The Regional School of Sanitary Regulation: Towards Strengthening the Regulatory Sciences in Mexico and Latin America

La Escuela Regional de Regulación Sanitaria: hacia el fortalecimiento de las ciencias regulatorias en México y América Latina

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Abstract
The Regional School of Sanitary Regulation (ERRS) is a groundbreaking initiative aimed at reinforcing regulatory systems in Latin America that will provide training and education to professionals in the field of sanitary regulation to ensure the safety, efficacy, and quality of medical products and services available in the region. The ERRS is a collaborative effort between the COFEPRIS, the European Union, and the Pan American Health Organization, through the University of Health of Mexico City, and has the potential to reduce health gaps, promote innovation, increase public trust in sanitary regulatory systems, and prepare the region for future challenges. It is also a key tool for achieving self-sufficiency in health matters in Latin America and the Caribbean.

Resumen
La Escuela Regional de Regulación Sanitaria (ERRS) es una iniciativa innovadora que busca fortalecer los sistemas regulatorios de Latinoamérica, que ofrecerá formación para garantizar la seguridad, la eficacia y la calidad de los productos y servicios médicos disponibles en la región. La ERRS es un esfuerzo conjunto de la COFEPRIS, la Unión Europea y la Organización Panamericana de la Salud, a través de la Universidad de la Salud, y tiene el potencial para reducir las brechas en salud, aumentar la confianza en los sistemas regulatorios sanitarios y preparar a la región para futuros desafíos, así como lograr la autosuficiencia en la materia.

Keywords
Health Regulation, Regional School of Sanitary Regulation, national regulatory agencies, pharmaceutical industry, medicines, public health

Palabras clave
Regulación Sanitaria, Escuela Regional de Regulación Sanitaria, agencias de regulación nacional, industria farmacéutica, medicamentos, salud pública

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Introduction

Today, regulatory sciences are a set of disciplines and policies responsible for establishing rules and regulations to ensure the protection of public health, safety and well-being of society at large. They cover areas such as the regulation of medicines, foods, chemicals, medical devices, cosmetics and other products and services that may have an impact on people's health and safety.[1]

Regulatory sciences are based on the application of scientific and technical knowledge to assess and control the risks associated with different products and activities. To do so, it is necessary to carry out studies, tests and evaluations to determine the safety, efficacy and quality of products, as well as the establishment of standards and regulations for their manufacture, marketing and proper use.

Regulatory policies are a fundamental component of regulatory sciences, as they establish the rules and legal requirements that manufacturers, distributors and users of regulated products and services must comply

[1] "OPS: México presidirá agencias reguladoras sanitarias" in América Economía, November 29, 2019, at *https://www.americaeconomia.com/ops-mexico-presidira-agencias-reguladoras-sanitarias (*date of access: July 15, 2024).

with. These policies are based on national and international laws, regulations, guidelines and agreements, and aim to protect the health and safety of the population, promote the quality and efficacy of products, and ensure transparency and trust in regulatory processes.

In Latin America, different health regulatory agencies have implemented regulatory sciences to improve their efficiency and effectiveness. These include institutions such as the National Administration of Drugs, Food and Medical Technology (ANMAT) in Argentina; the National Institute for the Surveillance of Drugs and Food (INVIMA) in Colombia; the Center for State Control of Drugs, Equipment and Medical Devices in Cuba (CECMED); and the National Health Surveillance Agency (ANVISA) in Brazil. However, the lack of specialized knowledge in health regulation limits the ability of professionals to adapt to international standards and the changing demands of the health sector, which in turn affects the quality of medical care and patient protection.

Measures being taken in the region to improve the focus on regulatory sciences include reforms to update the curricula of health-related courses and include specific content on these sciences and health regulation. In addition, the aim is to increase the visibility and recognition of these disciplines in the health field, promoting the training of professionals with optimal and updated tools to face regulatory challenges and guarantee the quality and safety of health products and services in these countries.[2]

In the field of public health, regulation plays a fundamental role. In recent years, the new approach called *regulatory science*[3] has sought to strengthen regulatory decision-making, basing it on solid scientific evidence.

Although this concept is not new, its adoption in Mexico has been a gradual process. The first explicit mentions of it can be seen from 2018, when Federal Commission for Protection against Sanitary Risks (COFEPRIS) published, within the framework of the Second International

[2] "Regulatory Science Strategy", in European Medicines Agency, at *https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy* (date of access: 15 July 2024).

[3] Marie Camadro *et al*., "Science réglementaire en santé publique : de quoi parle-t-on ?", in *Santé Publique*, vol. 30, no. 2, March-April 2018, pp. 187-196, at *https://www.cairn.info/revue-sante-publique-2018-2-page-187.htm* (date of access: 15 July 2024).

Week of Regulatory Science and Good Practices, a statement addressed to the general population and health professionals in which the importance of communicating the possible risks associated with medicines and vaccines was emphasized.[4] The main topics discussed at the event were emerging global threats to health; regulatory science and its contribution to health; harmonization, convergence, trust and international standards in regulation; and policies and good practices and professional competencies for professionals.

For 2023, within the framework of the Meeting of Regional Reference National Regulatory Authorities of the Pan American Health Organization (PAHO), COFEPRIS presented the Regional School of Sanitary Regulation (ERRS) project. This is an initiative to establish an educational space specialized in the training of professionals with the necessary skills to strengthen health regulatory systems in Latin America.[5] After establishing it, in December 2023, the Commission, in collaboration with the University of Health (UNISA), a decentralized public body of the Government of Mexico City, called on people interested in pursuing a specialty in Health Regulation of Medicines and Vaccines.[6]

Background on health regulation in Mexico

According to Rogelio Godínez and Patricia Aceves, pharmaceutical industrialization emerged in Europe during the 19th century. However, in Mex-

[4] COFEPRIS, "Segunda Semana Internacional de Ciencia Regulatoria y Buenas Prácticas", press release 362, September 20, 2018, at *https://www.gob.mx/Cofepris/prensa/Cofepris-organiza-segunda-semana-internacional-de-ciencia-regulatoria-y-buenas-practicas-175448* (date of access: 15 July 2024).

[5] COFEPRIS, "Presenta en OPS proyecto de Escuela Regional de Regulación Sanitaria", press release 77/2023, July 13, 2023, at *https://www.gob.mx/Cofepris/articulos/Cofepris-presenta-en-ops-proyecto-de-escuela-regional-de-regulacion-sanitaria* (date of access: July 15, 2024).

[6] COFEPRIS and the Government of Mexico City, "COFEPRIS y Gobierno de CDMX ponen en marcha Especialidad en Regulación Sanitaria de Medicamentos y Vacunas", joint statement, January 11, 2024, at *https://www.gob.mx/Cofepris/articulos/Cofepris-y-gobierno-de-cdmx-ponen-en-marcha-especialidad-en-regulacion-sanitaria-de-medicamentos-y-vacunas* (date of access: July 15, 2024).

ico, advances in chemistry had not yet generated interest in creating an industry that produced drugs and medicines. In addition, pharmacies (the origin of the pharmaceutical industry in Europe) were not equipped to carry out industrial activities and were mainly dedicated to the sale of master or pharmaceutical formulas. The lack of Mexican entrepreneurs with sufficient capital was another factor why this type of industry did not emerge in Mexico, in addition to the latter's distrust of this productive branch.[7] In addition, although the creation of various industrial branches was promoted in Mexico through the participation of foreign investments that contributed to the development of industrial capitalism in Mexico, the project of creating a pharmaceutical industry was not a priority for the State, given that other sectors monopolized its attention. Although some factors were introduced in the country at the end of the 19th century that could facilitate the mass production of medicines (such as the studies carried out since 1888 on medicinal fauna and flora at the National Medical Institute), these were not sufficient to develop the pharmaceutical industry.[8]

In the 20th century, one of the first pharmaceutical companies to be established in Mexico was the French company Alexandre Rueff y Cía. According to Godínez and Aceves, this company was established in 1901 in Mexico City with a significant amount of capital and managed medicines among its different products, although at first the sale of medicinal presentations was not its priority. In 1919, the Department of Public Health (the highest health regulatory body at the time) approved the establishment of a company office for the sale and importation of patent medicines, mainly of French origin. By 1930, Alexandre Rueff y Cía. moved to its new facilities to manufacture medicines, including Urodonal (used as a uric acid solvent and urinary antiseptic).[9] Around 1908, businessman

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7 Rogelio Godínez Reséndiz and Patricia Aceves Pastrana, "El surgimiento de la industria farmacéutica en México (1917-1940)", in *Revista Mexicana de Ciencias Farmacéuticas*, vol. 45, no. 2, April-June 2014, p. 57, at *https://www.redalyc.org/articulo.oa?id=57932294007* (date of access: July 15, 2024).

8 *Idem*.

9 *Ibid*., p. 58.

Andrés Senosiain founded Farmacia San José in Matehuala, San Luis Potosí. In 1915, the pharmacy moved to Mexico City under the name Farmacia Santa Ana, which focused primarily on producing plant derivatives, hydrogen peroxide, and borated talc, and in a secondary line it distributed industrial or patented products brought from abroad. By 1917, the family business imported raw materials from Germany to produce its first patented pharmaceutical product: Superina, a product based on acetylsalicylic acid. Beginning in 1928 (the year considered the year of its founding), the Mexican-owned Senosiain Laboratories began manufacturing medicines such as glycerin suppositories and mercurochrome, with national coverage.[10]

Between 1933 and 1940, the national industry grew intensely and various productive sectors achieved significant development, including the pharmaceutical industry. In the third industrial census published in 1940, according to Godínez and Aceves, it was reported that in 1939 there were 77 pharmaceutical companies established in Mexican territory with a total annual production of 23 504 360 pesos. Production almost tripled in five years, even though the number of companies remained even, which means that the pharmaceutical industry in Mexico, in five years, had exponentially increased its production, compared to what had been achieved in previous decades. Despite this, the country continued to depend mainly on the consumption of foreign raw materials (6 155 904 pesos in imported material and 2 277 397 pesos in national material) for the manufacture of products. According to the census, 59 companies were owned by Mexican shareholders and 18 by foreigners. Regarding the nationality of the managers and directors, Mexicans were the majority in number (75) compared to foreigners (49). Regarding the total number of employees, 497 were Mexican and 67 foreigners. Apparently, the protectionist policies supporting Mexican workers and the beginnings of union organization were also being impacting the case of the pharmaceutical industry.[11]

According to the research of Godínez and Aceves, by the end of the 1930s pharmaceutical companies in Mexico with Mexican capital had increased

[10] *Idem.*

[11] *Ibid*., p. 64.

and represented the majority, although they had not yet achieved the desired industrial development and were beginning to acquire experience in the field. For their part, companies founded and supported by foreign capital dominated the market before 1940 through the massive importation and manufacture of medicines, and their strong distribution and advertising systems.[12]

In 2014, the WHO recognized COFEPRIS as a functional health agency for vaccines and, seven years later, on November 17, 2021, the Commission received approval as a member of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).[13] This ratification made Mexico the first Spanish-speaking country with this distinction and a strategic and competitive destination for conducting clinical trials, eliminating the need to duplicate tests carried out during research and development of new drugs, with processes homologated to those in Europe and countries such as the United States, Canada and Japan.[14]

Having a national regulatory agency (NRA) with such distinctions fosters a favorable environment for pharmaceutical development, by encouraging new technologies and the introduction of new drugs accepted worldwide. This allows for equitable access and availability of innovative therapies to prevent health risks among the more than 129 million people who live and travel between Latin America, Central America and the Caribbean. This work of health control and surveillance, through verification visits and the process of file analysis and certification, as well as the quality control actions implemented by the different areas of COFEPRIS, has led

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12 *Ibid*., pp. 64-65.

13 COFEPRIS, "México avanza hacia la recertificación de su agencia de regulación sanitaria", press release 21/2021, June 16, 2021, at *https://www.gob.mx/cofepris/es/articulos/mexico-avanza-hacia-la-recertificacion-de-su-agencia-de-regulacion-sanitaria* (date of access: July 15, 2024).

14 COFEPRIS, "México, primer país hispanohablante miembro de ICH, máximo foro regulatorio de productos farmacéuticos", press release 35/2021, November 17, 2021, at *https://www.gob.mx/cofepris/es/articulos/mexico-primer-pais-hispanohablante-miembro-de-ich-maximo-foro-regulatorio-de-productos-farmaceuticos* (date of access: July 15, 2024).

to ensuring a team of health verifiers with knowledge in the application of drug and vaccine regulation in each phase of its cycle.

Likewise, the different actors involved in the pharmaceutical industry have sought to train their personnel in the regulatory field to comply with the established official regulations. However, to date there is no formal alternative for academic degree education in the field of medicines and vaccines, resulting in various associations and private organizations offering isolated courses with no official recognition by an educational institution.

However, it is worth highlighting that there have been efforts by public universities, such as the National Autonomous University of Mexico, to develop programs such as the Diploma in Sanitary Regulation of Health Supplies. This aims to deepen knowledge of the national and international legal framework applicable to health supplies.

The University of Chile also offers an online Diploma in Regulatory Affairs for Medicines, Biological Products, Cosmetics and Medical Devices, which complies with the new regulatory scenarios of the amendments to the Sanitary Code (January 2014). However, this option is centered on a local regulatory framework.

The above highlights the need for highly specialized education to address such emergencies. The covid-19 pandemic required streamlining and fine-tuning the drug and vaccine authorization processes, the resolution of ethical dilemmas, conflicts of interest, standards regarding research and regulation, and equal access to health in Mexico and the world.

In Mexico, the NRA proposed strengthening the health situation through the training of human resources in the field. With this purpose, the first specialty in Regulation of Medicines and Vaccines was offered then, and the necessary actions were conducted for the birth of the ERRS, in alliance with a public university, which would bring together its scientific, technical and humanistic capacities to serve the country by offering a virtual format for inclusive, equitable and quality education.[15]

[15] COFEPRIS and Government of Mexico City, *op. cit.*

The ERRS as a path to the development of Latin America[16]

The Regional School of Sanitary Regulation (ERRS) is an initiative that seeks to promote regulatory convergence in the region, fostering health self-sufficiency and creating an educational space to train professionals in regulatory sciences and health regulation. The ERRS focuses on improving regulatory capacity to ensure the safety, efficacy and quality of health-related products and services in the region.

Furthermore, this school is a space for training human resources specialized in the subject and the first step towards creating a health supplies agency for Latin America and the Caribbean. Its primary objective is to close inequality gaps in health and regulatory matters in Latin America and the Caribbean, since the lack of human capital in our region brings with it difficulties in implementing innovation strategies and, above all, regulatory harmonization.

The ERRS served as the main strategy to accelerate the adoption of new technologies and methods in sanitary regulation in the country. Mexico, through COFEPRIS and the Ministry of Foreign Affairs (SRE), announced that it would host it in collaboration with the University of Health (UNISA). Likewise, for the consolidation and materialization of the ERRS, the European Union and the PAHO established a cooperation project including funding to start this project.

COFEPRIS is a decentralized agency of the Ministry of Health with powers in matters of regulation, control and sanitary promotion, in accordance with the General Health Law and other applicable legal provisions, but not an authority in educational matters. For this reason, investment in the training of actors involved in the health field was supported through UNISA.

As an educational institution with a social vocation, it has begun to design quality, innovative and socio-culturally relevant study curricula and programs, focused on meeting educational needs in sanitary regulation. Likewise, through specific collaboration agreements with other

[16] This section was prepared based on an Internal Document on the ERRS of the Sanitary Promotion Commission of COFEPRIS, 2024.

universities, teaching centers and national and international organizations, it seeks to establish cooperation to host training stays and have a larger staff of teachers and specialists in the subject.

With this, the ERRS is positioned as the epicenter where all health regulatory authorities in the region can converge, discuss and agree on strategies that promote regulatory excellence on the continent. In addition, it aims to consolidate itself as a benchmark for education and global avant-garde, contributing significantly to the integration of Latin America and the Caribbean.

Educational components of the ERRS (in Mexico)

In 2024, the ERRS plans to create three educational components. These seek to respond to the internal needs of COFEPRIS, of national interests, and of the technical and operational capabilities in the region.

In the first edition of the Accreditation Program for Verifiers and Certifiers in Health Services (April-August 2023), participated more than one hundred verifiers and certifiers from all states of the federation. In an in-person exercise during the month of August, in Mexico City, the participants carried out a verification exercise at more than 20 hospitals to test all the knowledge acquired through the ERRS. The Program, carried out in collaboration with the School of Public Administration of Mexico City (EAP), culminated in the accreditation of three competencies: evaluation of compliance with regulatory requirements in the authorization process of hospital medical care establishments, verification visits to monitor compliance with sanitary legislation for hospitals and medical care establishments, and analysis of findings in the verification visit, with the aim of issuing an opinion to determine the level of compliance.

The accreditation seeks to consolidate a body of highly trained professionals committed to the fair and efficient application of health regulations. The second edition of the program began on February 12, 2024, with the participation of more than 240 people from all federal entities.

Professional training in health regulation

The Specialty in Sanitary Regulation of Medicines and Vaccines opens a window in this field to favor the professional development of public

officials, as well as of all personnel working in the pharmaceutical sector in the different factories or laboratories producing medicines or biological products for human use in Mexico within the establishments with the authorized category of "sterile biotechnological" that could manufacture or do manufacture vaccines. This educational space also benefits members of Latin American countries NRAs and individuals who have graduated from bachelor's degrees related to health sciences. This academic degree seeks to train, based on the principles of equality, gender equity, sustainability, non-discrimination, equity, accessibility, quality and relevance, specialists who have the tools and capacities for a responsible professional practice both at the state and federal level, with the objective of participating in the creation of resources, research, and legal and regulatory frameworks. These actions would contribute to the consolidation of a proactive culture of safety and quality in the care of society, based on processes of excellence with ethical rigor, and guided by the human right to access to quality and humane health.

Final Thoughts: A Healthier Future for the Americas through Health Regulation

The NRAs play a fundamental role in the health regulatory landscape of each country. These agencies are responsible for ensuring the safety, efficacy and quality of medical products and services, thereby protecting public health. This project is part of the integration efforts promoted by COFEPRIS, INVIMA and CECMED, together with other organizations such as the SRE, the European Union and the PAHO, in order to strengthen regulatory, oversight and control capacities in the Americas region.

The ERRS emerges as a beacon of hope in the public health landscape in Latin America. This innovative initiative represents a crucial step towards strengthening the region's sanitary regulatory systems. Furthermore, the ERRS has the potential to reduce health gaps by strengthening the regulatory capacity of Latin American countries and reducing inequalities in access to medicines, vaccines and other essential medical products, in addition to promoting innovation. A solid and efficient regulatory framework can encourage research and development of new products and technologies

that benefit public health, contribute to increasing the population's trust in sanitary regulatory systems, and improve adherence to medical treatments and the adoption of preventive measures. These tools would prepare the region for future challenges in an increasingly globalized world with new threats to public health.