

Strengthening of regulatory systems for medicines in the Americas

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Health regulation is regarded as one of public health's basic functions. Effective regulation of medicines promotes and protects the public's health by guaranteeing medicines quality, safety, and efficacy; promoting the adequate manufacture, storage, and distribution of medicines; facilitating the fight against substandard, spurious, falsely labeled, falsified, or counterfeit medical products; providing the necessary information to health professionals and patients so they can use medicines rationally; and ensuring that access to medicines is not hindered by inefficient regulatory frameworks. Developing a strong national regulatory system is, therefore, a critical component of a national health system.

In this context, we are pleased to present the first ever special issue of the *Pan American Journal of Public Health* to focus on strengthening of regulatory systems for medicines and other technologies. This special issue is an expression of the resolve of the governments of the Americas in implementing the Pan American Health Organization Directing Council Resolution CD50.R9 (2010) "Strengthening National Regulatory Authorities for Medicines and Biologicals," and more recently of the Member States of the World Health Organization in the adoption of resolution WHA67.20 (2014), "Regulatory system strengthening for medical products."

While regulatory systems are critical to ensure access to safe, effective and high-quality medicines and other medical products—and provide the necessary environment for enabling research, development and innovation—they are not universally understood or appreciated. Strong regulatory systems are fundamental to sound public health outcomes, and to the achievement of universal access to health and universal health coverage. Competent regulatory systems also help to increase efficiencies in health-care delivery, facilitate trade between countries, and support economic development and growth, all of which contribute to secure, viable and healthy populations, economies and nations. This special issue of the journal has been prepared to share perspectives, opportunities and challenges in the regulation of medical products identified by the very experts who work daily in the regulatory environment for the benefit of individual, family and community health, domestically and globally.

The journal brings together articles from regulatory experts within the Region of the Americas as well as from global experts, who bring an array of experiences to the fore. They present the essential underpinning of science and regulation that bring life-saving and innovative products to the marketplace; analysis of key contributions from international fora and public-private coalitions that can add to regulatory science and the development of good regulatory practices; and the ever-evolving challenges that regulators face to build inter-linked and convergent regulatory systems within the context of limited capacity, human and financial resources, nationally and globally.

However, such challenges present us with an opportunity for innovation and the development of sustainable collaborative strategies in the regulation of medicines and other health technologies. The papers presented in this special issue are a reflection of the collaborative spirit that exists among regulators from the Region of the Americas, most notably through the National Regulatory Authorities of Regional Reference and the Pan American Network for Drug Regulatory Harmonization, and from around the globe. On many informal and formal levels, and through existing venues such

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as the International Conference of Drug Regulatory Authorities (ICDRA), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or the International Medical Device Regulators Forum (IMDRF), regulators come together to share experiences, leverage data and information for better decision and actions and to apply novel strategies to expand their regulatory reach, individually and collectively.

We hope this special issue reinforces the view that the safety and quality of medical products are essential elements to the health, well-being and lives of our populations. This is true for a person battling cancer or diabetes, an HIV/AIDS or malaria patient, for parents vaccinating their children, or for the global community in the fight against emerging or evolving diseases, such as Ebola or Zika. With the pace of science, information and data flows, and innovation increasing at record speeds, regulators around the world must not only be at the forefront, but also stay ahead of such a pace to ensure the quality, efficacy and safety of the products they regulate, and to continue to work together to build collaborative and convergent regulatory systems.

Regulators must further engage with the global donor community to convey the critical need for continued investments in regulatory system strengthening to ensure resilience in health systems, and sustained economic growth and development. Well-functioning regulatory systems combined with a scientific and risk based approach to regulation are key toward the attainment of a number of the United Nations Sustainable Development Goals.

The Pan American Health Organization and national regulatory authorities from the Americas stand ready to build upon our current efforts and engage in the necessary dialogue to ensure that the roles regulators play in global health is more broadly understood. This special issue of the *Pan American Journal of Public Health* is a notable contribution in this direction.