World Health Organization
Western Pacific Region

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

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# ABBREVIATIONS

| | |
|---|---|
| **AEFI** | adverse event following immunization |
| **AHPRA** | Australian Health Practitioner Regulation Agency |
| **AMR** | antimicrobial resistance |
| **APEC** | Asia-Pacific Economic Cooperation |
| **ASEAN** | Association of Southeast Asian Nations |
| **CPD** | continuing professional development |
| **CPP** | certificate of pharmaceutical products |
| **EU** | European Union |
| **GMP** | good manufacturing practice |
| **GUNTM** | Global University Network of Traditional Medicine |
| **HPCA** | Health Practitioners Competence Assurance, New Zealand |
| **HPDT** | Health Practitioners Disciplinary Tribunal, New Zealand |
| **IAMRA** | International Association of Medical Regulatory Authorities |
| **ICDRA** | International Conference of Drug Regulatory Authorities |
| **ICH** | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| **IGBA** | International Generic and Biosimilar Medicines Association |
| **IPRF** | International Pharmaceutical Regulators Forum |
| **IRCH** | International Regulatory Cooperation for Herbal Medicines |
| **IGDRP** | WHO-International Generic Drug Regulators' Pilot |
| **MRA** | mutual recognition agreement |
| **PIC/S** | Pharmaceutical Inspection Co-operation Scheme |
| **PQF** | Pacific Qualifications Framework |
| **SSFFC** | substandard, spurious, falsely labelled, falsified and counterfeit |
| **TGA** | Therapeutic Goods Administration, Australia |
| **UHC** | universal health coverage |
| **WHO** | World Health Organization |

# EXECUTIVE SUMMARY

**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