

Building Health Sovereignty in Mercosur: the Experience of the Vaccine Development and Production Course

Construindo a soberania sanitária no Mercosul: a experiência do curso de desenvolvimento e produção de vacinas

Construyendo Soberanía Sanitaria en el Mercosur: la Experiencia del Curso de Desarrollo y Producción de Vacunas

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Received: Aug 7, 2024 Approved: Nov 13, 2024

How to cite: Tobar S, Costa JCS, Gouvea MN, Medeiros MA, Delgado IF. Building Health Sovereignty in Mercosur: the Experience of the Vaccine Development and Production Course. Vigil Sanit Debate, Rio de Janeiro, 2024, v.12: e02363. https://doi.org/10.22239/2317-269X.02363

ABSTRACT

Introduction: This paper reports on the experience of the Vaccine Development and Production Course, an initiative promoted by Fiocruz within the framework of the MERCOSUR Health Ministers' Meetings. The experience was developed in the second half of 2023, with the participation of students from Argentina, Brazil, Paraguay, and Uruguay as member states of the bloc and Chile as an associate state. Objective: To support the hypothesis that we will only be able to advance health sovereignty in the field of vaccines if we simultaneously implement sovereignty in terms of strategy and the process of training human resources, articulating the region's capabilities in a network. Method: This is a report that presents reflections on health sovereignty in the production of biological products, based on a training experience that involved the mobilisation of existing capacities at Fiocruz, Instituto Butantan and Nortec, based on synchronous remote classes and personal technical visits. Results: Details of this experience were presented and based on this, we sought to outline appropriate strategies for continuing professional development in the region, with the aim of achieving health sovereignty in terms of regional vaccine production with a view to selfsufficiency. Conclusions: It is noted that despite the language barriers and institutional differences between the bloc and the associated countries, the evaluation carried out at the end of the course confirms the relevance and the need to expand experiences such as the one developed. The need to create capacities in the region to effectively achieve health sovereignty is evident, as well as the importance of incorporating some strategic themes identified by the students to continue the qualification of professionals in the region, in a continuous and permanent training process.

KEYWORDS: Vaccines; Vaccine Development and Production; Health Sovereignty; Networking

RESUMO

Introdução: Este trabalho relata a experiência do curso de "Desenvolvimento e produção de vacinas", promovido pela Fiocruz, no âmbito das reuniões de Ministros da Saúde do Mercosul. A experiência foi desenvolvida no segundo semestre de 2023, com a participação de discentes da Argentina, Brasil, Paraguai e Uruguai como estados-membros do bloco e do Chile como Estado-Associado. Objetivo: Apoiar a hipótese de que só conseguiremos avançar na soberania sanitária no campo das vacinas se simultaneamente implantarmos a soberania em termos de estratégia e processo de formação de recursos humanos, articulando as capacidades da região em rede. Método: Trata-se de um relato que apresenta reflexões sobre a soberania em saúde na produção de produtos biológicos a partir de uma experiência de formação que envolveu a mobilização de capacidades existentes na Fiocruz, no Instituto Butantan e Nortec, a partir de aulas remotas síncronas e visitas técnicas presenciais. Resultados: Foram apresentados detalhes desta experiência, ao mesmo tempo que,



a partir dela, buscamos traçar estratégias adequadas para a qualificação profissional continuada na região, com a finalidade de atingir a soberania sanitária em termos de produção regional de vacinas com vista à autossuficiência. **Conclusões:** Apesar das barreiras linguísticas e das diferenças institucionais entre o bloco e os países associados, a avaliação realizada ao final do curso confirma a pertinência e a necessidade de ampliarmos experiências como a desenvolvida. Fica evidente a necessidade de criar capacidades na região para alcançar efetivamente a soberania sanitária, bem como, a importância de incorporar alguns temas estratégicos identificados pelos discentes para dar continuidade à qualificação dos profissionais da região, em um processo de formação contínuo e permanente.

PALAVRAS-CHAVE: Vacinas; Desenvolvimento e Produção de Vacinas; Soberania Sanitária; Formação em rede

RESUMEN

Introducción: Este trabajo relata la experiencia del Curso de Desarrollo y Producción de Vacunas, iniciativa promovida por la Fiocruz, en el ámbito de las Reuniones de Ministros de Salud del Mercosur. La experiencia fue desarrollada en el segundo semestre de 2023, con la participación de alumnos de Argentina, Brasil, Paraguay y Uruguay como Estados parte del bloque y de Chile como Estado Asociado. **Objetivo:** Apoyar la hipótesis de que solo conseguiremos avanzar en la Soberanía Sanitaria en el campo de vacunas, si simultáneamente avanzamos en la Soberanía Sanitaria en términos de una estrategia y proceso de Formación de recursos humanos, articulandolas capacidades de la región en red. **Método:** Se trata de un relato que presenta reflexiones sobre la Soberanía en salud en la producción de productos biológicos a partir de una formación que involucra la movilización de capacidades existentes en la Fiocruz, Butantan y Nortec, a partir de clases remotas sincrónicas y visitas técnicas presenciales. **Resultados:** Fueron presentados detalles de esta experiencia, al mismo tiempo que a partir de ella buscamos trazar estrategias adecuadas para la calificación profesional continuada en la región, con la finalidad de alcanzar la Soberanía sanitaria en términos de producción regional de vacunas con miras a la autosuficiencia. **Conclusiones:** Se observa que a pesar de las diferencias lingüísticas y de las diferencias institucionales entre el bloque y los países Asociados, la evaluación realizada al final del curso confirma la pertinencia y la necesidad de ampliar la experiencia desarrollada. Queda evidente la necesidad de crear capacidades en la región para alcanzar la Soberanía Sanitaria, así como, la importancia de incorporar algunos temas estratégicos identificados por los participantes para dar la continuidad a la calificación de los profesionales de la región, en un proceso de Formación continua y permanente.

PALABRAS CLAVE: Vacunas; Desarrollo y Producción de Vacunas; Soberanía Sanitaria; Capacitación en Red

INTRODUCTION

Access to pharmaceutical products, vaccines, and other medical and health technologies is an essential part of the right to health, a fundamental human right that must be guaranteed through the implementation of public health policies by national governments.

At a global level, many countries, including most countries in the Southern Common Market (Mercosur) region, have incorporated the right to health into their constitutions. However, large population groups, especially in developing countries, still have restricted access to essential health actions and products, and often incomplete vaccination schedules.

The COVID-19 pandemic has highlighted the strategic nature of the availability of health products in the context of a health emergency and, on the other hand, demonstrated the limited production capacity of some regions of the world. Market mechanisms have hampered health actions and put global solidarity strategies to the test.

One of the first crises observed during the pandemic was the shortage of personal protective equipment (PPE) and household products, which led to the interruption of health services and an increase in morbidity and mortality. This was followed by a shortage of some medical and hospital technologies, such as mechanical ventilators, oxygen production technologies, oximeters, and

pharmaceutical products for hospital use, specifically those used in intensive care units¹.

Regarding the production and distribution of COVID-19 vaccines, the richer countries had access to much larger quantities of doses in the early stages of the pandemic, while the global "Covax-WHO" mechanism failed to guarantee access to immunobiologicals in the first few months².

Although research efforts and technological development for vaccine production have been carried out in record time, the crisis related to the pandemic has exposed the weaknesses of regional development patterns and inequality in access to vaccines. Some developed countries promoted "vaccine nationalism", acquiring double or triple the doses needed to immunize their population, thus leaving other less developed countries with significant access difficulties^{3,4}. Thus, in the light of the COVID-19 pandemic, we have witnessed our region's high degree of technological dependence on imports of vaccines, medicines, active ingredients and pharmaceutical chemicals, as well as health equipment and products, and we have experienced the devastating effects of this dependence.

The region then began to debate the need to build "health sovereignty", understood as the idea of overcoming the health



sector's dependence on strategic inputs imported from other regions. Advancing regional sovereignty in health involves the willingness of countries in the region to integrate their experiences and knowledge in the field of health, cooperating and solving health problems that transcend borders, joining forces around common challenges and through cooperation. Regional sovereignty in health - which involves the field of vaccines and other strategic biological medicines - presupposes overcoming the isolation of each country, building alliances and integrating research, innovation, and development production chains at regional level to guarantee the right to health in the countries involved.

The Oswaldo Cruz Foundation (Fiocruz) made a major contribution to the conceptualization of the "Health Economic-Industrial Complex" (HEIC), which is part of the current Brazilian government policy and is an important step towards the country's scientific and technological development. From this perspective, progress in the industrialization of the health sector increases the country's autonomy and capacity for international cooperation and negotiation with other countries, with the potential to overcome the cycle of underdevelopment of the Brazilian economy in relation to global capitalism, historically characterized by the external determination of accumulation, which generates structural vulnerabilities for social policies^{5,6}.

BACKGROUND

As we have seen during the crisis related to the COVID-19 pandemic, there are major regional asymmetries in the production and distribution of vaccines, as a large number of doses are often concentrated in developed countries and few doses are available in developing countries. In fact, there is a lack of vaccine production capacity in most Latin American countries. The concentration of global vaccine production reproduces the international asymmetries that have historically distinguished developed countries from others (center-periphery relationship)⁷.

The Ministers of Health of the Americas recently took an important step towards promoting regional health sovereignty in the field of medicines and vaccines. Meeting at the 59th Session of the Directing Council of the Pan American Health Organization (PAHO), from September 20 to 24, 2021, they approved Directing Council (DC) Resolution No. 59/8, which provides for "increasing production capacities for essential medicines and health technologies"¹. In point 1.C, it urges Member States, considering their contexts, needs, vulnerabilities, and priorities, to:

"Strengthen national capacity for the development and production of raw materials and essential medicines and other health technologies, including the training of skilled human resources and, where applicable, the strengthening or development of national infrastructure and clusters that support research, development, innovation, and production activities to better meet health needs and priorities." To make this resolution operational in the Mercosur countries, the Health Ministers decided to create the "Ad Hoc Committee to Promote the Expansion of Regional Production Capacity for Medicines, Immunizations and Health Technologies" (CAHECPR). Since the creation of the CAHECPR, Fiocruz has actively participated with the aim of making its research and technological development capacity available, as well as its historical experience in the production of vaccines, medicines and diagnostic supplies⁸. It should be noted that access to medicines and other essential health technologies requires, among other things, a guarantee of their safety, quality, and efficacy, as well as their accessible and timely availability according to need, and the availability of comprehensive health services that promote their rational use.

The important experience accumulated by Fiocruz, especially Bio-Manguinhos, in vaccine research, development, and production, reinforced the idea of formulating a "Vaccine Development and Production" course for Mercosur. Also noteworthy is the transfer of AstraZeneca's COVID-19 vaccine to Fiocruz and, more recently, the fact that the institution has been designated a hub for messenger RNA vaccines for the region.

VACCINE DEVELOPMENT AND PRODUCTION COURSE FOR MERCOSUR

The initiative for the "Vaccine Development and Production" course for Mercosur proposed inter-institutional coordination, mobilizing capacities and different players: Fiocruz, through the Vice-Presidency for Production and Innovation in Health (VPPIS), Bio-Manguinhos, Farmanguinhos and the Center for International Relations in Health (CRIS), the Butantan Institute, PAHO, and the pharmaceutical company Nortec Química.

The course was designed from the perspective of a hybrid training offer: a first remote part, which was developed through a virtual platform in an entirely synchronous way, in which a set of classes were planned, comprising seven learning modules.

Figure 1 shows the timetable for the process of formulating, executing and completing the first class of the course (November 2022 to November 2023).

The course proposal was received favorably by the Mercosur Health Ministers, and Fiocruz proposed the following objectives:

- Strengthen technical cooperation between the countries of the bloc;
- Promote the transfer of technology between the countries of the bloc;
- To address the main issues related to the development and industrial production of vaccines, production technologies and vaccine development and production platforms to professionals assigned by country, discussing the advantages and disadvantages of technologies and platforms;





Source: Prepared by the authors, 2024.

Figure 1. Timetable for the creation and implementation of the "Development and production of vaccines" course for Mercosur.

 Present the candidates for industrial-scale vaccine production and the mechanisms and methods for vaccine development, the relevant legislation and quality assurance aspects for vaccine production and associated processes.

Although it was already considered that countries have different realities and that not all of them had the installed capacity to produce vaccines at the time, it was proposed that the course should be aimed at a wide range of professionals. From those involved in research projects, development and production of vaccines or other biological products, to agents involved in regulatory science and managers of immunization programs, thus covering a broad spectrum of professionals. As for the participants, 24 professionals were nominated by the National Mercosur Coordination of the member countries, corresponding to five participants from Argentina, five from Brazil, five from Paraguay, five from Uruguay, one from Chile, and three from PAHO. This created the challenge of constructing a training strategy that would cater for a diverse target audience in terms of professional profiles and experiences.

The virtual modules of the course began in September 2023 and were taught twice a week, always on Tuesdays and Thursdays, from 9 a.m. to 12:30 p.m., until October 31, 2023. The total workload of the online modules was 50 hours. To facilitate the coordination of the course¹, a coordination team was formed with people from Fiocruz, the Butantan Institute, and PAHO who met weekly to monitor the teaching-learning process and schedule classes with guest speakers. The teaching staff invited for the first edition of the course was made up of professionals who were specialists in the topics selected as being of interest to the target audience. Most of the lecturers work professionally at Fiocruz or the Butantan Institute.

The course was structured into eight modules, seven virtual and one face-to-face, as detailed in Table 1. The face-to-face module was attended by 21 representatives from Argentina, Brazil, Chile, Paraguay, and Uruguay, as well as two representatives from PAHO.

COURSE EVALUATION

As part of the final activities of the group of coordinators, students were consulted using an electronic form, which asked questions about elements of course evaluation.

When asked about the syllabus, 91.6% of participants said it was "excellent" and 6.7% said it was "very good". Students were also asked about the teacher-student relationship and 97.7% of participants considered the relationship to be "excellent", while 2.3% said it was "very good". As for the infrastructure, 87.0% considered it "excellent" and 10.5% "very good". The teaching-learning process was rated as "excellent" by 67.0% of the participants, while 21.0% considered it "very good". Some students did not answer all the questions.

Students were asked to complete a self-assessment, asking if they had been able to understand the main concepts covered, if the course had introduced them to new concepts and if this had been important for their general education. They were also asked if the course gave them a better understanding of the area of vaccine development and production. In general terms, 73.0% of the participants said that the experience was "excellent" and 23.0% said it was "very good".

When participants were asked about the main positive aspects of the course, they said: (1) it offered a panoramic view of the vaccine production process in the region; (2) it enabled interaction with participants from other countries, (3) the exchange of new and up-to-date knowledge and (4) the opportunity to interact with teachers and other professionals through technical visits (Figure 2).

¹ Course coordinators: Jorge Carlos Santos da Costa from the Vice-Presidency for Production and Innovation in Health (VPPIS/Fiocruz), Mirian Nakamura Gouveia from the Butantan Institute, Marco Alberto Medeiros from Bio-Manguinhos/Fiocruz, Tomas Pippo, Iván Redini Blumenthal, Francisco Caccavo, and Eduardo Jorge Oliveira from PAHO/RT, and Carlos Arosquipa from PAHO/SAM.



Table 1. Vaccine development and production course for Mercosur: modules, syllabus, and modality.

Module	Syllabus	Modality
Module 1	Immunobiological R&D and Production Portfolio - Bio-Manguinhos and Instituto Butantan; Vaccinology: past, present, future - state of the art and vaccine policy and regulation in Brazil and worldwide.	Online
Module 2	Drug development process: from idea to product, life cycle; quality system - quality assurance and control; regulator; Infrastructure x development x good practices (GP); validation of process control methodologies; development and validation of analytical quality control methodologies; pre-clinical studies; scale-up; development of formulations and administration systems (adjuvants).	Online
Module 3	Production of clinical batches in GMP; Requirements and structure of manufacturing facilities, clean areas, containment for vaccine production; Biosafety in vaccine production; Platform in embryonated eggs (for example: influenza and yellow fever); Platform in prokaryotes (for example: Pertussis, diphtheria and tetanus); Antigen expression platform in yeast (e.g. hepatitis B and HPV); Platform in mammalian cells - inactivated, attenuated, and genetically modified vaccines (e.g. coronavac, measles, rubella, mumps, and rotavirus and dengue); New vaccine production platform (mRNA and viral vectors) and serum production.	Online
Module 4	Design and clinical trial, study file for authorization by the Health Surveillance Agency and Pharmacovigilance.	Online
Module 5	Registration and post-licensing of products and post-registration of biological products.	Online
Module 6	Organization, operation and the search for high vaccination coverage.	Online
Module 7	Immunization policies, production and vaccine value chains for the region of the Americas.	Online
Module 8	Technical visits to the Butantan Institute, Farmanguinhos/Fiocruz, Nortec Química and Bio- Manguinhos/Fiocruz.	In person

Source: Prepared by the authors, 2024.

As for points for improvement, the course participants pointed out the need for: (1) simultaneous translation of the lessons, (2) availability of supporting bibliographic material and sending it before the course starts, and (3) incorporation of other topics. The topics that emerged as being of interest to the course's target audience are: "Intellectual property", "Health Economic-Industrial Complex (HEIC)", "Technology transfer", "Storage and distribution logistics", and "Chemical synthesis of medicines".

PROSPECTS FOR FUTURE EDITIONS OF THE COURSE

This experience shows that the first course on "Vaccine development and production" for Mercosur was a successful one, and at the same time it provides us with information on how to improve the course's Pedagogical Project (PPC) with a view to offering new classes. To this end, some proposals are put forward:

Incorporation of simultaneous translation, by means of subtitles, in the Spanish language in synchronous remote classes;

Translation of the content of the presentations used by the teachers and the bibliographic material provided;

- Creation of the course's own layout and standardization of all material and lesson content with a single visual identity;
- Preparation of guides and tutorials with pedagogical guidelines for the group of teachers, seeking to contribute to more appropriate didactic-methodological choices for the hybrid format of the proposal;
- 3. Creation of virtual library and media library spaces;
- 4. Creation of virtual tours of factory production environments;



Source: Prepared by the authors, 2024.

Figure 2. Main aspects of the course evaluation by its participants.

Incorporation of new thematic modules and expansion of the course's workload.

In fact, the pandemic presented itself as a watershed in many aspects and practices, which is why new educational strategies became part of the daily experiences of institutions working in the field of academic and professional training^{9,10}. It was no different at Fiocruz^{11,12}. Adaptive capacities and possibilities for new discoveries and opportunities were revealed as a result of collective learning. In fact, the multifaceted nature of the pandemic has shown that, while on the one hand, the losses and damage suffered during the period are recognizable, on the other hand, extraordinary capacities for resilience and adaptation have been revealed. Some positive aspects of the adoption of emergency hybrid teaching have been revealed, such as:



greater inclusion and national and international coverage, less time and effort spent traveling, incorporation of active methodologies, diversification of educational strategies and resources, and pedagogical practices through a combination of synchronous and asynchronous activities¹³.

The professional background and significant previous experience of the course participants (coordinators, teachers and students) provided a virtuous learning process, in which each person's experiences enabled them to learn and share knowledge and practices with the other participants. This interaction is seen as a promising strategy and could open a window of opportunity for the creation of a community of practice¹⁴ that contributes to strengthening capacities in the development and production of vaccines in the region. From this perspective, the course presents itself as an opportunity for networking technical and managerial staff, seeking to induce decentralization and capillarity through interaction between professionals from different regions and, ultimately, aiming to make a substantial contribution to achieving health sovereignty in the region.

CONCLUSIONS

Vaccines are essential for protecting life and are an important segment of the global pharmaceutical market, which has economic trends marked by high asymmetries. The vaccine production sector is characterized by an increasing technological complexity of innovation processes, associated with rising innovation and development costs, which has led to a significant concentration of production. In fact, promoting health sovereignty, in terms of strengthening capacities to produce vaccines, medicines, and health technologies, is a priority for the region. However, to make progress on this priority, it is necessary to develop strategies that consider the process of continuous and permanent professional training and qualification, articulating the region's capacities in a network.

In this sense, the "Development and production of vaccines" course is a successful experience, a good practice in which different knowledge and capacities from institutions in the region have come together, generating a virtuous circle of benefits for the Mercosur countries.

As this experience report has shown, it is important to hold new editions of the course, improving its pedagogical project and expanding participation to professionals from other countries in the region. Advancing regional health sovereignty in terms of vaccines and other pharmaceutical products requires cooperation between different countries and institutions^{15,16}. Strengthening competencies for the development and production of vaccines will be a consequence of capacity building in the countries, which requires the continuity of networking processes, always taking into account the differences in national contexts and their health systems. There is undoubtedly a long road ahead, but as the Italian theologian Giambattista Vico (1668-1744) said, "Men are angels with only one wing. To fly, they must embrace each other".

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Authors' Contributions

Tobar S, Costa JCS, Gouvea MN, Medeiros MA, Delgado IF - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the paper. All the authors have approved the final version of the paper.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.



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