Access to Vaccines Due to a Health Emergency: The Case of Cooperation between Countries in the Region of the Americas

Acceso a vacunas por emergencia sanitaria: el caso de cooperación entre países de la Región de las Américas

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Abstract
The covid-19 pandemic was a challenging event in human history. It represented a great challenge for health agencies, due to the requirement of strict scientific rigor to guarantee the quality, safety, and effectiveness of vaccines against the disease. Likewise, the need to strengthen regulatory systems at the regional level to be better prepared for future epidemics was shown. This article addresses the case of Mexico to meet national demand and the implementation of a support system to the countries of the Region of the Americas.

Resumen
La pandemia de covid-19 fue un acontecimiento desafiante en la historia de la humanidad. Representó un gran reto a las agencias sanitarias, debido a la exigencia de una estricta rigurosidad científica para garantizar la calidad, la seguridad y la eficacia de las vacunas contra la enfermedad. Asimismo, se mostró la necesidad de fortalecer los sistemas regulatorios a nivel regional para estar mejor preparados para futuras epidemias. Este artículo trata sobre el caso de México para atender la demanda nacional y el despliegue de un sistema de apoyo a los países de la región de las Américas.

Keywords
Vaccines, covid-19, collaboration, national control laboratory, COFEPRIS, analysis

Palabras clave
Vacunas, covid-19, colaboración, laboratorio nacional de control, COFEPRIS, análisis

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Introduction

On January 11, 2020, the World Health Organization (WHO) declared the disease caused by a novel coronavirus called SARS-CoV-2, which causes covid-19, to be a pandemic. This was undoubtedly the greatest public health challenge that international organizations and governments around the world have faced in recent decades. This pandemic had unprecedented medical, social and economic consequences, and has laid bare national preparedness deficiencies in confronting a highly contagious and deadly disease.

To quickly respond to the pandemic, governments implemented various actions to prevent the spread of the disease. Immediately developing a vaccine capable of reducing the severity of the symptoms of the disease, and preventing its transmission became a priority. For their part, regulatory agencies adjusted their procedures, breaking with the scientific models established over time, while governments invested in vaccine research and development and in expanding their manufacturing capacity.[1]

[1] "Emergency Use Listing," in WHO, at *https://www.who.int/teams/regulation-prequalification/eul* (date of access: April 2, 2024).

Pharmaceutical companies and government research centers developed vaccines against covid-19 in record time; in some cases, less than a year elapsed between development and approval. For this reason, in less than two years, the WHO had already approved eleven vaccines and included them on the list for use in emergencies.[2]

Some of the factors that facilitated the development of vaccines were:

- Research that was being done on coronaviruses and viral vaccines during previous years.[3]
- Modification of regulatory agency processes regarding clinical trials and approval for emergency use.
- Investments made by certain governments for the development of vaccines, to both public and private companies.
- Government investment in advance purchases.

Thanks to these actions, the laboratories had assured demand, reduced development costs and significantly reduced the time to develop, generate and sell their products.

Advance purchases consisted of advancing and committing financial resources prior to readiness so that companies began manufacturing the vaccines as soon as possible, even before receiving regulatory approval, which would mean securing supplies in a shorter time without representing a high investment risk for the producer. However, this mechanism cannot be considered entirely acceptable or ethical if some countries use advance purchases to monopolize vaccines and leave a significant percentage of the world's population without access to them, as happened in this particular case.

Some of the contracts for advance purchases included non-disclosure agreements that prevented the terms, transactions and relationship

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[2] Yingzhu Li, *et al.*, "A Comprehensive Review of the Global Efforts on COVID-19 Vaccine Development," in *ACS Central Science*, vol. 7, no. 4, April 2021, pp. 512-553.

[3] Xiucui Han, Pengfei Xu and Qing Ye, "Analysis of COVID-19 Vaccines: Types, Thoughts, and Application", in *Journal of Clinical Laboratory Analysis*, vol. 35, no. 9, December 2021, at *https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1071&context=tdr* (date of access: April 2, 2024).

between the pharmaceutical company and the respective governments from being made public. Others included prohibitions on receiving or donating doses of the vaccine to other countries.[4] The countries that supported the development of the vaccines and that had negotiated advance purchase commitments were the first to receive the vaccines, followed by the countries with more resources. As a result, international programs that had been designed to achieve a certain level of equity in the distribution of vaccines were relegated to the background.

WHO created the COVAX mechanism to provide global equitable access to covid-19 vaccines, in collaboration with partners in the Access to Covid-19 Tools Accelerator (ACT), the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi, the Vaccine Alliance. The mechanism brought together all countries, regardless of their income level, to ensure that the procurement and distribution of vaccines was carried out quickly, equitably, and safely.

This platform aimed to facilitate rapid investment in the development of a wide variety of experimental vaccines, in addition to expanding manufacturing capacity and accelerating production prior to the authorization process to ensure their prompt application without delay, once their safety and effectiveness had been proven. The above considering that protecting people and health systems, while minimizing the impact on economies, should be the priority factors for distributing health products related to covid-19 in different countries. However, part of the problem was that the success of initiatives like this depended fundamentally on the goodwill of countries with greater resources and on pharmaceutical companies.[5]

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[4] "Merck CEO Ken Frazier & Tsedal Neeley talk COVID Vaccines, Racism & Why Leaders Need to Really Act," at Harvard Business School, July 13, 2020, at *https://hbswk.hbs.edu/item/merck-ceo-ken-frazier-speaks-about-a-covid-cure-racism-and-why-leaders-need-to-walk-the-talk* (date of access: March 25, 2024).

[5] Antonio Ugalde, Fernando Hellmann and Núria Homedes, "Desigualdad en el acceso a las vacunas: el fracaso de la respuesta mundial a la pandemia de covid-19," in *Salud Colectiva*, vol. 18, October 1, 2022, e4190, at *https://doi.org/10.18294/sc.2022.4190* (date of access: March 25, 2024).

Cooperation between countries in the Americas Region

The covid-19 pandemic highlighted the importance of international cooperation in responding to health emergencies. In the Americas Region, collaboration between countries is essential to ensure equitable access to vaccines and mitigate the devastating impacts of the disease.

Access to vaccines during health emergencies faces a range of challenges in the region. To overcome them, countries have implemented various cooperation strategies, such as joint negotiation of vaccine contracts, exchange of information on dose distribution, and collaboration on vaccine production and distribution at the regional level.

The experience of cooperation between these countries provides important lessons for future health emergencies. Effective coordination between governments, international organizations, and the private sector is needed to ensure equitable access to vaccines. Of equal importance is transparency in the vaccine acquisition and distribution processes, as well as investment in public health infrastructure to strengthen response capabilities.

Below is a list of a series of actions necessary to guarantee effective response to emergencies of this kind in the region:

- Cooperation between countries: during health emergencies such as the covid-19 pandemic, cooperation between countries is crucial to ensure equitable access to vaccines. In the Americas region, countries can collaborate through the exchange of information, resources and experience to improve distribution and administration.
- Regional initiatives: organizations such as the Pan American Health Organization (PAHO) play a fundamental role in coordinating regional efforts to ensure access to vaccines during health emergencies. PAHO works with member countries to facilitate their acquisition, promote equity in distribution, and provide technical support.
- Collaboration mechanisms: countries in the region can establish bilateral or multilateral agreements to ensure timely access to vaccines. These agreements may include joint purchases, the exchange of surplus doses, or cooperation in research and development.

Despite such cooperative efforts, there are still challenges and barriers that hinder equitable access to vaccines during health emergencies in the Americas region. These include the limited availability of vaccines, inequality in the distribution of resources, and the lack of infrastructure for their administration in remote or marginalized areas.

It is essential that vaccine cooperation and distribution focus on equity and inclusion. This involves ensuring that the most vulnerable communities have priority access to them and that there are no disparities in the distribution of doses. By addressing these issues and continuing to promote collaboration, the region can improve its ability to address these circumstances and ensure equitable access to vaccines to protect public health.

The case of Mexico

On December 2, 2020, the first vaccines against covid-19 began to be approved. Mexico's main objective was not to depend on a single vaccine or a single means to supply them, therefore, several of the strategies mentioned above were followed.[6]

The acquisition of the vaccines was carried out by the Ministry of Foreign Affairs (SRE), through the Undersecretariat for Multilateral Affairs and Human Rights (SAMDH), which carried out the worldwide search and negotiation efforts in a timely manner. Once the negotiations were concluded, the Ministry of Health (SS), through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), carried out the necessary verifications to establish authorizations for emergency use of the vaccines of interest. As a result, once all the procedures were completed, the manufacturing laboratories sent the vaccines or the active substance to Mexico by air for packaging.

In August 2020, it was announced that the governments of Mexico and Argentina would work together with the Carlos Slim Foundation to package and distribute the AstraZeneca and Oxford University vaccine, with the aim of providing it to the member states of the Community of Latin

[6] SRE, *La estrategia internacional de México en la pandemia de covid-19*, Mexico, SRE, 2021.

American and Caribbean States (CELAC). This initiative included the efforts of the Mexican laboratory Liomont, which was responsible for the formulation and packaging of the active substance from the Argentine laboratory mAbxience. This collaboration allowed the countries in the region to access the vaccine sooner than expected.

On December 23, 2020, Mexico received the first shipment of the covid-19 vaccine through advance purchase. Thus, Mexico became the first country in Latin America to receive active protection against the disease.

On February 11, 2021, the first bulk doses were received from CanSino Biologics laboratories in China, to be packaged and labeled in Mexico by Drugmex. On February 24, packaging of the first batches began and, finally, in March 2021, the first CanSino doses were ready for approval.

The priority of COFEPRIS is to ensure that the available vaccines meet national and international standards of quality, safety and effectiveness. During the pandemic, it was in charge of signing them off. Following WHO recommendations, the Commission carried out the control of covid-19 vaccines through the recognition of country-of-origin certificates from national regulatory agency (RNA)/national control laboratories (LNC) approved by the WHO.

The partial manufacturing of vaccines against covid-19 in Mexico meant that COFEPRIS, like ARN in Mexico, adapted its regulatory processes to international mechanisms without losing technical and scientific rigor. An example of this was the batch release process of the Astra Zeneca and CanSino vaccines in the laboratory analysis component.

Because the final manufacturing stage was completed in Mexico, this organization carried out the release of batches of these vaccines through the review of documentary and analytical information and the summary manufacturing protocol. Likewise, it carried out an analysis of each manufactured batch, a task undertaken in the national control laboratory, independently of the tests carried out by the manufacturing laboratory.

The pandemic represented a great challenge for both the NRAS and the LNCS, because it was necessary to guarantee the quality, safety and effectiveness of new vaccines from different technological platforms in the short term. These platforms, which have been used in inactivated virus vaccines and subunit vaccines, are combined with the use of viral vector and messenger ribonucleic acid technologies. Their evaluation requires specific methods.

The transfer of analytical methodologies for vaccine analysis had to be carried out in a short period of time, which involved a series of coordinated actions of a scientific, technical, material and human nature by the LNC. Furthermore, this commenced in a period when manufacturers were still in the process of verifying or validating their methodologies within their own laboratories.

Faced with covid-19, the LNC had to demonstrate its ability to adapt to new national and global demands and circumstances, optimizing spaces, supplies, processes, procedures, time and personnel in a short period of time. This rapid adaptation was achieved by taking advantage of the knowledge, capabilities, experience and abilities of the staff that makes up the LNC, which carries out the analysis of a wide range of methods to evaluate viral and bacterial vaccines, executing its processes under a quality management system that meets the highest national and international standards.

By achieving the analytical transfer of eleven methodologies in an average time of four months, the LNC collaborated to achieve vaccination coverage in the Mexican population, as well as the populations of other Latin American countries. These actions allowed us to reiterate the Mexican commitment to work in multilateral forums and organizations to promote timely access to the vaccine for all countries, particularly those in Latin America and the Caribbean. An example of this is that Mexico donated vaccines to seven countries in the region: Belize (100 000), Bolivia (150 000), El Salvador (100 800), Guatemala (300 000), Honduras (150 000), Jamaica (65 000) and Paraguay (150 000).[7]

Conclusion

Although the extremely negative consequences of the pandemic are acknowledged, this does not stop us reflecting on the learning that it has brought us and that must be taken into consideration in order to be pre-

[7] "WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination", in WHO, September 14, 2020, at *https://iris.who.int/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1* (date of access: March 25, 2024).

pared for another emergency of this nature. This disease has shown us the fragility of health systems and the few existing prevention and care strategies for this type of events, the lack of transparency, cooperation and interest in mutual support among nations and the importance of basic and clinical research in medicine, biomedicine, pharmacology and epidemiology for the creation of new vaccines. Likewise, the importance of cutting-edge technology in the manufacturing of vaccines to provide a rapid response to a new pandemic outbreak became evident. Current vaccines against SARS-CoV-2 have been shown to be safe and effective in preventing severe disease and mortality and have become a highly useful preventive tool.

For the first time since the beginning of the pandemic, the global supply of vaccines is not a constraint. However, a wake-up call to the international community is necessary, since the fastest way to end a pandemic is to guarantee that vaccines are available in all countries and are easily accessible to all people.

In this situation, it is worth remembering the code of values proposed by the WHO Strategic Advisory Group of Experts (SAGE), whose premise is to guarantee that covid-19 vaccines are a global public good. All governments must consider universal principles, such as the protection and promotion of human well-being, equal respect, global equity, national equity, the principle of reciprocity and legitimacy.

Finally, access to vaccines due to a health emergency in the Americas Region requires continuous and supportive collaboration between countries, as well as their commitment to defined vaccination plans. By establishing approaches based on equitable protection, the promotion of human well-being and cooperation, the region can better meet the challenges presented by future health emergencies and protect the health and well-being of its populations.