TECHNOLOGY TRANSFER CHALLENGES AND OPPORTUNITIES IN THE LATIN AMERICAN PHARMACEUTICAL INDUSTRY

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Abstract

The global activation of technology transfer scenarios is viewed as a strategic path to positively impact the development and strengthening of capabilities and scenarios for pharmaceutical production, through collaborative relationships. However, for these scenarios to effectively materialize, it is required to the develop adequate ecosystems with sufficient research and development (R+D) capacities, specialized work teams, technological resources, recognition of good manufacturing practices (GMP), high standards regarding regulatory processes, solid intellectual property systems, legal certainty, transparency and market conditions that enable the exploitation of the transferred technology. Technology transfer in the pharmaceutical sector entails a high level of capabilities from both the technology generating party and the receiving party. The latter must particularly count on certain conditions that will enable it to hold sufficient capacity in order to produce the transferred technology and meet the necessary technical, regulatory and commercial requirements. The Latin American outlook does not reflect a generalized dynamic in terms of technology transfer processes in the pharmaceutical industry. Notwithstanding, there is evidence of significant efforts in some countries regarding collaboration agreements focused on building and/or strengthening capabilities, at different levels, for the progressive development of scenarios that allow them to move forward on the path towards local pharmaceutical production.

1. Basic aspects regarding Technology Transfer in the Pharmaceutical Sector

Technology Transfer consists of the process whereby one party, the technology generator, transfers knowledge and technical elements to another party. The latter can then apply, develop and/or appropriate said technology and bring it to the market transformed into a product for consumers and/or patients.

A Technology Transfer process can arise more easily in an environment where technology is at an advanced level of maturity that allows it to be effectively conveyed. Thus, the receiving party is prepared to receive the knowledge and other technical elements in order to apply, develop and/or generate products from said technology. It also requires the existence of a solid technical process in order to carry out the transfer itself, as well as a clear contractual relationship that defines the key elements and transfer path between the parties involved. In addition to the aforementioned elements, it is paramount for the performance of a Technology Transfer process that the intellectual property associated with the technology to be transferred be adequately protected. In this regard, clear terms and conditions must be agreed upon between the parties, including economic aspects that protect the return on investment carried out by the technology generator.

Technology Transfer can be carried out in any technological sector. However, its understanding and execution is more demanding and complex in sectors such as the pharmaceutical. For example, if a laboratory located in any country intended to manufacture a drug that required high technical, economic, regulatory and commercial efforts, access to the information contained in a patent would not be enough, if there is a lack of technical capabilities, good manufacturing practices (GMP)[1] and infrastructure necessary to produce the drug. Therefore, the need arises to carry out technology transfer processes and technical elements that enable the receiving party to understand the technology in detail. Moreover, the latter would need to develop and/or strengthen its Research, Development and Innovation (R+D+i) capabilities to the point of being able to manufacture the product with the full technical and regulatory requirements[2] that guarantee the respective quality standards.

A successful Technology Transfer assumes an effective innovation ecosystem, a collaborative network between government bodies, the industry, and research institutions, as well as enabling factors such as human capital, Technology Transfer structures, and sophisticated business and market conditions.[3] The global activation of Technology Transfer scenarios in the pharmaceutical sector is viewed as a strategic path to positively impact the development and/or strengthening of capabilities and scenarios for pharmaceutical production through collaborative relationships. However, for said scenarios to be effectively carried out, it is required to develop ecosystems with sufficient R&D capabilities, work teams, technological resources, intellectual property rights protection, legal certainty, and conditions for the exploitation of the transferred technology.

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[1] *Good Manufacturing Practices (GMP): The part of quality assurance that ensures that pharmaceutical products are consistently produced and controlled with the appropriate quality standards for its intended use and as required by the authorization for its marketing (1). Retrieved from: https://www.paho.org/hq/dmdocuments/2011/Espanol-control-calidad-laboratorios-farmaceuticos.pdf*

[2] *World Health Organization (WHO). (August 2021). WHO Guidelines on technology transfer in pharmaceutical manufacturing. Retrieved from: https://cdn.who.int/media/docs/default-source/essential-medicines/norms-and-standards/qas20-869-transfer-of-technology.pdf?sfvrsn=2a4723bc_5*

[3] *World Intellectual Property Organization (WIPO). Intellectual Property and Technology Transfer. Retrieved from: https://www.wipo.int/technology-transfer/en/index.html*

In this sense, a Technology Transfer process in the pharmaceutical sector, besides requiring a highly qualified technology generator with proven capabilities that have allowed it to develop, produce and market the technology embodied in a product, also calls for a highly qualified receiving party. The latter must be able to receive the technology and possess full capacity to produce it under the necessary technical, regulatory and commercial conditions. It is important to point out that technology transfer processes[4] in the pharmaceutical sector can be of different levels and/or dimensions. In some cases, the capabilities of the potential receiving party may be sufficient only to achieve some components or phases of the production process, or even, only hold capabilities for the packaging phase - *fill and finish* - of the respective pharmaceutical product. This would imply the need to develop additional R+D+i capabilities, which necessarily demand high investments, complex technical processes and time in order to mature real pharmaceutical production scenarios.

2. An Overview of Technology Transfer in Latin America

From a Latin American standpoint, Technology Transfer in the pharmaceutical industry does not reflect widespread use, mainly due to the lack of sufficiently developed ecosystems for the transfer process to take place. The willingness of a country to mass-produce certain medicines, for example, would not be enough to firmly activate Technology Transfer scenarios with short-term results. Internally, said country would need to hold the infrastructure or necessary capabilities in local laboratories in order to carry out the generation of the pharmaceutical product with the required conditions. The maturation of favorable scenarios to perform Technological Transfer processes entails great efforts and high investments, especially by the potential receiving parties. This implies the development of a clear and attractive regulatory, legal and market conditions context, enabling the return on investment and efforts, while the economic benefits allow reinvestment in further R+D+i activities.

The transfer of processes and highly complex technical information, as well as highly specialized professional expertise, constitute core elements in a handover procedure that must occur between the technology generator and the receiving party seeking to act as local manufacturer.[5] That is why limiting a Technology Transfer process in the pharmaceutical industry by simply allowing access to technical information, such as the contents of a patent document,[6] would be incorrect. This would only be part of a preliminary stage of a complex process, which would later require entering technical phases whereby the receiving party must count on sufficient capabilities to receive the technology and hold the necessary conditions to be able to carry it out. In each case, said party must comply with the necessary technical, regulatory and commercial specifications.

[4] *Technology transfer processes are mainly carried out through the following mechanisms: sale/assignment of intellectual property rights, licensing of intellectual property rights, R+D+i collaboration agreements, and creation of Technology-Based Companies.*

[5] *World Health Organization (WHO). (Geneva, Switzerland 2011). WHO Guidelines on Transfer of Technology in Pharmaceutical Manufacturing. Retrieved from: https://extranet.who.int/pqweb/sites/default/files/documents/TRS_961_Annex7_2011.pdf*

[6] *World Intellectual Property Organization. STANDARD ST.16 Standardized code for the identification of the different types of patent documents. Retrieved from: https://www.wipo.int/export/sites/www/standards/es/pdf/03-16-01.pdf*

Within the Latin American landscape, in regards to R+D+i capacity building processes, Brazil, for example, through its Ministry of Health, has been working on the generation of productive development agreements (PDPs, *for its acronym in Portuguese*). These partnerships refer to technology transfer processes that are essentially carried out by private laboratories towards mainly public laboratories for the purpose of generating pharmaceutical production aimed at meeting the health priorities of the universal health system "SUS" (*for its acronym in Portuguese*), as defined by said Ministry. The priorities are established in accordance with the national interests and needs, safeguarding the rights of the private laboratory, including the right to the respective economic compensation through specific contractual terms[7]. These types of processes imply a great collaborative effort focused on the construction and/or strengthening of capabilities in the medium and long term.

Due to the challenges generated by Covid-19, Brazil[8], Mexico[9] and Argentina[10] feature recent cases of collaborative relationships that reveal important efforts in terms of Technology Transfer in the pharmaceutical sector. These relationships are focused on the development of capabilities for the vaccine production, medical technologies and pharmaceutical products in general. For example, among the different initiatives developed worldwide, the platform to advance the availability of essential medical technologies within the Pan American Health Organization (PAHO) region stands out. It fostered two important Latin American research centers to become part of an international Technology Transfer project serving as a regional node at the Latin American level for the development and production of mRNA vaccines.[11] In these cases, prior R+D investment carried out in each of these countries became an important factor in advancing towards enabling Technology Transfer scenarios, given the developed and matured capabilities installed in local laboratories.

On the other hand, countries such as Chile[12], Colombia[13], Ecuador[14] and Uruguay[15] have reported progress at entering into agreements with international allies for the undertaking of processes for the construction of internal capabilities and infrastructure, focusing on local production or regional distribution of vaccines. Other countries in the region require greater development of ecosystems that imply public policy efforts in regards to health innovation, investment related to R+D+i capabilities and infrastructure, intellectual property rights protection, and a strategic collaborative relationship with international allies from the pharmaceutical industry.

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[7] *Ministry of Health. Partnerships for Productive Development (PDP). Retrieved from: https://www.gov.br/saude/pt-br/composicao/sctie/deciis/pdp*

[8] *In Brazil, the Oswaldo Cruz Foundation (Fiocruz) entered into a local production agreement with AstraZeneca that, in a first stage, provides for the importation of the active pharmaceutical ingredient. As of August 30, 2021, 87.9 million doses had been produced. On the other hand, within the framework of a technology transfer agreement entered into with Sinovac, the Butantan Institute began manufacturing the CoronaVac vaccine and had delivered 92 million doses by August 30, 2021. In August, Pfizer-BioNtech reached an agreement with Eurofarma Laboratories to carry out the vaccine filling and packaging processes as from 2022, with a capacity of 100 million doses per year. Pending emergency authorization by the government, União Quimica would also produce the Sputnik V vaccine within the country, with a capacity of 8 million doses per month. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/47252/1/S2100557_es.pdf*

[9] *In Mexico, Drugmex packages CanSinoBIO's Convidecia vaccines. As of August 6, 2021, it had produced 4.5 million doses. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/47252/1/S2100557_es.pdf*

[10] *In Argentina, Richmond Laboratories produces the first and second components of the Sputnik V vaccine, with an estimated capacity of 40 million doses in 2021 and 200 million in 2022. The first stage foresees the importation of the active pharmaceutical ingredient. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/47252/1/S2100557_es.pdf*

[11] *Pan American Health Organization (PAHO). (March 24, 2022). Latin American manufacturers complete first training in mRNA technology in bid to improve regional vaccine production. Retrieved from: https://www.paho.org/en/news/24-3-2022-latin-american-manufacturers-complete-first-training-mrna-technology-bid-improve*

[12] *Ministry of Science, Technology, Knowledge and Innovation. (May 12, 2022). "Minister Flavio Salazar said regarding the start of construction of the Sinovac plant in Chile: "This project once again introduces our country into the vaccine production process.". Recovered from: https://www.minciencia.gob.cl/noticias/ministro-flavio-salazar-por-el-inicio-de-la-construccion-de-planta-de-sinovac-en-chile-este-proyecto-introduce-nuevamente-a-nuestro-pais-en-el-proceso-de-produccion-de-vacunas/*

[13] *Ministry of Health and Social Protection. (August 9, 2021). Minister of Health held meeting with Sinovac Vice President. Recovered from: https://www.minsalud.gov.co/Paginas/Minsalud-sostuvo-reunion-con-vicepresidente-de-Sinovac.aspx*

[14] *Ministry of Public Health. (February 14, 2022). Sinovac approves vaccine plant project in Ecuador. Recovered from: https://www.salud.gob.ec/sinovac-aprueba-proyecto-de-planta-de-vacunas-en-ecuador/*

[15] *Ministry of Foreign Affairs. (May 24, 2022). Joint statement regarding the bilateral meeting between Uruguay and the United Kingdom. Retrieved from: https://www.gub.uy/ministerio-relaciones-exteriores/comunicacion/comunicados/declaracion-conjunta-sobre-reunion-bilateral-entre-uruguay-reino-unido*

3. Necessary conditions regarding the activation of favorable ecosystems for Technology Transfer in Latin America:

The activation of Technology Transfer processes in the pharmaceutical industry entails certain enabling conditions for the performance of the relationship between the technology generating party and the receiving party. According to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the following elements are decisive for an adequate context regarding the activation of Technology Transfer cases: legal certainty and security, political stability, transparency and high ethical standards, highly qualified allies, favorable innovation environments with solid intellectual property rights, compliance with high regulatory standards and the existence of an accessible local market.[16]

In light of the above, the following are some key conditions that could develop an adequate ecosystem in Latin America to activate Technology Transfer scenarios, particularly applicable to the pharmaceutical industry:

Innovation and Intellectual Property

According to the World Intellectual Property Organization (WIPO), to innovate means doing something new that improves a product, process or service. Innovation is related to intellectual property since many innovations can be protected by intellectual property rights. On the other hand, innovation in health[17] promotes new ways to prevent, diagnose and monitor health problems, as well as new medicines and devices to address the treatment of diseases.[18] The protection of new medicines and devices through intellectual property turns out to be an essential tool to guarantee and foster the continuous generation of innovations in health. It also encourages research and development (R+D) investment carried out by different actors in the pharmaceutical industry, both domestic and foreign.

Thanks to the research, development and innovation (R+D+i) efforts in the pharmaceutical industry, it is possible to generate quick solutions that respond to the challenges and needs presented by the health sector worldwide. Likewise, thanks to the collaborative relationship between different actors within the ecosystem, these innovative products can be extended to other latitudes, through allies, acting as local producers. An example was the development of innovative solutions in record time, including the generation of vaccines[19] during the recent pandemic. The innovative capacity and experience in Technology Transfer on the part of global players in the pharmaceutical industry played a leading role. During

[16] *Op. Cit. IFPMA*
[17] *Following the 2020 trend, healthcare-related technologies continued to post the fastest growth among all fields of technology. (Global Innovation Index 2022 - prepared by the World Intellectual Property Organization (WIPO)).*
[18] *World Intellectual Property Organization (WIPO). Innovation and Health. Retrieved from: https://www.wipo.int/global_innovation_index/es/2019/health_ai_bigdata.html*
[19] *International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). Technology Transfer: A Collaborative Approach to Improve Global Health. Recovered from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf*

the first year of existence of the COVID-19 vaccines, around 300 agreements for its manufacturing and production were entered into between actors around the world. The vast majority involved some type of licensing of intellectual property rights and Technology Transfer agreements in general. [20]

In Latin American countries, the promotion and protection of innovation[21] is essential in order to further develop R+D+i ecosystems. One of the key elements to achieve this is through the strengthening of intellectual property rights. This protection encourages the generation of innovative technical solutions by different actors who, by protecting their inventions through patents, for example, will be able to recover the investment carried out during R+D+i activities. Moreover, it will boost swifter relationships between said actors and allies for the activation of Technology Transfer scenarios, both regional and/or international, based on collaborative agreements.[22] In an opposite setting, where intellectual property protection can be weakened or even suspended at any time, there would be risks for potential manufacturers of medicines or medical devices. The manufacturers would not hold any certainty regarding the recovery of R+D+I investment costs, nor while exploiting their rights associated with the generated development. Hence, this would consequently cause a negative outlook for activating Technology Transfer scenarios. The generation of health innovations in its different manifestations, centered upon intellectual property protection, encourages the actors' dynamics towards solving problems in the health sector, which benefits society in general.

Specialized R+D Capabilities and Infrastructure

Technology Transfer in the pharmaceutical sector not only consists of sharing the basic elements to develop or produce a medicine or a vaccine on the part of the technology generating party. It also requires the transfer of expertise between research teams, the existence of human capabilities from the receiving party for the understanding and use of the technology, access and use of equipment or technological resources. In general terms, it refers to the conveyance of information, knowledge, techniques and processes related to the technology being transferred.

Human capital is a key element of the Technology Transfer process. The successful absorption of technology and know-how in the receiving country and its materialization in greater economic development depends on the availability of a qualified labor force in said country.[23] In this sense, several Latin American countries are at a disadvantage, given that many of its researchers[24] with high R+D

[20] *Ibid.*
[21] *In Latin America, Chile was the country that in 2022 stood out for being the most innovative economy in the region. It was the only Latin American country in the top 50. (Global Innovation Index 2022 - prepared by the World Intellectual Property Organization (WIPO))*
[22] *International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). Technology Transfer: A Collaborative Approach to Improve Global Health. Recovered from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf*
[23] *International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). Technology Transfer: A Collaborative Approach to Improve Global Health. Retrieved from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf*
[24] *As of 2018, Argentina was the Latin American country with the highest number of researchers dedicated to research and development per million inhabitants. Retrieved from: https://datos.bancomundial.org/indicador/SP.POP.SCIE.RD.P6?end=2018&locations=AR&start=1997*

capabilities have migrated to countries with better opportunities. However, internal investment[25] carried out in each country could be an alternative. By means of specialized training, human capital can strengthen its R+D capabilities and the country can offer more attractive conditions when advancing in transfer processes. Technology Transfer in the pharmaceutical sector also involves the transfer of instruments, equipment, and necessary elements so that a pharmaceutical product can be manufactured or packaged by the receiving country under the same technical and quality conditions.

Latin America holds productive and research capabilities, developed thanks to the investments that the countries of the region have carried out over the years. However, these capabilities need to be strengthened since currently in many countries of the region they may not be enough to attract the attention and interest of actors in the pharmaceutical sector who want to invest in R+D+i. In this sense, in order to attract investment, it is necessary to prioritize the development of capabilities in the pharmaceutical industry at a national and regional level, through the strengthening of national productive capabilities, the increase of investments during the research and development stages, and the consolidation and regional integration in matters of regulation, standards, as well as production and distribution chains.[26]

International Collaborative Relationships

Several actors participate in the Technology Transfer processes, such as companies, public institutions, pharmaceutical laboratories, research centers, educational institutions, among others. Due to collaborative relationships, these organizations manage to provide quick solutions to the requirements presented by the health sector. A clear example is the aforementioned, worldwide coverage achieved with the production of COVID-19 vaccines, which were driven by different manufacturing and production agreements. Among other agreements that facilitate Technology Transfer, many involved intellectual property rights licenses.[27]

In the case of Latin America, it is worth noting that it is one of the regions with the lowest vaccine production capacity. Notwithstanding, within this group, Argentina and Brazil have stood out as the countries that carried out the largest investments in science, technology and innovation. This effort helped them to advance in Technology Transfer agreements with important worldwide laboratories for the manufacture of vaccines.[28] Moreover, in 2021, Research Centers from these countries were selected by the Pan American Health Organization to produce

[25] *Of all Latin American countries, Brazil was the one that invested the highest percentage of GDP in research and development up to 2019 (1.21). Retrieved from: https://datos.bancomundial.org/indicador/GB.XPD.RSDV.GD.ZS?name_desc=false*

[26] *Economic Commission for Latin America and the Caribbean (ECLAC). (2022). Foreign Direct Investment in Latin America and the Caribbean. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/48520/S2200562_es.pdf?sequence=3&isAllowed=y*

[27] *Due to the COVID-19 pandemic, an emerging phenomenon of collaborations on specific projects has been observed between large pharmaceutical companies for the development of COVID-19 vaccines, taking advantage of the complementarities of their assets. For example, Sanofi invested in the development of two vaccines (one based on mRNA and one based on recombinant proteins), but used its manufacturing capabilities to support the dosing and packaging of the Pfizer-BioNTech and Johnson & Johnson vaccines. For its part, Novartis has not invested in manufacturing its own vaccine, but has instead used its production facilities to manufacture the Pfizer-BioNTech vaccine. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/48520/S2200562_es.pdf?sequence=3&isAllowed=y*

[28] *BETANCOURT CRUZ, DAVID ENRIQUE. (September 13, 2021). Vacunas: Transferencia de Tecnologías, Producción y Acceso Equitativo [Vaccines: Technology Transfer, Production and Equitable Access]. Retrieved from: https://derechoeconomico.uexternado.edu.co/uaem/vacunas-transferencia-de-tecnologias-produccion-y-acceso-equitativo/*

mRNA vaccines against COVID-19 and to prepare for the next challenges of infectious diseases. [29]

Experiences such as those reflected through the *Accelerator Act*[30], an initiative led by CEPI[31], Alianza Gavi para las Vacunas [Gavi Alliance for Vaccines], and the WHO, set in motion to speed up the development, production and equitable access to diagnostic tests, treatments and vaccines against Covid-19, managed to expedite access to vaccines for countries globally. It also has contributed to actions focused on building and developing capabilities for manufacturing and distributing vaccines. As of this collaborative relationship, COVAX emerged as the pillar of the vaccines of the *Accelerator Act*. It was generated as a solution proposed by world leaders and which sought to respond to the need to promote access to vaccines against COVID-19. It was essential that countries with and without the economic resources could gain access to the vaccines.[32]

The collaborative relationship between different actors within the R+D+i ecosystem in Latin America is decisive to increasingly develop the appropriate scenarios for the activation of Technology Transfer processes. This step, in turn, can accelerate internal capacity building processes in the hands of actors with high experience in the pharmaceutical industry.

Legal Certainty

Latin American countries need to enact and comply with legal systems that provide legal certainty to investors. This translates into solid, stable and transparent regulations, constituting a key element for stimulating investment in R+D+i activities focused on the generation of pharmaceutical production. Otherwise, the possibility of materializing deals or agreements decreases due to the risks that investors would assume.

According to the latest Foreign Direct Investment report issued by the Economic Commission for Latin America and the Caribbean (ECLAC), foreign direct investment in Latin America and the Caribbean during 2021 recovered from the sharp drop registered in 2020. Brazil[33] was highlighted as the country that received the most investments, where the European Union and the United States were the main investors in 2021, representing 36% and 34% of the total. In Brazil and Mexico between 2006 and 2021, the annual inflows of Foreign Direct Investment (FDI) to the pharmaceutical industry averaged around 600 million dollars per year. As of 2021, the cumulative total for Brazil and Mexico was 9.785 billion dollars and 9.68 billion dollars, respectively.[34] With respect to research and development (R+D) investment in Latin America, an increase is reflected in recent years, where Brazil,

[29] Pan American Health Organization (PAHO). (September 21, (2021). PAHO selects centers in Argentina and Brazil to develop mRNA vaccines against COVID-19. Retrieved from: https://www.paho.org/es/noticias/21-9-2021-ops-selecciona-centros-argentina-brasil-para-desarrollar-vacunas-arnm-contra
[30] What is the Act Accelerator? Retrieved from: https://www.who.int/initiatives/act-accelerator/about
[31] Coalition for Epidemic Preparedness Innovations. See: https://cepi.net/
[32] Covax. Retrieved from: https://www.who.int/initiatives/act-accelerator/covax
[33] In Brazil, the pharmaceutical industry ranked tenth among the main recipients of Foreign Direct Investment (FDI) in manufacturing. Recovered from: https://repositorio.cepal.org/bitstream/handle/11362/48520/S2200562_es.pdf?sequence=3&isAllowed=y
[34] Economic Commission for Latin America and the Caribbean (ECLAC). (2022). Foreign Direct Investment in Latin America and the Caribbean. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/48520/S2200562_es.pdf?sequence=3&isAllowed=y

Argentina and Chile stand out.[35] However, the maturation of favorable scenarios for local pharmaceutical production requires greater investment and development efforts.

Regulatory Efficiency

In order to guarantee the quality, safety and efficacy of its medicines and patient well-being, the pharmaceutical industry is one of the most regulated sectors.[36] In order to carry out Technology Transfer processes in the pharmaceutical sector, the compliance with high regulatory standards is required. Thus, for Latin American countries, meeting these standards is an essential condition. Efficient regulation in Latin American countries, where the laws, policies and regulations guarantee that pharmaceutical products are safe and meet technical and sanitary conditions, can facilitate Technology Transfer activities. Generally, the technology holders make the decision to transfer to a specific country due to its local regulations and ability to comply with international standards, enabling them to maintain product quality to protect the safety of users and patients.

For countries, efficient regulation in research, development and innovation issues translates into an opportunity to strengthen the capabilities of the domestic industrial sector, an element that attracts investment from national and foreign actors. The Pan American Health Organization indicates that, although the legal and institutional frameworks in the region have been strengthened considerably in the past ten years, much remains to be done to address regulatory capacity in smaller countries.[37] Argentina, Brazil, Chile, Colombia, and Mexico are some of the Latin American countries that have developed advanced legal bases and organizational frameworks for regulation and have instituted national regulatory authorities. All of these authorities are considered to hold stronger monitoring and enforcement mandates.[38] It is also important to highlight, as a positive aspect for the countries at the regulatory level, the use of mechanisms such as *reliance*[39], whereby national regulatory agencies take into consideration evaluations carried out by agencies of other countries with high standards, simplifying internal procedures for approval.[40]

[35] https://unesdoc.unesco.org/ark/48223/pf0000377462/PDF/377462eng.pdf.multi
[36] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). Technology Transfer: A Collaborative Approach to Improve Global Health. Retrieved from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf
[37] Pan American Health Organization (PAHO). (2021). Fortalecimiento de los sistemas regulatorios en la región de las Américas: Resumen de las enseñanzas obtenidas de las autoridades regulatorias nacionales de referencia regional [Regulatory system strengthening in the Americas region: Summary of lessons learned from the national regulatory authorities of regional reference]. Retrieved from: https://iris.paho.org/bitstream/handle/10665.2/53794/OPSHSSMT210005_spa.pdf
[38] Pan American Health Organization (PAHO). (2022). Regulatory system strengthening in the Americas. Lessons learned from the national regulatory authorities of regional reference. Recovered from: https://iris.paho.org/bitstream/handle/10665.2/53793/9789275123447_eng.pdf?sequence=5&isAllowed=y
[39] According to WHO, reliance is, "the act whereby the NRA in one jurisdiction may consider and give significant weight to—i.e. totally or partially rely upon—evaluations performed by another NRA or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken even when it relies on the decisions and information of others. World Health Organization. Good regulatory practices: 5 guidelines for national regulatory authorities for medical products. Oct 2016. Available from: http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf
[40] PAHO. Regulatory Reliance Principals: concept note and recommendations. Retrieved from: https://iris.paho.org/bitstream/handle/10665.2/51549/PAHOHSS19003_eng.pdf?sequence=1&isAllowed=y

Market Conditions

In a Technology Transfer process, the receiving country must feature a viable and accessible local market so that the transferred technology can become a real product for circulation at the market level. There is no single formula to determine the ideal market size that ensures the economic viability of national production. Nonetheless, the larger the country or geographic block, the greater the market potential and attractiveness for investment.[41] Countries benefit from Technology Transfer processes when they ensure access to markets not only to domestic companies, but also facilitate this access to foreign companies while providing them similar treatment. Consequently, this generates a collaborative dynamic, based on greater alliances of Technology Transfer between different R+D+i actors of the Pharmaceutical Industry, which in turn favors the construction and/or strengthening of local capabilities at different stages.[42] The existence of market limitations, reflected in high restrictions for suppliers, market price affectation, barriers to negotiation and closing of agreements, can affect favorable ecosystems for the generation of technology transfer agreements.

The existence of stable market conditions in a country are paramount for the generation of favorable scenarios for Technology Transfer. Faced with an attractive market, the different actors of the pharmaceutical industry will be able to invest in R+D+i activities that will enable them to provide users and patients the production generated collaboratively with local allies.

4. General recommendations for promoting Technology Transfer in the pharmaceutical industry in Latin America:

Based upon the proposed context, below we describe some general recommendations focused on the development of necessary conditions for the generation of Technology Transfer cases in the pharmaceutical industry in Latin America:

Having a robust and accessible intellectual property system is crucial for various stakeholders engaged in research and development of innovative solutions. Such a system provides legal certainty, which in turn, encourages investment and provides clear support for protecting and leveraging technological advancements. As a result, an environment is created that fosters continued investment in research and development activities, leading to the availability of pharmaceutical innovation for consumers and patients.

[41] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). Technology Transfer: A Collaborative Approach to Improve Global Health. Retrieved from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf

[42] World Intellectual Property Organization (WIPO). (December 2022). Why vaccine independence is so important for Africa. Retrieved from: https://www.wipo.int/wipo_magazine/en/2022/04/article_0005.html
https://www.google.com/url?q=https://www.wipo.int/wipo_magazine/en/2022/04/article_0005.html&source=gmail&ust=1673442408833000&usg=AOvVaw2XOX4SnhZtVKAmlPS84tYr

An efficient regulatory system can enhance the ability of various stakeholders within the R+D+i ecosystem to quickly respond to social problems by developing innovative technologies. This, in turn, makes the R+D+i investment more attractive by providing clear approval routes to effectively bring innovation to patients, making the process more viable.

An adequate landscape for Technology Transfer will require mapping different types of actors who possess capabilities, equipment, and infrastructure at various levels and dimensions on a local, regional, and global scale. This allows to explore the potential relationship scenarios among technology generators, recipients, and collaborators involved in technology transfer processes.

Clear and stable market conditions in a country are determinants for the generation of favorable scenarios for Technology Transfer. When presented with an appealing market, various stakeholders in the pharmaceutical industry can invest in R+D+i activities, which will enable them to produce collaboratively with local allies and provide users and patients with high-quality products.

Referencias

- Massachusetts Institute of Technology. *Technology Transfer Process.* Retrieved from: https://tlo.mit.edu/learn-about-intellectual-property/technology-transfer-process
- Good Manufacturing Practices (GMP). Retrieved from: https://www.paho.org/hq/dmdocuments/2011/Espanol-control-calidad-laboratorios-farmaceuticos.pdf
- World Health Organization (WHO). (August 2021). *WHO Guidelines on technology transfer in pharmaceutical manufacturing*. Retrieved from: https://cdn.who.int/media/docs/default-source/essential-medicines/norms-and-standards/qas20-869-transfer-of-technology.pdf?sfvrsn=2a4723bc_5
- World Intellectual Property Organization (WIPO). *Intellectual Property and Technology Transfer.* Retrieved from: https://www.wipo.int/technology-transfer/en/index.html
- World Health Organization (WHO). (Geneva, Switzerland 2011). *WHO Guidelines on Transfer of Technology in Pharmaceutical Manufacturing*. Retrieved from: https://extranet.who.int/pqweb/sites/default/files/documents/TRS_961_Annex7_2011.pdf
- World Intellectual Property Organization. STANDARD ST.16 Standardized code for the identification of the different types of patent documents. Retrieved from: https://www.wipo.int/export/sites/www/standards/es/pdf/03-16-01.pdf
- Colombian Ministry of Health and Social Protection. (August 9, 2021). *Minsalud sostuvo reunión con vicepresidente de Sinovac* [Minister of Health held meeting with Sinovac Vice President]. Recovered from: https://www.minsalud.gov.co/Paginas/Minsalud-sostuvo-reunion-con-vicepresidente-de-Sinovac.aspx
- Ecuadorian Ministry of Public Health. (February 14, 2022). *Sinovac aprueba proyecto de planta de vacunas en Ecuador* [Sinovac approves vaccine plant project in Ecuador]. Retrieved from: https://www.salud.gob.ec/sinovac-aprueba-proyecto-de-planta-de-vacunas-en-ecuador/
- Brazilian Ministry of Health. *Parcerias para o Desenvolvimento Produtivo (PDP)* [Partnerships for Productive Development]. Recovered from: https://www.gov.br/saude/pt-br/composicao/sctie/deciis/pdp
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (November 2021). *Technology Transfer: A Collaborative Approach to Improve Global Health*. Recovered from: https://www.ifpma.org/wp-content/uploads/2021/12/IFPMA_Tech-Transfer_A-collaborative-approach-to-improve-global-health_Position-Paper.pdf
- Economic Commission for Latin America and the Caribbean (ECLAC). (2022). *La Inversión Extranjera Directa en América Latina y el Caribe* [Foreign Direct Investment in Latin America and the Caribbean]. Retrieved from: https://repositorio.cepal.org/bitstream/handle/11362/48520/S2200562_es.pdf?sequence=3&isAllowed=y
- BETANCOURT CRUZ, DAVID ENRIQUE. (September 13, 2021). *Vacunas: Transferencia de Tecnologías, Producción y Acceso Equitativo* [Vaccines: Technology Transfer, Production and Equitable Access.]. Retrieved from: https://derechoeconomico.uexternado.edu.co/uaem/vacunas-transferencia-de-tecnologias-produccion-y-acceso-equitativo/
- https://unesdoc.unesco.org/ark:/48223/pf0000377462/PDF/377462eng.pdf.multi
- Pan American Health Organization (PAHO). (2021). *Fortalecimiento de los sistemas regulatorios en la región de las Américas: Resumen de las enseñanzas obtenidas de las autoridades regulatorias nacionales de referencia regional* [Regulatory system strengthening in the Americas region: Summary of lessons learned from the national regulatory authorities of regional reference]. Retrieved from: https://iris.paho.org/bitstream/handle/10665.2/53794/OPSHSSMT210005_spa.pdf
- Pan American Health Organization (PAHO). (2022). *Regulatory system strengthening in the Americas. Lessons learned from the national regulatory authorities of regional reference*. Retrieved from: https://iris.paho.org/bitstream/handle/10665.2/53793/9789275123447_eng.pdf?sequence=5&isAllowed=y

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