the Council). Practitioner has a right to a hearing and to be represented. Council may dismiss the matter, send a letter of advice, reprimand, remove name from register, attach conditions, issue a warning letter or make an order for costs. Practitioner and complainant both have a right to be legally represented. Inquiry hearings are open to the public. Medical Council: Initial assessment of complaint by President of Council: - preliminary inquiry by Preliminary Investigation Committee, - collects evidence and either summarily dismisses complaint or advises Council to conduct inquiry, - Council inquiry may reprimand, suspend registration or erase name from Register for serious professional misconduct.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Authority on disciplinary decisions</strong></td>
<td>ALL PROFESSIONS: Immediate Action Committees, Health Panels, and Performance and Professional Standards Panels; State and Territory Tribunals (professional misconduct)</td>
<td>MEDICAL PROFESSION: Medical Council on recommendation from a Preliminary Investigation Committee, Health or Education and Accreditation Committee</td>
<td>ALL PROFESSIONS: Each council or board has specific disciplinary jurisdiction</td>
</tr>
</tbody>
</table>
### New Zealand

**Pathway for patients to lodge complaints**
- Health and Disability Commissioner (HDC); directly with responsible authority

**Complaints investigation and disciplinary process**
- HDC makes a preliminary assessment. HDC may refer the complaint on to, or back to, the responsible authority.
- The responsible authority may refer the complaint on to:
  - Professional Conduct Committee for investigation,
  - Performance Assessment Committee for investigation, or
  - HDC if the complaint is from a patient or health consumer.
- Tribunal can impose a range of penalties including:
  - cancellation,
  - suspension for up to three years,
  - imposition of conditions for up to three years,
  - censure, or
  - imposition of a fine.
- Medical Council: Complaints Panel of Council appoints Complaints Committee to assess and order:
  - complaint be dismissed,
  - issue letter of advice or warning,
  - practitioner to undergo medical or psychiatric treatment or counselling,
  - practitioner to do further education or training,
  - practitioner to report on practice or take advice on management of practice.

A complainant can appeal if unhappy with an outcome.

### Singapore

**Pathway for patients to lodge complaints**
- Online lodgement Medical Council website

**Complaints investigation and disciplinary process**
- Article 74 of the Law on Examination and Treatment (LET):
  - request for settlement of a dispute over medical examination and treatment upon occurrence of an incident to patient,
  - professional council set up by head of medical examination and treatment establishment, or competent health state agency directly managing establishment.

Assess professional and/or technical errors. Conclusions of the professional council serve as basis for dispute settlement. Damages may be awarded.

### Viet Nam

**Pathway for patients to lodge complaints**
- Telephone hotline

**Complaints investigation and disciplinary process**
- ALL PROFESSIONS: Health Practitioners Disciplinary Tribunal hears and determines disciplinary proceedings
- MEDICAL PROFESSION: Immediate Orders Committees, Complaints Committees, Disciplinary Tribunals and Health Committees

**Authority on disciplinary decisions**
- ALL PROFESSIONS: Professional Council under Article 75 of the LET
As noted above, in many Member States, the regulatory systems themselves are in need of substantive review, facing challenges such as:

- **Limited technical capacity to undertake meaningful assessment of competency** – Structured assessment of the competency of health workers upon entering practice and re-registration of those in the workforce are uncommon, as is assessment of those migrating from another country. Furthermore, in small island countries, lack of economies of scale result in inadequate financing, management and technical capacity to sustain an effective and efficient regulatory system.

- **Inadequate resources to maintain quality systems of accreditation, licensure, CPD and disciplinary processes** – Regulatory authorities in many Member States rely significantly on grant support or fund themselves solely through the collection of regulation fees. In the absence of public funding, these authorities find it difficult to leverage resources compatible with essential regulatory functions.

- **Insufficient authority to ensure that educators and health workers adhere to mandated educational and practice standards** – Even when regulators are mandated by practice
acts to ensure accreditation, licensure and CPD, they often lack the ability to enforce compliance. Many Member States, for example, Cambodia and Papua New Guinea, have difficulty in simply ensuring that health workers maintain their registration.

- **Ensuring that overseas-qualified health workers seeking registration have completed an education programme that meets country standards, achieved the required core competencies and maintained their competencies in a manner consistent with the country’s continuing professional development requirements** – Fraudulent documentation of educational transcripts, diplomas, degrees and registration certificates exacerbates this problem. High-profile cases where registrants with significant criminal histories have been able to obtain a licence or continued to practise without a history being disclosed have underlined the importance of criminal history checks. Few countries have processes in place for criminal history checks, possibly due to the lack of jurisdictional authority for regulators in one country to access this information from another. In other countries such as Australia, a criminal record check is performed on initial registration and a statutory declaration required on an annual basis. International criminal record checks are performed on all professionals with an overseas background.
5.4 ENSURING COMPARABILITY OF REGULATORY SYSTEMS AND STANDARDS

While strengthening regulatory systems is a core strategy for improving health system performance, this has been difficult due to the above-mentioned challenges. Regulatory convergence for the health workforce in the Region offers an opportunity for Member States to understand the complementarity of trends and cooperate on health workforce regulatory functions.

Despite variations across countries in the Region, all regulatory systems aim to protect, promote and maintain public health and safety. However, from a Member State perspective, differentiated regulatory regimes can have negative implications for service provision. For instance, in developing economies the costs associated with establishing a regulatory system can effectively dissuade investment, resulting in health workers with weak competencies. From a health workers’ perspective, the need to demonstrate competence to multiple regulatory bodies can severely limit their mobility, capacity to specialize and assimilate in destination country labour markets. Differences in regulatory processes across Member States also can create potential inefficiencies through onerous and repetitive procedural requirements. Such differences in the standards, codes, compliance procedures and similar mechanisms impose costs and distortions that undermine regulatory systems. These costs can be direct, such as capital and operating costs, or indirect, in the form of reduced compliance, low productivity and skill underutilization.

Regulatory convergence can potentially address the above concerns both from an individual and system perspective. Convergence is often described as a continuum, ranging from the least formal approach, such as basic information sharing, to complete harmonization. Through continuous dialogue and the development of common standards, best practices and guidance, regulatory convergence processes can improve cross-border cooperation and regulatory capacity among countries with diverse regulatory styles, legislative practices, institutional arrangements and implementation experiences. It facilitates comparability of approaches and practices, consistent application and capacity-building in Member States with a less-developed regulatory culture. Such cooperation and coordination can strengthen national regulatory procedures and also improve health service quality. For instance, common curriculum standards aligned to a regional qualification framework can potentially reduce complexity and ambiguity in training across Member States, improve health workers’ fitness for practice, make it easier for them to move between Member States and gain valuable international work experience, and reduce unemployment and underemployment.
Experiences from Member States offer useful lessons for enhancing compatibility and improving compliance and enforcement of regulatory processes. To enhance efficiency, many governments are developing regulatory convergence initiatives to improve efficiency and enhance policy effectiveness and results. Such cooperation can be bilateral, for example, the Trans-Tasman Mutual Recognition Agreement between Australia and New Zealand; regional, as among ASEAN member states; or multilateral, as among signatories to the World Trade Organization General Agreement on Trade in Services.

Towards standardized qualifications – The Pacific Qualification Framework

The Pacific region is progressing towards achieving common levels of higher-education qualifications, a common quality assurance approach to the registration of education providers and common methods of accrediting programmes. These activities are facilitated by the implementation of the Pacific Register of Qualifications and Standards managed by the Pacific Community.

Until these region-wide objectives are achieved, education providers in the Member States of the region are acting independently – establishing diplomatic and professional ties for assistance on training, seeing increasing professional mobility, managing staffing shortages, addressing course equivalencies and transfer of credits, and duplicating educational standards and resources. The anticipated regional action on standardization of qualifications may not solve all the outlined problems, but it is expected to make their management easier and the outcomes safer.

The Pacific Qualifications Framework (PQF) has been adopted as a common Pacific reference framework that would link countries’ qualifications systems, acting as a “translation device” to make qualifications more understandable across different countries and systems in the Pacific. PQF can also be considered as a meta-framework that enables various qualifications frameworks to be related to each other and subsequently to allow comparisons of individual qualifications. Such comparisons would form the basis of greater recognition and transfer of the learning outcomes, in the form of qualifications, acquired by individuals. PQF would not replace national frameworks, but its viability would rest on building links with such frameworks.

The region, however, still has significant progress to make in terms of achieving comparability of courses and qualifications. A recent review of the health professions education courses available in Pacific countries identified more than 250 individual programmes in all disciplines and all levels. Each programme has different entry-level requirements; standards, learning outcomes and competencies; programme assessment criteria; institutional governance arrangements; and common processes of programme accreditation. These variances are expected, as qualifications have traditionally been deeply embedded in specific social and economic contexts and institutional settings.

Transnational qualifications frameworks such as PQF present an opportunity to standardize as well as increase the portability and recognition of qualifications. These have been successfully used by
the international community to address issues related to qualification recognition. For instance, the Caribbean Community and the European Union (EU) have frameworks for the recognition of qualifications across countries within the same region. Similarly, the ASEAN Qualifications Reference Framework provides a common reference framework that enables comparisons of education qualifications across participating ASEAN member states.


5.5 PATHWAYS FOR REGULATORY CONVERGENCE AND COOPERATION

Information sharing

The International Association of Medical Regulatory Authorities (IAMRA)\(^\text{36}\) undertakes a range of activities to improve the exchange of information among medical regulatory authorities about the medical practitioners they register in the public interest. IAMRA has developed new guidelines to improve the data sharing among international medical regulators, including the Public Registers Listing. The guidelines, Statement of Intent on Proactive Information Sharing, protect patients and the public by encouraging the sharing of disciplinary information about medical practitioners who move from one country to another. The Statement stresses the importance of medical regulators sharing information more consistently, defining the circumstances in which information should be shared and when it should be shared. The Statement also underscores the importance of due process and security of information exchanged.

For traditional medicine practitioners, existing mechanisms for information sharing are very limited. The only notable effort includes the Global University Network of Traditional Medicine (GUNTM),\(^\text{37}\) which aims to share information on the education system among a few education institutes in Australia, China, Hong Kong SAR (China) and the Republic of Korea.

Recognized qualifications

Laws in some Member States, such as Brunei Darussalam,\(^\text{38}\) Malaysia\(^\text{39}\) and Singapore,\(^\text{40}\) list equivalent or recognized qualifications and education providers while in others they

simply grant the authority to boards or councils to determine equivalence on a case-by-case basis. The law in Singapore also lists a few education providers for traditional Chinese medicine practitioners.

In Australia and New Zealand overseas-qualified medical graduates who have a primary qualification awarded by a training institution recognized by both the Australian Medical Council and the World Directory of Medical Schools and who have completed training or an assessment with an approved competent authority (General Medical Council—United Kingdom, Medical Council of Canada, Educational Commission for Foreign Medical Graduates of the United States, Medical Council of New Zealand and Medical Council of Ireland) may apply for provisional registration via the Competent Authority pathway. Japan accepts applicants for licensure from foreign medical graduates who have completed six years of medical education in a school listed in the World Directory of Medical Schools. While this means that licensure in Japan is relatively open to foreign-trained medical professionals, applicants still must take the national examination, which is in Japanese, thus reducing the potential pool of candidates.

**Mutual recognition agreements**

The number, purpose and success of memoranda of understanding, mutual recognition agreements or bilateral agreements between Member States that exist for the purpose of training and supply into practice vary considerably. Many Member States have no health workforce training, relying entirely on overseas-qualified personnel. For example, Macao SAR (China) relies on China or Hong Kong SAR (China); Palau relies on Fiji, New Zealand and the United States of America; and many smaller Pacific island countries and areas rely on Australia, Fiji, New Zealand and Papua New Guinea.

The diverse reciprocal and mutual recognition agreements across the Region to facilitate training and workforce supply may include numerous interconnected arrangements among governments, states, training providers, international agencies and individual Member States. Even where bilateral agreements are in place, such as between Australia and New Zealand, there is variability between professions on whether courses and qualifications are recognized from each country.

Aside from agreements in place for states and territories of the United States of America and ASEAN member states, information on other arrangements is limited.

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ASEAN Mutual Recognition Arrangements

The ASEAN Mutual Recognition Arrangements (MRAs) are framework agreements signed by the governments of Brunei Darussalam, Cambodia, the Lao People’s Democratic Republic, Malaysia, the Philippines, Singapore and Viet Nam that aim to promote free trade in services. Between 2005 and 2014, MRAs were for signed for eight professions, including nursing (2006) and medicine and dentistry (2009). The objective of the MRAs is to facilitate mobility of professionals; exchange information and expertise in standards and qualifications; promote adoption of best practices on standards and qualifications; and provide opportunities for capacity-building and training in nursing, medicine and dentistry.

The MRAs state that each host country, subject to its own domestic regulations, is responsible for evaluating the qualifications, training and experiences of overseas-qualified medical, nursing and dental practitioners, and can impose any other requirements or assessments for registration, as applicable. Once registered, practice is assessed, monitored and disciplined according to the professional and ethical codes of conduct and standards of practice of the host country. To facilitate the implementation of the MRAs and to encourage standardization and adoption of mechanisms and procedures for their implementation, ASEAN has established joint coordinating committees on medical, nursing and dental practitioners. The joint committees also encourage the exchange of information regarding laws and developments in the practice of medicine, nursing and dentistry within the Region with a view to harmonization in accordance with regional and/or international standards. Despite the intent, the implementation of the MRAs, including those for health professionals has been lagging. Efforts to register professionals with ASEAN-level councils and to collect and report data have not progressed uniformly.

At the regional level, absence of consistent harmonized data across ASEAN countries and across professions makes it difficult to track the status of the MRAs. However, reviews conducted to date indicate that the intraregional skilled mobility facilitated by MRAs is rather minimal. Support to an ASEAN-level data collection effort will be important to address the information needs and gaps.

At the national level, implementation of the MRAs has been slowed by many technical and institutional hurdles, which has increased the processing time. Moreover, access to destination-country labour markets has often been tightly controlled by domestic regulations. Addressing these barriers will require collective efforts involving a diverse range of stakeholders – employers, professional associations, government and regulatory authorities, educational institutions, service providers and the general public.

Overall, the alignment of regulatory structures, issues, objectives and preferences among Member States is a key determinant of success of regulatory convergence. This needs to take account of the extent of similarity in regulatory problems; regulatory objectives in a given field; standards for determining whether objectives are met; and social, economic and political – as well as technological – conditions. The design of the cooperation itself and the process through which it is developed will have an important role in determining its success.

**KEY MESSAGES**

- Health workforce regulation is an identified priority for safeguarding quality and public safety in all Member States.
- Considerable variability exists in regulatory arrangements and functions across Member States.
- Strengthening the regulation of health workers requires a life-course approach, from entry to practice requirements to in-practice monitoring and exit-from-practice processes.
- Limited technical capacity and financial resources pose challenges for efforts to strengthen health workforce regulation.
- Depending on the health system context, Member States need to invest in building the capacity of regulatory authorities and regulators to ensure availability of judgement-safe health workers.
- Regulatory strengthening and convergence mechanisms provide an opportunity to improve regulation of health workers in countries and in the Region.
6. THE ROLE OF REGULATORY CONVERGENCE AND COOPERATION IN THE REGION

Member States agree on the need to strengthen regulatory systems for both medicines and human resources, but they also recognize the challenges. However, countries lack sufficient funds for substantial investments in infrastructure and systems, and they often lack the in-country institutions and resources to develop local expertise and competence in regulatory science, administration and governance. At the same time, they need to regularly upgrade and improve their regulatory systems to keep up with technological advances. It is therefore difficult for countries, especially resource-constrained countries, to develop regulatory systems entirely on their own.

In addition, regulatory systems will continue to evolve to keep up with dynamic development and changing health needs. As markets expand and populations move, countries will increasingly need to share responsibility and accountability in raising the capacity of the entire Western Pacific Region to protect public health, safety and welfare. In this context, regulatory strengthening becomes a shared responsibility of all Member States in the Region, particularly in tackling the many public health challenges that transcend borders. This necessitates cooperation and convergence across national regulatory systems.

**Strengthening of national regulatory systems** — Regulatory convergence and cooperation can support strengthening of national regulatory systems through the following means:

- **Setting of standards** — Regulatory convergence and cooperation can facilitate the setting, monitoring and enforcement of standards. Divergent regulatory standards create unequal regulatory outcomes, duplicative processes and testing requirements, divergent conformity procedures, different documentation requirements,
corresponding delays and substantial additional costs. In addition, new technologies and professions evolve over time, requiring the development of new standards and regulatory procedures.

- **Sharing of good regulatory practices** – Regulations need to reflect country contexts and priorities, the availability of resources and infrastructure, the health system, the disease burden and the legal system. However, resourced-constrained countries are often uncertain of the regulatory approaches and pathways to take, thus burdening their regulatory systems and wasting resources. More efficient approaches to regulation, as well as internationally recognized processes and procedures to improve the quality and cost-effectiveness of national regulations, can be shared across countries.

- **Information exchange** – Regulatory strengthening and convergence increases the transparent flow of reliable and comparable information and thereby supports decision-making processes. Regulators need to continuously assess scientific studies and risks. Information exchange across regulators also enhances trust and confidence among regulators and by the public. Cooperation, communication and trust among national regulatory authorities based on common principles and harmonized approaches can strengthen the effectiveness of national regulation and international collaboration.

- **Development of legal frameworks** – Regulatory convergence can help strengthen the capacity of national regulatory authorities. It can provide a legal framework for implementing and enforcing internationally accepted standards across countries that disregard differences in domestic regulations and fill the vacuum where national laws are non-existent. Strategic multilateral cooperation among regulatory authorities can also strengthen predictability, trust, synergies, better use of collective resources and work products, and the sharing of best practices. Harmonization of legal frameworks can trigger legal reform and modernization in countries.

### 6.1 PLATFORM TO COLLECTIVELY ADDRESS PUBLIC HEALTH CONCERNS

A number of public health concerns, including, among others, public health emergencies, antimicrobial resistance, and counterfeit and substandard medicines, transcend borders, thus necessitating collective response and actions by countries.

### 6.2 RESPONSE TO EMERGENCIES

Public health emergencies often overwhelm the response capacity of Member States. International support can help contain outbreaks, provide emergency and humanitarian relief and support recovery. The availability of the health workforce and essential medical products is a core component of this process.

In general, however, national regulatory systems do not have provisions that allow the entry and dispatch of life-saving medicines, including vaccines, and health workers in cases of public health emergencies. Various regulatory requirements, including restrictive and prolonged registration processes and requirements of local clinical trials for new medicines and vaccines, can deter the timely availability of medicines and vaccines in emergencies. The Ebola crisis prompted recognition of the need for swift deployment of a skilled and multidisciplinary health workforce and trained teams of certified responders, combining the expertise of public health scientists, doctors, nurses and other health workers, such as logisticians, project managers, social scientists, communications experts and community workers – all available for immediate deployment.\(^{47}\) Regulatory convergence and cooperation can help support this process through emergency registration procedures or regional registration systems for health workforce in emergencies.

### 6.3 COUNTERFEIT AND SUBSTANDARD MEDICINES

Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products are a global threat to public health. They harm patients and undermine confidence in medical products, health-care professionals and health systems.\(^{48}\) The globalization of the medicines market, including the role played by the Internet, necessitates urgent international collaboration to prevent such products from reaching patients.\(^{49}\) Regulatory convergence and cooperation to implement the interregional surveillance and monitoring system, as well as common legal frameworks for seizure of products and apprehension of suppliers and distributors across borders, could support regional and global efforts to combat SSFFCs.

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6.4 ANTIMICROBIAL RESISTANCE

The increasing prevalence of antimicrobial resistance (AMR), spanning a broad range of microorganisms, threatens human and animal health, locally and globally. Regulations for medicines and the health workforce can play a crucial role in fighting AMR.

Uniform application of regulatory actions across countries along the following lines can help reduce the uncontrolled supply and use of antibiotics in communities, the health system, animal production and agriculture:

- **Labelling regulations:** Labelling and information for antimicrobials should prominently state that these drugs should be used only to treat infections and require adequate counselling of patients prior to use.51

- **Stricter monitoring of the quality of antimicrobials in the market, the prevalence of substandard medicines for human and veterinary use, and inappropriate or unregulated use of antimicrobials in agriculture necessitate regional sharing of results of substandard antimicrobials.**

- **A common regulatory framework for restricting the supply chain of antimicrobials, including regulations to prohibit and monitor sales through the Internet. Laws and regulations that restrict the use of antibiotics in humans and animals, including development of restrictive lists and the control of supply of antibiotics, and that ensure that antibiotics for human use do not cross over into veterinary use.**

- **Establishment of surveillance systems for antibiotic consumption and regional and global sharing of information.**

Health workers have an important role in controlling AMR, but inadequate knowledge, practices, and perverse incentives in the sale, prescription and dispensing of antimicrobials are prevalent across countries.

In general, most Member States have defined regulations around the separation of the role of physicians and pharmacists with regard to prescribing and dispensing of medicines, established codes of conduct for ethical behaviour, adherence to standard treatment guidelines, and the promotion informed decision-making on the use of antibiotics. However, these measures have not been sufficient to fully address the problem of antimicrobial use.


Antibiotic prescribing and dispensing practices are determined and driven by multiple factors, including management and supervision systems and monetary and non-monetary incentives, including the regulation of practice.\textsuperscript{52}

It is widely recognized that the education of health workers in the appropriate prescribing, dispensing and use of antibiotics is critical to addressing misuse and overuse, a known driver for the development of AMR. Key areas of intervention may include the development of a global multidisciplinary competency framework for AMR and antimicrobial stewardship education and global prototype curricula for AMR education tailored to roles and cadres.\textsuperscript{53} National and regional accreditation bodies may also consider including these as requirements for health worker pre-service education and in-service training.

The perverse incentives around the sale, prescription and dispensing of drugs merit ethical and disciplinary measures, and antimicrobials can be the point for entry. Among such measures, regulations that prohibit the marketing and detailing of pharmaceuticals in hospitals and controlling marketing activities aimed at prescribers, other health-care practitioners and users. In addition, the crossover of the industry and health-care professionals into the areas of research, continuing medical education, clinical trials and other similar interactions requires mechanisms for the declaration of conflicts of interest for both health professionals and the industry.


\textsuperscript{53} WHO. Expert consultation meeting on health workforce education and antimicrobial resistance control (http://www.who.int/hrh/news/2017/AMR2017-2.pdf?ua=1).
7. GAPS IN REGULATORY CONVERGENCE & COOPERATION

Regulatory convergence and cooperation require that participating regulatory authorities have comparable levels of maturity or proficiency in implementing selected regulatory functions. Cooperating regimes often set stringent criteria for participation that are necessary to ensure a level of trust and reliance among cooperating regimes. For this reason, regulatory convergence and cooperation in their current form benefit mostly more-developed countries, as a certain level of maturity and capacity is needed for regulatory systems to effectively collaborate. This leaves less-mature regulatory systems behind. Continuing such arrangements will only widen the capacity gap between more-mature and less-mature regulatory systems, creating inequities in the degree of protection and safety of populations.

It is also important to note that countries with more advanced regulatory systems and which are faster in adopting and applying international norms and standards have not necessarily impacted overall regulatory strengthening in the Region, as they tend to cooperate more with countries outside the Region with similar levels of development. Although some countries, such as Australia, Japan and the Republic of Korea, have recently initiated programmes to support regulatory systems in less-developed countries, a more coordinated approach is needed to support such initiatives.
The Western Pacific Region will continue to experience increasing demand for and supply of both medicines and health workers, and an increasing interdependence among regulatory systems will be needed to meet local as well as regional needs. The considerable variation in existing regulatory arrangements, approaches and processes across the Region indicate the need to strengthen and adopt comparable approaches and practices, including building capacity in Member States with a less-developed regulatory culture. Regulatory strengthening should be a priority for Member States, and convergence mechanisms offer an opportunity to build and share best regulatory practices. A series of concrete steps at the regional and national levels can be taken now that will help realize the potential that strengthened efforts and collaboration hold for the future. These include:

**a. Follow a stepwise approach in strengthening regulatory systems**

Efforts to strengthen regulatory systems and processes must be targeted and prioritized, with a view to enhancing sustainability. Due to the complexity of regulatory functions and resource constraints, Member States may not be able to implement all regulatory functions at the same time, or in a manner that is consistent to international best practices. Nevertheless, all regulatory systems should have several foundational elements, regardless of their development status. A stepwise approach can enable countries to prioritize the development or implementation of regulatory functions based on their context and needs.

For medicines and medical products, the stepwise approach should begin with an assessment of country needs and context and the development of a legal framework as the foundation for the performance of regulatory functions. This includes a system for registration and licencing of medical products; a mechanism for pharmacovigilance that includes clear procedures for product withdrawal, and the authority to restrict or remove a medical product from market circulation. The range of regulatory functions to
be developed is underpinned to a large extent by the pharmaceutical profile or activity of the country. Fig. 2 presents the stepwise approach for developing medicines regulatory systems in countries.

For the health workforce, a stepwise approach includes a system for registration, licencing and relicencing of health workers, including clear procedures for complaints and disciplinary actions, as well as the authority to restrict or remove health workers from professional practice. Fig. 3 presents the stepwise approach for developing health workforce regulatory systems in countries.

**FIG. 2**  Stepwise approach for strengthening medicines regulation

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<td>Licencing of establishments (importation, distribution and retail)</td>
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These essential regulatory functions should be supported by: a) a strong legislative framework and political leadership, with a clear focus on public safety and transparency in decision-making; b) a common understanding of the design of the regulatory regime, the institutions and bodies responsible for implementation and enforcement, funding mechanisms, and related infrastructure and personnel requirements; and c) a protocol for various regulatory agencies to share information and oversight on regulatory processes and functions. There should be a shared understanding on how to introduce additional regulatory functions that may become necessary in the interest of public safety, and as determined by the system capacity.
b. Ensure that regulation accounts for the lack of separation between practising and prescribing in traditional medicine

In the Region, traditional medicines are often prescribed, produced and dispensed by traditional medicine practitioners or dispensers. In Member States where there is no capacity and infrastructure to produce traditional medicines in manufacturing facilities, traditional medicines that are produced by individual practitioners comprise the majority of the traditional medicines market. However, the quality and safety of such products cannot be assured by conventional approaches to regulate medicines since these products are produced by individual practitioners rather than through standardized production. Control of the quality and safety of these products, therefore, is closely linked to regulation of the practitioners and their services.

Furthermore, traditional medicines sometimes include toxic medicinal plants. Another critical issue to be considered in the regulation of traditional medicines is potential interactions between traditional medicines and pharmaceuticals. These factors again highlight the importance of the regulatory system for practitioners to ensure the quality and safety of their products as well as their safe use by the providers and consumers.

Regulatory functions such as registration or licencing, education and training for practitioners to meet qualifications, and an ethical code of conduct for the health workforce can have a great impact on hygienic production, ethical practice in production and the safe use of the traditional medicine products. Thus, Member States may consider establishing or strengthening the regulatory system for traditional medicine practitioners.
There are also challenges in setting registration requirements and standards for education for traditional medicine practitioners in resource-limited countries and areas. Active information sharing on the regulatory system and standards for traditional medicine practitioners among Member States in the Region will provide useful and critical information to countries and areas in developing country-specific strategies to strengthen or establish the regulatory system for traditional medicine.

c. Measure and report on performance

Regulatory authorities need to develop and implement a performance measurement and reporting framework that measures, monitors and reports on their own performance. Performance information systems should be designed to inform internal and external stakeholders about the performance of regulatory agencies with respect to the stated policy objectives, the costs associated with administering the regulation and the cost of compliance for regulated entities. Regularly monitoring and reporting against agreed benchmarks can assist in managing stakeholder expectations in relation to the regulatory process, in increasing transparency and accountability, and in helping monitor and assess operational performance.

Self-evaluation to identify strengths and opportunities for the improvement in regulatory functions could be an important starting point for regulatory system strengthening. Such evaluations can inform the formulation of plans to strengthen the institutional capacity of regulating authorities. The plans may also facilitate the identification of gaps in technically complex areas that may be addressed via different mechanism, including potential collaboration and convergence across more advanced regulatory authorities and institutions.

d. Build the capacity of regulators

One challenge that Member States face is building a competent regulatory staff, with competent professionals. Regulators often come from diverse disciplinary backgrounds and lack prior training and experience in the regulatory field. Effective regulatory professionals need competency in science and technology; the ability to interface with other experts involved throughout product life cycle; the ability to link science, clinical practice, regulation and policy; an understanding of business processes; strong organizational and communications skills; and strong analytical and critical thinking skills.54 These competencies and skills can be acquired through a combination of institutional learning, as well as training in actual regulatory settings.

e. Ensure effective governance of regulatory functions

An effective governance mechanism is important because regulatory processes are often implemented by various institutions within and outside government that use different regulatory approaches, including voluntary regulation and self-regulation. In this context, the role and responsibilities of each institution should be clearly defined, along with a common understanding of the goals of good governance that is transparency, accountability, legitimacy, trust and efficiency.

Regulatory governance can be strengthened through the implementation of a combination of: a) a legislative framework that clearly articulates regulatory mandates and roles; b) strengthened regulatory agencies with transparent, accountable and consistent decision-making processes; c) introduction of audit processes to evaluate the effectiveness of regulations, policy tools and programmes; and d) the establishment of appropriate internal communications and information-sharing mechanisms that can facilitate consistency in decision-making and information sharing across the organization.35

In addition, encouraging the participation of stakeholders in the regulatory process through consultation and feedback can assist in understanding the role of regulation in promoting both quality and safety practices, including the efficiency and effectiveness of the regulatory regime.

f. Enable countries to participate and benefit from existing regulatory convergence mechanisms

Regulation of medicines and health workers requires coordination across borders and among countries, as no one regulatory authority can perform all the functions at the same time with optimal resources and capacity.

The process of regulatory convergence for both medicines and the health workforce has proven useful in supporting the implementation, recognition and enforcement of regulatory standards across countries. It also reduces duplication and backlogs, and it improves the overall efficiency of regulatory processes in countries and at supranational levels.

Existing convergence initiatives, however, do not enable participation by all countries. So far, only national regulatory authorities with high-level capacity and resources can participate in these platforms and those that have fewer resourced cannot participate or benefit.

These may imply, therefore, the need to:

i. revisit the structure of the existing convergence initiatives so as to enable countries to participate at various stages while building their capacity in the process; and

ii. establish a mechanism for sharing existing tools and capacity-building initiatives of the existing convergence initiatives with non-participating countries.

9. RECOMMENDATIONS

9.1 RECOMMENDATIONS FOR MEMBER STATES

a. Strengthen national regulatory authorities for medicines and the health workforce, as appropriate, including by:
   — Setting priorities for regulatory system strengthening based on the country-specific context and public health needs, including identification of a core set of regulatory functions to be performed.
   — Applying a self-evaluation tool on regulatory system performance.
   — Formulating plans to address the capacity gaps and other weaknesses in regulatory system performance.
   — Developing the required technical, statutory and administrative competencies of regulatory authorities to effectively implement and administer the relevant regulatory functions.
   — Drawing on standards and practices of other countries to accelerate strengthening of weak national regulatory systems.

b. Engage in global, regional and subregional networks of national regulatory authorities for medicines and the health workforce, as appropriate, including by:
   — Recognizing the importance of convergence and collaboration in reducing duplication and pooling regulatory capacity to promote greater access to quality and safe medicines and the health workforce.
   — Collaborating on developing policies that lay the foundation for regulatory strengthening and convergence and increased cooperation, which should include efforts to promote the standardization of quality assurance by implementing
internationally accepted, contemporary regulatory approaches that cover medicines and the health workforce.

— Identifying opportunities for regulatory convergence efforts to help strengthen national regulatory systems, especially where substantial gaps exist, such as technically complex and resource-intensive regulatory functions.

— Promoting various forms of convergence including information sharing, cooperation, collaboration, reliance, mutual recognition and work sharing, depending on the country context and needs.

c. Put in place systems, incentives and policies to collect, report, analyse, and use reliable and impartial regulatory data, including as a means to enhance transparency, accountability and the performance of regulatory systems.

d. Improve the quality of data and strengthen policies to address information gaps on the scale, composition and direction of movements of health workers.

9.2 RECOMMENDATIONS FOR WHO

a. Continue to support Member States to strengthen their national regulatory systems, as appropriate, including by:

— Raising awareness of the importance of effective regulatory systems to improve quality and safety within the health system, thereby protecting public health and advancing universal health coverage (UHC).

— Engaging in policy advocacy and dialogue to support legislative reform and regulatory systems strengthening, including engagement with lawmakers to galvanize political commitment and action.

— Supporting Member States in applying self-evaluation tools and using the results to inform policies and actions to strengthen regulatory system performance.

— Providing technical support to implement institutional development plans in national regulatory authorities, thereby strengthening capacity on core regulatory functions.

b. Strengthen and coordinate global, regional and subregional networks of national regulatory authorities, as appropriate, including by:

— Promoting greater participation by Member States in existing or evolving networks for convergence.

— Facilitating the dissemination of information, best practices and experiences across the convergence and cooperation initiatives.

— Assisting in the development of appropriate regulatory standards and guidelines.

— Advocating for prioritization of initiatives that will support strengthening of regulatory systems in less-resourced countries.
Glossary

**Accreditation**
A process of review and approval by which an institution, programme or specific service is granted a time-limited recognition of having met certain established standards beyond those that are minimally acceptable.

**Adverse event following immunization (AEFI)**
Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

**Biologicals**
Biological products can be defined according to their source material and method of manufacture. Biological products are derived from cells, tissues or microorganisms and reflect the inherent variability characteristic of living materials. The active substances in biological products are often too complex to be fully characterized by utilizing physicochemical testing methods alone and may show a marked heterogeneity from one preparation and/or batch to the next.

**Biosimilar**
A therapeutic product of biological origin that is similar in terms of quality, safety and efficacy to an already licenced reference biotherapeutic product.

**Certification**
A voluntary time-limited process by which a nongovernmental organization within a profession or specialty grants recognition of competence to an individual who has met pre-established eligibility requirements and standards.

**Certificate of Pharmaceutical Product (CPP)**
It is a certificate that establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

**Clinical trial**
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
**Common technical document (CTD)**
A set of specifications for an application dossier for the registration of medical products. It is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries.

**Continuing professional development (CPD)**
The establishment of higher levels of competence in the range of knowledge, skills and abilities needed to perform duties or support interventions, be they in clinical practice, management, education, research, regulation or policy-making.

**Credentialing**
Credentialing is a term applied to processes used to designate that an individual, programme, institution or product have met established standards set by an agent (governmental or nongovernmental) recognized as qualified to carry out this task. The standards may be minimal and mandatory or above the minimum and voluntary. Licensure, registration, accreditation, approval, certification, recognition or endorsement may be used to describe different credentialing processes.

**Efficacy**
The extent to which a specific intervention, procedure, regimen or service produces the intended results under ideal conditions.

**Equivalency**
Equivalence refers to the process where, although two differing standards or procedures remain intact, they are treated as if they are the same because, in theory, they produce the same or similar result.

**Good agricultural and collection practice**
Quality and safety issues for traditional medicines often result from the use of raw medicinal plants that are not of a sufficiently high-quality standard. Inadvertent contamination by microbial or chemical agents during any of the production stages can lead to deterioration in safety and quality. Medicinal plants collected in the wild may also be contaminated by other species or plant parts through misidentification, accidental contamination or intentional adulteration, all of which may have unsafe consequences. In addition, it has impact on sustainable use of natural resources and environment. Thus, good agricultural and collection practices aim to provide technical guidance on obtaining raw medicinal plants of good quality to improve the quality, safety and efficacy of finished products and ensure sustainable production of traditional medicines.
**Good distribution practices**
That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

**Good manufacturing practices (GMP)**
That part of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. GMP is concerned with both production and quality control. GMP is aimed primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products.

**Good storage practices**
That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout storage.

**Guidelines**
Interpretative statements, which serve to extend and clarify meaning, but are not intended as an absolute standard.

**Health workforce**
The human resources for health includes physicians, nurses and midwives, but also laboratory technicians, public health professionals, community health workers, pharmacists and all other support workers whose main function relates to delivering preventive, promotive or curative health services.

**Licence**
An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using international non-proprietary names or national generic names where they exist), the shelf life and storage conditions and packaging characteristics. It also contains all information approved for health professionals and the public (except promotional information), the sales category, the name and address of the holder, and the period of validity of the licence.
Lot release

Lot release is the process of evaluating each individual lot of a licenced product before giving approval for its release into the market. This process is carried out for vaccines and other biologicals in most countries. General practices of release involve the review of the manufacturer’s production data and quality-control test results (product summary protocol) by the national regulatory authorities (NRA) and national control laboratories. This may or may not be supplemented by laboratory testing by the national control laboratory, or by an agency or contracted laboratory performing tests for the NRA.

Mandatory regulation

This term is usually applied when the authority for regulation is governmental, usually through a statute, and approval for practice is legally required. Standards are usually set at the minimum required for public protection.

Marketing authorization (as a certificate)

A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf life.

Marketing authorization (as a process)

Process of reviewing and assessing the dossier to support a medicinal product in view of its marketing (also called licencing, registration, approval, etc.), finalized by granting of a document also called a Marketing Authorization (MA) (equivalent: product licence). This process is performed within a legislative framework which defines the requirements necessary for application to the concerned (competent) regulatory authority, details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where a marketing authorization already granted may be withdrawn, suspended or revoked.

Market surveillance and control

Market surveillance and control functions are the strategies and actions to protect consumers from dangerous products and to ensure a level playing field for reputable businesses. As part of this function relevant national authorities check whether products meet the applicable safety requirements, they take necessary steps to make sure that products are compliant, and apply sanctions when necessary. Market surveillance and control focus on four areas: 1) control of import and export activities; 2) combating substandard and falsified products; 3) market surveillance for quality checks; and 4) control of promotion, marketing and advertisement activities.
Maturity
A measurement of the ability of an organization for continuous improvement in a particular discipline. The higher the maturity, the higher will be the chances that incidents or errors will lead to improvements either in the quality or in the use of the resources of the discipline as implemented by the organization. Most maturity models assess qualitatively people/culture, processes/structures, and objects/technology.

Mutual recognition
A vehicle for regulatory convergence based on equivalence, or external criteria such as the host country’s standards or other mutually agreed standards, or international standards. In a mutual recognition agreement, two or more parties agree to recognize and accept all, or selected aspects of each other’s regulatory results because they are judged to be equivalent, or because they satisfy other agreed-upon external criteria.

Pharmaceutical products
More commonly known as medicines or drugs, pharmaceutical products are defined as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and as articles intended to affect the structure or any function of the body of humans or animals. They are a fundamental component of both modern and traditional medicine. It is essential that such products are safe, effective and of good quality, and are prescribed and used rationally.

Pharmacovigilance
Pharmacovigilance encompasses the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.

Quality
The suitability of either an active pharmaceutical ingredient or a pharmaceutical product for its intended use. This term includes such attributes as identity, strength and purity.

Quality assurance
Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas: development, quality control, production, distribution and inspections.
Quality-control laboratory

Pharmaceutical quality-control laboratories serve as an important function in pharmaceutical production and control. A significant portion of GMP regulations pertain to the quality-control laboratory, and product testing and pre-market analysis are used for registration. Many national quality-control laboratories also perform post-market surveillance by sampling and testing products already in the market to monitor the quality and safety of products after marketing authorization. It assists the regulatory authority to assess the actual quality in the market and identify problems.

Recall and market withdrawal

A system to withdraw from the market, promptly and effectively, products known or suspected to be defective. The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, a suspect product or any other serious quality problems with a product.

Recognition

Formal acceptance of an institution, programme or service by another institution or public authority. It may also mean the acceptance of knowledge, skills or formal qualifications of an individual and the granting of advanced standing or credit.

Registration

Process of providing authority to use an exclusive title to those persons entered on a register.

Regulatory body/authority

A formal organization designated by a statute or an authorized governmental agency to implement the regulatory forms and processes whereby order, consistency and control are brought to the profession and its practice.

Regulatory convergence

The process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices.

Regulatory governance

Refers to the different ways that regulatory organizations or institutions manage their affairs. Governance is the act of governing and thus involves the application of laws and regulations, but also of customs, ethical standards and norms. Good governance means that affairs are managed well, not that the laws, regulations or norms are themselves necessarily “good”.

Regulatory harmonization
The process in which technical guidelines are developed to be uniform across participating authorities.

Regulatory inspections
The purpose of regulatory inspections is to evaluate the manufacturer’s compliance with GMP in all aspects of production and quality control. The regulatory inspection programme should be designed to detect any shortcomings in the implementation of GMP and to recommend the necessary corrective actions.

Regulatory strengthening
Strategies and efforts to support national regulatory authorities to fulfil their mandate in an effective, efficient, predictable and transparent manner, which is of critical importance in ensuring the quality, safety and efficacy of health products in an increasingly complex global environment.

Reliance
The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – totally or partially – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

(Re)-Licensure
The process, sanctioned by the law, of granting exclusive power or privilege to persons meeting established standards, which allows them to engage in a given occupation or profession, and to use a specific title.

Risk-based approach
Methodology that allows prioritization of activities based on the previous analysis of data. The risk-based approach allows prioritization based on highest risk, and identifies risks faster, providing efficiency and savings to the systems. It requires data collection and analysis.

Safety
Safety is defined in terms of a risk. Currently, safety is discussed in terms of probability and the magnitude of benefit or harm and it is specified by several common factors: medical problem, population affected and conditions of use. A technology may provide benefits, but the value of those benefits depends on the risks involved in using the technology.
**Standard**

The desirable and achievable level of performance against which actual practice is compared.

**Statutory regulation**

Regulation that is mandated by law, act, decree or statute.

**Traditional and complementary medicine**

Traditional and complementary medicine merges the terms “traditional medicine” and “complementary medicine”. Traditional medicine often refers to indigenous traditional medicine, and complementary medicine refers to a broad set of health-care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. The terms are used interchangeably in some countries.

**Traditional medicine**

Traditional medicine is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

**Vaccine**

Medical products containing antigens capable of inducing an active immune response for the prevention, amelioration or treatment of infectious diseases.

**Voluntary regulation**

Regulation that is conducted by an authority external to the government. The credential or qualification thus earned is not legally required for practice or the service to be rendered.