



Improving safety, quality and efficacy of medicines in the Americas

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In the Region of the Americas, access to medicines and other health technologies constitutes a priority for countries as they continue to move towards universal access to health and universal health coverage. Ensuring the availability of affordable medicines and health technologies within health services is required as part of the comprehensive approach to disease prevention and control. Through the adoption of pharmaceutical policies and strategies at the national level, governments establish the framework that will ensure equitable access and affordability of medicines and health technologies, while promoting their rational use. Core to such policies and strategies is the principle of quality, safety and efficacy. The pharmaceutical and health technology sector plays a critical role in the health promotion and protection by ensuring that those products and technologies made available through the health systems respond to international norms of quality and safety. The role of the government, and in particular the ministry of health, jointly with interested stakeholders, is to create a regulatory environment that guarantees the quality of the product throughout its life cycle, to ensure patient safety and optimize health outcomes. As globalization continues, with an ever increasing flow of people and products across borders, product quality and safety becomes a co-responsibility between countries and interconnected regulatory systems—nationally, regionally and globally. The regulatory landscape for medicines and health technologies is complex, given the multiple different types of product (medicines, biologicals, medical devices, etc.), the co-existing of single, limited and multiple source products within the market, the increasing technological complexity of new products entering the market (genomic, biotechnical products, etc.), and the critical array of regulatory functions (clinical studies, manufacturing, distribution, post marketing surveillance, etc.). Just as health systems differ significantly between countries in terms of structure and organization, national regulatory systems similarly differ depending on the capacity of the pharmaceutical research, development and manufacturing sector, and the objectives of the health system. Nonetheless, national regulatory systems for medicines and health technologies must guarantee a set of essential functions to ensure that medicines produced nationally, exported or imported meet international norms in quality, safety and efficacy.

Within this context, information exchange, sharing of regulatory experience and joint cooperation between National Regulatory Authorities are critical to ensure quality and safety, as well efficiency in facilitating access to essential medicines and health technologies. The Pan American Health Organization/World Health Organization (PAHO/WHO) Member States reaffirmed their commitment to strengthening regulatory capacity for health technologies during PAHO's 50th Directing Council (2010) through the adoption of Resolution CD50.R9 "Strengthening Regulatory Authorities for Medicines and Biologicals". Within the framework of this resolution, the *Pan American Journal of Public Health*, with the support of the US Food and Drug Administration (US FDA) and an editorial committee comprised of global experts in the field, identified in 2014 four critical areas of work that would require further research and analysis to support Member States in the development of integrated and functional regulatory systems.

The first area of work identified was related to implementation of core regulatory functions and development of innovative models for regulatory systems, in particular models for regulatory systems operations and novel approaches for transforming, improving and/or developing national regulatory systems in settings with limited resources and/or capacity through cooperation and collaboration. Articles related to the regulation of medicines, medical devices and laboratories were presented and highlight national experiences and innovative approaches to strengthen regulatory capacity in these areas.

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The second area of work was related to the competencies in the implementation of good regulatory practices and regulatory sciences. Recognizing that regulatory systems cannot develop without technical and scientific competencies, organized within a framework of good regulatory practices, papers were sought to present experiences from countries including strategies for competencies development, and the use of regulator science to support decision making processes.

Harmonization, convergence, cooperation, and reliance was the third area of work proposed for this special issue. Articles were sought to assess the experience of countries within the Region in their participation in harmonization and convergence mechanisms, and in more informal collaborative fora where regulatory information is shared between regulatory authorities to facilitate regulatory decisions. Articles were received on regional, sub-regional and intra-regional collaboration in the regulation of medicines and health technologies, leveraging information and regulatory decisions issued by third party regulators. Another specific topic covered by the articles related to the adoption and effective use of common standards in the Region.

The relationship between the development of regulatory systems and economic development was also a subject of interest for this special issue. Evidence was sought to assess the contribution of regulatory systems, not only with respect to the protection and promotion of public health but more broadly to trade, economic development, and national security.

The articles presented reflect the diversity of the Region, highlighting some of the challenges facing national regulatory authorities as a component of national health systems supporting the movement towards universal health, but also as an entity critical to the implementation of research, development and innovation policies in the pharmaceutical and health technology sector, as well as industrial policy.

Increasing access to medicines and other health technologies is a priority issue at the national, regional and global level. Investing in regulatory systems is necessary to ensure the efficacy, safety and quality of medical products in national and global markets and to protect the health of people. As we work collectively towards this objective, collaboration between regulatory authorities must be intensified to continue with the development of interconnected regulatory systems that will facilitate the achievement of this goal. As we move forward, PAHO/WHO will continue to play a key role in supporting national regulatory authorities, to support the development of the regulatory frameworks and systems that meet national needs, and to provide technical cooperation to strengthen capacity, increase transparency and promote increasing levels of regulatory convergence within the Region of the Americas and beyond.

Appreciation

The *Pan American Journal of Public Health* (RPSP/PAJPH) recognizes with appreciation the contributions of the members of the Editorial Committee/authors of the Overview article. Their contributions and dedication to this issue on Strengthening of Regulatory Systems for Medicines and other Technologies in the Region of the Americas were extraordinary and helped make the manuscripts more interesting, more accurate, and more useful to our readers and all others who work to improve the health of the peoples of the Americas.

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