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**REGULATORY STRENGTHENING AND CONVERGENCE FOR
MEDICINES AND HEALTH WORKFORCE**

Strong, effective national regulatory systems for medicines and the health workforce are necessary to ensure the quality and safety of health services, protect public welfare and help achieve universal health coverage. This involves a range of regulatory functions that regulate entry, ensure continuing quality assurance, and implement recall of medical products as well as delisting of health professionals from service when international standards are not met.

The regulatory landscape for medicines and the health workforce is varied across the Western Pacific Region. Some Member States have highly functional regulatory systems, while others have relatively weak systems or no formal regulations. This has resulted in wide differences in the degree and level of protection afforded to the populations across the Region. In addition, the rapid development and introduction of new therapeutic products and the increasing demand for new medical services add pressure to those countries that are already weak and poorly resourced. Regulatory convergence and cooperation have been recognized as mechanisms to reduce the burden by individual countries, extend the reach beyond borders and drive continuous improvement of national regulatory systems. However, only the more mature regulatory regimes are able to participate, leaving the less-resourced countries behind and further widening the gap among national regulatory systems in the Region.

The Regional Committee for the Western Pacific is requested to consider for endorsement the *draft Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce*.

1. CURRENT SITUATION

The quality and safety of both medicines and the health workforce are fundamental to ensure effective health services, protect the public welfare and help achieve universal health coverage (UHC). The *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* guides Member States in strengthening regulatory systems at the national level and across national borders. The Regional Action Agenda provides a framework for cooperation among Member States and their participation in and utilization of global, regional and bilateral convergence and cooperation platforms.

Competent regulatory authorities are the foundation for the effective regulation of medicines and the health workforce – from their entry into the market or into practice, for ongoing quality assurance, and to oversee the exit of medicines from the market and of health practitioners from practice when internationally accepted standards and good practices are not met. The regulatory landscape for medicines and the health workforce varies across the 37 countries and areas in the Western Pacific Region, depending on their stage of development and context. While some Member States have highly functional regulatory authorities, others have relatively weak systems or no formal regulations at all. As a result, significant differences exist in the implementation of standards for quality and safety of medicines as well as in standards of practice for the health workforce.

In the case of medicines, countries in the Region regulate a wide range of products, including medicines, vaccines and biologicals, traditional medicines, and other forms of therapy. 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. Countries like China, Malaysia, the Philippines and Viet Nam have regulatory systems in place, but they are dealing with the challenges of expanding pharmaceutical products and the 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 terms of traditional medicines, the regulatory landscape is also diverse across Member States. Many countries have legislative frameworks for regulations, but their implementation and enforcement remain a cause for concern. Despite such substantial variation in the level of

development of the regulatory systems, countries face common challenges in ensuring the quality, safety and effectiveness of traditional medicines.

In the case of human resources, 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. All Member States have legislation that mandates regulations of a range of health professionals. The number of regulated health professions, however, is not indicative of the maturity of a regulatory system.

The rise in globalization and market expansion in the Region are resulting in the rapid introduction of new therapies and technologies as well as the increasing mobility of the health workforce across borders. This situation necessitates extending regulations beyond national jurisdictions.

Member States acknowledge the need for strengthening regulatory authorities and for the regulatory burden to be increasingly shared across countries. Over the years, initiatives have evolved for regulatory convergence and cooperation with regulatory regimes across countries or regions becoming similar, aligned or compatible to achieve a common outcome. These initiatives have enabled countries to participate in information-sharing, standard setting, and the development of processes and guidelines, thus creating opportunities for capacity-building and the mutual recognition of regulatory functions. However, there are barriers for participation in these convergence mechanisms that often leave less developed countries behind.

2. ISSUES

2.1 The regulatory capacity for medicines and the health workforce is varied across the Western Pacific Region.

The maturity of regulatory systems varies significantly across the Member States in the Region. Some have highly functional regulatory systems, while others have relatively weak systems or no formal regulations, resulting in wide differences in the degree and level of protection that are afforded to the populations across the Region.

Regulation of both medicines and the health workforce involves a wide range of regulatory functions that need to be enforced through the life cycle of a product and throughout the tenure of

health workers. The statutory frameworks and technical competence of many regulatory systems in the Region to effectively perform these functions are inadequate.

Weak regulatory systems expose health systems and communities to the dangers of substandard and poor-quality products and unqualified health practitioners. Weak regulation and enforcement put people at risk and can lead to higher health system costs from compromised efficiency. At the regional level, the variation in the capacity of the regulatory systems threatens coordinated policy, action and interoperability, especially in relation to efforts to protect public health and security.

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 in particular 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.

2.2 The rapid introduction of therapeutic products, increasing demand of the population for health services and increasing mobility of medicines and the health workforce exert pressure on national regulatory systems.

The increasing demand for health services as well as the rapid introduction of therapeutic products and new technologies and services necessitate the continuous improvement of national regulatory systems and therefore add pressure to those countries that are already weak and poorly resourced.

New products and technologies contribute to the rapid evolution of regulatory science. This process requires countries to adjust and adopt new tools, standards and approaches to assess their safety, efficacy, quality and performance. The increasing expectations by health-care providers and patients for timely access to services have increased pressure on national regulatory authorities for expedited processes, in particular in relation to medicines.

Regulation of both medicines and the health workforce involves a wide range of regulatory functions that need to be enforced through the life cycle of a product and throughout the tenure of service of health workers. The execution of these regulatory functions is normally performed by specialized agencies with a mix of technical and scientific expertise as well as administrative and statutory competence.

Countries with fewer resources are not able to perform the full range of the regulatory functions. Thus, convergence and cooperation with other regulatory authorities around the Region could be an option.

Regulatory convergence and cooperation can support national regulatory systems strengthening through standard setting, sharing of best regulatory practices, information exchange and the development of legal frameworks. Convergence mechanisms can provide countries with weaker regulatory systems an opportunity to access and learn from international best practices. Convergence also reduces duplication and backlogs, and improves the overall efficiency of regulatory processes.

In addition, convergence and cooperation will allow countries to collectively address the increasing demand for health services, including public health issues that transcend borders such as facilitating the entry of medicines and health workers during emergencies, preventing and controlling the entry of counterfeit and substandard medicines, and developing common regulatory actions against antimicrobial resistance.

2.3. Regulatory convergence and cooperation needs to be facilitated to better support less-resourced countries to strengthen their national regulatory systems.

Countries with fewer resources have limited opportunities for participating in regional and global mechanisms. In any form of regulatory cooperation and convergence, a country's level of regulatory competence must first be established so that other countries and authorities can evaluate the regulatory functions performed or decisions made by that country. Stringent criteria for participation are set to ensure a level of trust among and reliance upon cooperating regimes. For this reason, regulatory convergence and cooperation currently benefit mostly those countries that are more developed, leaving behind those with less developed regulatory systems. As a result, the capacity gap between more mature and less mature regulatory systems creates inequities in the degree of protection and safety of populations.

Countries with more advanced regulatory systems, as well as those that are quicker in adopting and applying international norms and standards, tend to cooperate more with countries outside the Region that enjoy similar levels of development. As a result, those countries with more advanced regulatory systems do not necessarily have an impact on overall regulatory strengthening in the Region. 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.

These gaps must be addressed to enable countries with fewer resources to participate in regulatory activities, while they work in a stepwise manner to strengthen their own regulatory systems.

3. ACTIONS PROPOSED

The Regional Committee for the Western Pacific is requested to consider for endorsement the draft *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce*.