Science Diplomacy for Strengthening the Medicines Regulatory Systems in the Americas: A Regional Experience

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Introduction

Science diplomacy is the use of scientific collaborations among nations to address the common problems facing 21st century humanity and to build constructive international partnerships (Fedoroff, 2009) this also applies in the field of the health regulations and regulatory science.

Good Health and Well Being is the objective 3 of the Sustainable Development Goals, the aim is to achieve universal health coverage, and provide access to safe and affordable medicines and vaccines for all (United Nation, 2015). Supporting research and development for vaccines is an essential part of this process as well (United Nation, 2015). Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation. The National Regulatory Authorities (NRA) are the government entities responsible for ensuring the safety, efficacy and quality of medicines and play a vital role in the health care system by providing regulatory oversight of all medical products.

During the last decades, a growing number of networks and initiatives have been developed to strengthen medicines regulatory systems. The region of the Americas, developed an initiative to strengthen health regulatory systems through an evaluation and certification process that allows the appointment of Regional Reference Regulatory Authorities of medicines and biological products (NRAr). The NRAr work jointly, through

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cooperation mechanism, on capacity building in other countries of the region that allow the strengthening of their regulatory systems and act as a group with consensual positions in the different international forums.

Strengthening Regulatory Systems in the Americas

National Regulatory Authorities play a vital role in the health care system by providing regulatory oversight of all medical products such as medicines, vaccines, blood products, traditional or herbal medicines and medical devices. They perform their mandate based on a legal framework and a set of recommended regulatory functions that span the medical product lifecycle including clinical trial oversight, marketing authorization and registration, licensing and inspection of premises, market surveillance and enforcement activities when required.

The Americas is a region of deep asymmetries where inequalities in access in poor and vulnerable populations persist, and there is still fragmentation and segmentation in systems that guarantee access to health technologies. In the particular case of the national regulatory authorities, there are large differences in the structure and autonomy of the regulatory bodies, the financing systems and their regulatory capacity to ensure effective compliance with its functions (Ojeda, 2016).

In the last two decades a group of global and regional initiatives have been developed aimed at strengthening the NRA capacities based on the population right to access to quality medicines according to the science and technology advances. One of these initiatives is the evaluation and certification of Regional Reference Regulatory Authorities process in the Americas,

In 2006 a group of five regulatory authorities from Latin America (Argentina, Brazil, Chile, Cuba and Mexico) met in Oaxaca, Mexico, with the proposal to build a common agenda that would consolidate mutual trust in regulatory matters for the benefit of the economic well-being and public health of the inhabitants of the region(1). As a result arose the proposal of an NRA evaluation process as a regional mechanism of certification of the drugs regulatory authorities focused on evaluating its performance in the fulfillment of its functions and also served as a capacity building mechanism in the regulation of medicinal products field. The evaluation process concludes with the rating of the authority assessed, according to its results, in one of four levels; a Regional Reference Authority is that which reaches the level IV, this describes an authority that is competent and efficient in fulfilling the functions recommended by PAHO/WHO to ensure the efficacy, safety and quality of medicines. The Pan American Health Organization (PAHO) acts as a facilitator of the process, leads the evaluations and gives the certification of Regional Reference Regulatory Authority for medicinal products and biologists to those NRA that reached the level IV.

To date, 8 national regulatory authorities have been recognized by PAHO/WHO as National Regulatory Authorities of Regional Reference: Argentina's National Administration of Drugs, Food and Medical Technology (ANMAT), Brazil's National Health Surveillance Agency (ANVISA), the Center for State Control of Drug and Medical Devices of Cuba (CECMED), the National Institute of Food and Drug Monitory of Colombia (INVIMA), the Federal Commission for Protection against Sanitary Risks of the United Mexican States (COFEPRlS), Canada's Health Canada, US Food and Drug Administration and Chile's Institute of Public Health (PAHO, 2018)

A significant milestone was the discussion of this initiative at the 50th PAHO Directing Council meeting, carried out in September 2010, and the approval of the CD50. R9 resolution: "Strengthening National Regulatory Authorities for Medicines and Biologicals". In this resolution PAHO Member States are urged to: strengthen and evaluate their regulatory capabilities with respect to the functions characteristic of a regulatory and oversight agency for medicines and biologicals, through an examination of the performance of their essential functions; to use the results of the qualification activity and the designation of the regulatory authorities of regional reference

to strengthen their performance in terms of the steering role of the health authority; and support national regulatory authorities so they can benefit from the processes and information from national regulatory authorities of reference. (PAHO, 2010)

The regional reference authorities works as a network, which together with PAHO are committed to to support efforts to strengthen other regulatory agencies, based on its own experience, by promoting exchange and cooperation among countries, and by actively participating in regulatory harmonization efforts within the framework of the Pan American Network for Drug Regulatory Harmonization (PANDRH). In this sense they develop a wide range of cooperation activities for capacity building in other NRA. From 2010 to date, more than 30 courses have been carried out in several countries of the region, also bilateral consultancies and internships in the ARNr (2). They also lead the different regional projects on pharmaceutical regulation approved by PANDRH. (PAHO, 2016)

On the other hand these reference authorities working in build trust among them and share information on their best practices, also exchange technical information in order to achieve mutual recognition of they regulatory decisions to faster the drugs approval processes allowing better access.. Regulatory collaboration, as inter-agency work and data-sharing help strengthen the regulatory capacity of all partners by promoting sustainable exchange of technical knowledge. In these sense is important to highlight the inspection final report exchange, considering the large number of pharmaceutical companies, and the cost of in situ inspections, some bilateral agreements have been established to establish mutual recognition of Good Manufacturing Practices Compliance

Regional Reference Authorities in Multilateral Forums

In the year 2011 the group of ARNr was created, this group carries out two annual meetings, in the first semester of the year review the results of the work of the previous year and define the strategies and working plan for the the new year. (3) ; in the second semester they held a meeting with PAHO to evaluate the progress of their jointly work to strengthen regulatory systems in the region.

Of the regional work done we can highlight

The Regional Working Group on Medical Device Regulation: Established during he "1st Regional Meeting of the Regulatory Authorities for the Strengthening of Regulatory Capacity on Medical Devices in the Americas Region" held in La Habana, Cuba s currently comprised of 16 NRAs; countries join the Working Group voluntarily, with the commitment to advance towards achieving the strengthening the Regulatory Capacity on Medical Devices through Regional exchange of information joint projects and training strategies towards the harmonization of regulatory requirements. This group mislead by CECMED, the cuban NRA (PAHO, 2018b)

Specialist from regional reference authorities are Convocation of experts in NRA acting as PAHO advisory experts of the system for evaluation of national reference regulatory authorities; 26 ARN have already been evaluated.

Center for the State Control of Drugs and Medical Devices (CECMED) and Medical Devices is working with PAHO and the Ministry of Health to strengthen the Nicaraguan national regulatory Authority of Drugs as part of the technology transfer project for the production of biological and inmuno-biological, that takes place between the governments of Russia and Nicaragua. (PAHO,2018a)

The regional reference NRA group is coordinated by one of its members who exercises coordination for a two years period. In these meetings they also review the different international forums and meetings that will take place during the year, the most current topics that are being discussed and the initiatives in which they participate and what are their criteria, concerns and position about it. After a discussion process they try to adopt joint positions that respond to regional interests .

These actions were of particular importance during the international consultation process

on the strengthening of the regulatory systems developed by WHO since October 2014 aimed to reach a Global Benchmarking Tool (GBT) for the evaluation of national regulatory system of medical products. The World Health Organization began assessing regulatory systems in 1997 using a set of indicators designed to evaluate the regulatory programes for vaccines. Since that time, a number of tools and revisions were introduced. In 2014 work began on the development of a unified tool for evaluation medicines and vaccines regulatory programs following a mapping of existing tools in use within and external to WHO. (WHO 2018)

Recently WHO published a new documents (Revision VI) that takes into consideration input received from two international consultations with Member States in 2015, a public consultation in early 2018 and a series of meetings involving experts from regulatory authorities from different parts of the world, in which the work of the Americas region, represented by PAHO, was significant, particularly as a region that already had a tool and an evaluation process with 8 years of experience that has given important achievement.(WHO, 2018) This last document contains a large part of the recommendations and criteria made by the NRAr and incorporate indicators and measures criteria of the evaluation tool used in the process developed in the Americas. This document will be use to evaluate and publicly designate WHO-listed authorities (WLAs) that have been objectively documented to perform at high maturity levels in 2019

Conclusion

2019 is 9 years of the establishment of the process of evaluation and certification of Regional Reference National Regulatory Authorities in the Americas.Throughout these years, the initiative has succeeded in build capacities in the drug regulatory agency in the region strengthening their medicines regulatory systems. The jointly work of the regional reference authorities could be an example of real implementation of science diplomacy, based on the international collaboration in health in order to assure safety, efficacy and quality of medicines. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes.

Endnotes

1 The meeting reports and commitment of the meetings between the regulatory authorities are not always public domain, they are working documents between them. For further information are available presentation of Dr Jose Pena Ruz p.e https://www.redeami.net/docs/docs/encuentros/ix_encuentro/7.1-Proceso_evaluacion_OPS-Jose_Pena.pdf

2 Capacity building activities could be found on each National Regulatory web site.

3 Press release and information on Regional Reference NRA anual meeting are available on the RNA websites that have hosted the meetings. (CECMED, ANMAT, COFREPRIS, INVIMA, HEALTH CANADA AND CHILE ISP.

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