Science Diplomacy to Strengthen an Innovative Regulatory Agenda: Inputs from Medicines Regulatory Agencies

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Diplomacy employs dialogue and negotiation as elements of the established diplomatic infrastructure and the functions performed in diplomatic relations between states and on international forums. It can be an influential and versatile method to promote friendly relations and facilitate the development of favourable economic, cultural and scientific relations between states despite the existing differences or problems.[1]

Globalisation and increasing interconnectivity have demonstrated that diplomatic relations are not developed only at a bilateral level. States can also relate at a regional or global level, taking into account specific or common interests as well as their geographical location in a given region.

The complexity of issues such as environment, health, access to medicines and their impact on human lives on the global level has led to a specialisation in the diplomatic arena. We are no longer talking about discussion environments based purely on international politics. It has now become essential to document scientific knowledge and evidence in negotiation processes and the recognition of appropriate mechanisms for dialogue. Based on scientific knowledge, new working methods and greater confidence toward innovation in national regulatory systems can be generated. The universal language of science and innovation guided by academic knowledge and standards enables building constructive dialogue across states to overcome global challenges and crises. Likewise, cooperation and the exchange of good practices can be increased, positioning these issues as a priority in regional and international environments, making it possible to achieve International policy objectives and health self-sufficiency.

The difficulty in accessing medicines, pandemics and climate change, among others, are global challenges that impact each of our societies. That is why scientific knowledge, technology and innovation must be essential drivers for the development of society and its adaptability to the changing environment of international relations. A country's capacity to generate knowledge and technological innovation enhance its image in the international community. Science, technology and innovation have become vital elements of international relations as they are, in turn, components of economic progress and equitable and sustainable development of societies. They also provide scientific evidence for good governance, development of public policies and appropriate decision-making, allowing us to address the global challenges more quickly and effectively.

The establishment of a space for interaction between science, innovation and diplomacy is conducive to building a common ground for the scientific and diplomatic communities to build trust and mutual

understanding. This process of cohesion between the two communities does not usually occur. So, the development of emerging diplomacy, with a framework of negotiation and dialogue based on scientific evidence, is transformative, beneficial and relevant to responding to the present and future challenges faced by the international community.

Much less well known is the interrelationship between science, innovation, the medicine regulatory environment and the diplomatic contribution to strengthening regional and global health governance, leadership and funding of projects and initiatives that foster cooperation between regulatory agencies. A multidimensional approach fostering the principles of anticipating, driving and translating innovation in the regulatory environment enables the participation of different actors (academia, industry and regulatory agencies, among others), driving viable policies and programs from the countries to the knowledge economy. Accordingly, the formalisation and expansion of cooperation and coordination mechanisms strengthen networks and collaborations between scientists and regulatory experts to increase the quality of good regulatory practices. There, too, the decision-making based on scientific pieces of evidence, in line with international standards, opens new markets and consequently achieves greater competitiveness at the global level. Moreover, strengthening and promoting the participation of developing countries in projects of regional or global impact promotes capacity building, access to resources and first-class infrastructure and the exchange of experts.

In the Latin American region, the interrelationship between science, diplomacy, technological innovation, and regulatory agencies for medicines and medical devices, should be analysed from a perspective that considers the existing diversity of regulatory frameworks. The development of an integrated and innovative regulatory agenda focused on the harmonisation of national regulations related to the marketing of drugs and medical devices, allowing decision-making based on the criteria of quality, safety and efficacy. Similarly, the possibility of assessing the risk-benefit ratio is strategic for adopting efficient, rapid procedures that allow for closer cooperation and coordination among national medicines regulatory authorities, directly impacting trade agreements, supply chains and timely access to medicines, vaccines, etc. A regional regulatory structure based on the construction of integration in the areas of health, access to medicines, accessibility to innovative products and greater production capacities at the regional level is essential to lead programs, resources and policies that improve access to health in the region.

Equally, the alignment of the regional regulatory systems advocating for a regional framework will have a direct impact on the modality of collective and diplomatic action vis-à-vis international actors in terms of the right to health. In September 2021, the member countries of the Community of Latin American and Caribbean States (CELAC) unanimously approved lines of action and proposals for a plan for self-sufficiency in health matters in Latin America and the Caribbean, a programmatic roadmap presented by the Economic Commission for Latin America and the Caribbean (ECLAC) for strengthening the production and distribution of medicines, especially vaccines, in the region's countries and reducing external dependence.[2] This document highlights the importance of strengthening convergence mechanisms between regulatory agencies for medicines. Convergence efforts within the region can facilitate communication, information sharing and accelerate the approval of quality and effective medical products.

The region already has developing work at the regulatory level promoting synergy and joint work, such as the example of the regional reference agencies.[3] These agencies were certified through an evaluation and qualification process based on the verification of indicators contained in the data collection tool of the Pan American Health Organisation (PAHO) and based on the recommendations of the World Health Organisation for the strengthening of regulatory agencies. In addition, the National Regulatory Authorities of the Region and the Pan American Health Organisation established the Pan American Network for the Harmonisation of Pharmaceutical Regulation (PARF Network) initiative, which supports the processes of harmonisation of pharmaceutical regulation in the Americas, within the framework of national and sub-regional health realities and policies and the recognition of pre-existing asymmetries.[4]

The regulatory, scientific and diplomatic environment must value the impact of regulatory sciences and scientific evidence in the anticipation of trends, which would enable the adaptability and updating of regulatory frameworks. It is imperative that our region, to achieve greater prominence at the global level, should immerse itself proactively and cohesively with innovative initiatives that articulate regional

cooperation mechanisms in the regulatory environment. Taking the experience of other regions, we must advance in regional bloc processes through the existing regulatory compatibility or convergence, while maintaining our autonomy and the interests of each country. COVID-19 and its impact have demonstrated the strategic importance of increasing intra-regional trade, strengthening the health technology industry, regional pharmacovigilance systems, coordination mechanisms for the development of clinical trials and betting on mutual recognition of the results of clinical trials. Additionally, more than a romantic view of a common regulatory framework, there is a real need to balance competing interests from national regulatory agencies encouraging work coordination and expediting the exchange of key information about medicines and innovative medical products.

The regulatory sector has had to face a series of challenges to its traditional working methods. The implementation of flexibilities in its regulatory frameworks, the use of emergency use authorisation with a public health approach and the development of adaptive clinical trials have led to the generation of a series of data based on scientific evidence. At the same time, the creation of synergies for the genuine development of regional platforms or organisations that allow the dynamisation of our international regulatory cooperation networks is required.

According to Chapter II of the Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals[2], the implementation of a regional clinical trials platform was listed as one of the main lines of action in the document. To advance in this challenge, it is necessary to promote joint reviews of applications for conducting clinical trials among national regulatory agencies. A platform that prioritised the collection and sharing of information on medical products helps to build strong partnerships between ethics committees and regulators of member states. For the region to become more active in ensuring the procurement of medical supplies and health sector regulations with emphasis on public purchases, timely access to accurate and adequate information should be reinforced. Therefore, collaboration on inspection of drug manufacturing sites, access to and network of the services available in quality control laboratory services within national regulatory authorities will generate consistency in medical products evaluation, thereby enhancing the region's scientific and innovation development.

The presence of a regulatory body for Latin America represents a unique strategy to build regulatory capacities and contribute to the development of regulatory science and innovation in the 21st century. The strong performance of regional integration initiatives to promote better health achievements will depend on the dynamic relationship between the diplomatic and scientific dimensions. It will require administrative, infrastructural and influence on member states to create an autonomous new regulatory governance structure for medicines and medical devices. However, there are practical challenges like operational norms and procedures, sustainable financing, political will and regional leadership to overcome. Scientists, regulators and diplomats must be aware of the impact and exercise of their respective functions. Science diplomacy and regulatory sciences should be in closer relation to promote trust-building transformative agenda and tools. Regulatory science offers the analytical focus on how regulations are successful and includes their translation into regulatory practice. This analytical and science-based approach in support of best practices and institutional governance at a global and regional level is a crucial resource for diplomats and government officials. Likewise, the interrelation between knowledge diplomacy, regulatory sciences, innovation and access to new technologies become tools for the region's participation in international forums and the sustainability and development of the health of our societies.

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