

## Chapter 5

# Drugmex, the Family-Owned Company Which Delivered the First COVID-19 Vaccine to Mexico

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### Introduction

In 2021, amid the COVID-19 pandemic, the Chinese company Bio CanSino chose the family business Dromex to fill and finish their COVID-19 vaccine Convidencia® (Silva Castrejón et al., 2022; Stezano et al., 2022) for the Mexican market. Dromex operates in Argentina, Mexico, Brazil and Spain. The business was named ‘Drugmex’ for the Mexican operation for name recognition, understanding and language purposes. Thus, Drugmex became the first laboratory to formulate a COVID-19 vaccine in Mexico (Silva et al., 2022; Stezano et al., 2022). Although Drugmex’s experience was not in biotechnological products, its technical capabilities and adaptability allowed it to fill and package the vaccine against COVID-19 during the sanitary emergency caused by the pandemic (Silva et al., 2022; Stezano et al., 2022). This case study investigates the origin, trajectory, capabilities and competencies of Drugmex and prospects for future technological development.

Dromex was initially developed in 1990 when Julio Scardigli, an accountant from Argentina, detected an opportunity to act as a commercial agent for two European manufacturers who were looking to sell active product ingredients (API) to local Argentinean generic pharmaceutical finish-dosage laboratories. In 1996, Julio invited three friends into the business to expand into manufacturing and acquire a pharmaceutical factory in Buenos Aires. These friends provided

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finance, knowledge of the industry and functional expertise. The three friends were all of similar age (30s) at the time: Oscar Andres, an Argentinean accountant; Oswaldo Ramirez, a Mexican engineer and Alec Delaney, an Argentinean veterinary surgeon. The company is closely identified with at least two generations of the Scardigli family. The family and their descendants possess 25% of the decision-making as per share capital.

The company inaugurated commercial offices in Brazil and Barcelona in 1999. Drugmex' expansion into Mexico was as a greenfield site in 2008, and after some hurdles was officially inaugurated in 2016 as a pharmaceutical plant for sterile products.

This case outlines how the family business grew and evolved into a major pharmaceutical organisation and was chosen to fill and finish the COVID-19 vaccine in Mexico, thereby demonstrating how their ethos and values translate from and to Sustainable Development Goal 3 (SDG#3) ([UN General Assembly, 2015](#)).

## **Vision and Mission**

According to Alec Delaney, one of the company partners and who oversees the Mexican (Drugmex) plant, 'The vision of Dromex is to be the first company a pharmaceutical laboratory would think of when needing to overcome a challenge, be it needing an active product ingredient of quality, technical support for registering a medicine, or looking for a responsible contractor to formulate their products. Our mission is to be the best partner in solving the production problems of our customers' (Delaney, 2023).

As a family-owned business, they are open about their ethical values. According to Alec, their mission is, 'based on four main pillars – inspired by their religious beliefs: human dignity, the common good, solidarity, and subsidiarity. Some other auxiliary principles could be added, such as gratuitousness, social justice, the preferential option for people experiencing poverty, stewardship of the environment, social responsibility, and philanthropy'. Furthermore, they believe it is only possible to fulfil one principle by considering the others. For example, the human dignity principle can only be fulfilled by considering, for instance, the principle of justice (see [Naughton & Laczniak, 1993](#); [Salamanca, 2015](#)).

## **Products and Services Offered by Drugmex**

Dromex (the original business name encompassing all plants) is a trader and contractor in the pharmaceutical industry. A contract manufacturer formulates finished pharmaceutical products for third parties. This type of service is rare in Mexico. A lack of cooperation between the players in the market and intense competition underpin the business culture for pharmaceuticals in Mexico.

The decision to formulate the COVID-19 vaccine was largely driven by the Mexican government, which tasked Drugmex to manufacture this vaccine, and which Drugmex did willingly. This reflected an alignment between SDG#3b and

SDG#3d in supporting research, development and universal access to affordable vaccines and medicines, as well as strengthening the capacity of all countries, particularly developing countries, for early warning, risk reduction and management of national and global health risks.

## **Background to Drugmex**

### *The Beginnings and Early Years*

The origin of Drugmex stems from Argentina. It is important to note the country and regional context of this business and Argentina's political and economic situation 30 years ago. The hyperinflation of 1989 and 1990 in Argentina under President Alfonsín created the momentum for a structural reformation in the country, which crystallised when a new government headed by Dr Carlos Menem assumed and launched the so-called Convertibility Plan of 1991, which in fact, was a dollarisation of the economy. The changes included extensive public sector reforms, deregulations, privatisation of public companies and removal of restrictions on capital movements and trade (Pou, 2000). Further measures, such as the reduction of import duties and the elimination of restrictions on the importation of goods, opened the Argentine economy, and foreign companies started to show a renewed interest in the region (Pou, 2000).

In this context, a young Argentine accountant, Julio Scardigli, detected an opportunity to launch an operation in Buenos Aires, the capital city of Argentina, as commercial agents of two European manufacturers seeking to sell API to local Argentinean generic pharmaceutical finish dosage laboratories on a free on board Europe basis. Julio rented an office, hired an assistant, bought a fax and named his company Dromex. The agency contracts were vague, as usually happens in those cases (Bradley, 1995). However, Dromex's performance was much above the expectations of the European principal in terms of volumes, conditions and prices.

A factor in the success is that the owner (as in the case of many family businesses) was acting as the salesperson – visiting the customers, closing the sales, and, in the process, setting up friendly relationships with the owners of the laboratories (an essential point in the Latin American culture, see for example, Hofstede, 2001). Eventually, the founder invited three close friends of his – an engineer, a veterinarian and another accountant, all of whom had extensive managerial experience in the pharmaceutical business, to join the business as partners. The original owner kept over 25% of the shares. Given the development taking place in the business, the partners decided to open a subsidiary in Sao Paulo (Brazil) and another in Barcelona (Spain) to cater to the markets of Brazil, the North of Africa and the Middle East, respectively (Silva et al., 2022).

The business operates both technically and culturally as a family business, which aligns externally with the culture of the Latin American marketplace. In terms of the business, Dromex is closely identified with at least two generations of a family, and this family linkage has a mutual influence on the company policy and the interests and objectives of the family (Donnelley, 1988). Additionally,

there is an expectation of succession by a family member (Churchill & Hatten, 1987). Also, Julio, who established the business, possesses 25% of the decision-making rights mandated by their share capital.

In relation to the market context, there were some favourable extrinsic factors as well; for instance, the Argentine pharmaceutical market size, estimated at USD 6 billion at the end of the 21st century, represented something like 11% of the market share in Latin America (e.g. Mendoza, 2023; Tanner Pharma, n.d.). Argentina was, and still is today, the third largest player in the pharmaceutical in Latin America after Mexico and Brazil. Moreover, globally, Argentina is the 12th largest pharmaceutical market in value terms (e.g. Mendoza, 2023; Tanner Pharma, n.d.). Another feature favourable to a company like Dromex was that of the 200 pharmaceutical laboratories active in the country, around 84% of them are owned and run by local or domestic Argentine entrepreneurs (e.g. Boni et al., 2023; CILFA, 2021). Local entrepreneurs are keen to use the services of domestic companies, while foreign multinationals usually must follow protocols and limit their purchases to suppliers approved by their headquarters abroad (Bradley, 1995).

A few wholesalers dominate the marketing of the finished formulated product in pharmacies, hospitals and others. Indeed, five distributors monopolise up to 90% of the over 6,000 medicines registered in the country (e.g. Boni et al., 2023). Moreover, those distributors were not independent but sister companies to the large domestic laboratories. Dromex established a solid and sustainable business with those large domestic laboratories. Fig. 1 shows the locations of Dromex plants, including its overseas operations.

### ***Background to the Founder and the Partners in the Business***

The founder, Julio Scardigli, born in 1960 in Argentina, is an accountant who started as an API salesman and fell in love with the pharmaceutical industry. Julio is devoted to his family and friends and is a soccer fan. He is interested in travelling and learning about different cultures. Julio is a philanthropist, collaborating



Fig. 1. Location of Dromex Plants.

with several organisations, soup kitchens and others. In 1998, driven by his vision, he invited a select group of close friends to join what was then known as Dromex. These friends included two accountants, Oscar Andres and Oswaldo Ramirez, as well as Alejandro (Alec) Delaney, a veterinarian. These individuals brought their experience in the pharmaceutical industry, contributing to its expansion both in terms of capital and scope of services. The following table highlights the key landmark events that serve as significant milestones in the development of Dromex and the establishment of the Drugmex plant in Mexico in 2016.

***The Inception of Drugmex***

The factors outlined in [Table 1](#) played an important part in the establishment of Drugmex in Mexico. In 2016, Drugmex inaugurated its 30,000 sq ft plant in the El Marqués industrial park in Querétaro, Mexico (see [Fig. 2](#) for the Drugmex plant in Querétaro). Drugmex was the only factory in El Marqués, employing between 50 and 250 workers (in the whole of Mexico, there are only 124 plants in this range of employment). The plant possesses the required facilities, equipment and instruments to function under the good manufacturing practices (GMPs) standards required in pharmaceutical activity ([Stezano et al., 2022](#)).

Table 1. Historical Development – Some Milestones.

1987–1990s	Dromex was founded in 1990; however, the company owners had started to do some ‘spot’ businesses together since 1987. Diversification into manufacturing; looking to diversify and reduce risk, the Dromex partners also decided to expand from purely commercial activity into manufacturing.
1990	In the late 1990s, with enormous efforts, the company bought a freeze-dry (lyophilisation) old plant in Buenos Aires, named Instituto Biologico Contemporaneo (IBC), to formulate lyophilised finished products for third parties. Dromex would supply API to their customers and formulate for them through Dromex’ subsidiary IBC, acting as a contractor.
1998	The 3 friends/partners joined the business. The IBC plant in Buenos Aires was remodelled and updated, exceeding the norms and existing regulations of the time, knowing that standards may become more stringent. All this represented an investment of USD 5 million in cash and bank loans.
Early 2000s	As IBC became more efficient and ordered, the operation became profitable. Therefore, the partners escalated their commitment to the business by acquiring two further turnkey pharmaceutical injectable plants on the outskirts of Buenos Aires. With those, IBC became a significant player in the Latin American injectable and lyophilisation business and a leading contractor for commercial laboratories.

Table 1. (Continued)

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2008s	In 2008 Drugmex, with a Pharmaceutical plant of 3,900 m <sup>2</sup> , was started, with production lines of freeze-dried sterile and high-tech injectable solutions, and an estimated capacity of 7 million freeze-dried vials per year and 6 million injectable solutions per year.
2016	Drugmex officially opened its plant in Queretaro, a strategic location in the central part of Mexico, about 135 miles (220 km) northwest of Mexico City.
2023	The company has roughly 300 employees as of July 2023 and is now at a crossroads as regards, selling the business or being taken over by the next generation.

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Fig. 2. Picture of Drugmex Plant in El Marqués Industrial Park in Querétaro.

### **SDG#3 – Good Health and Well-being 2023 and Drugmex**

Drugmex focuses on SDG#3 as an ethos, an underlying company philosophy that transcends all the work that they do. Specifically, Drugmex focuses on SDG#3 Target 3.b, which focuses on supporting the research and development (R&D) of vaccines and medicines, and SDG#3.d, which aims to strengthen the capacity of developing countries in reducing global health risks.

There was a realisation by the originally named Dromex, right from the beginning, that unfavourable environmental factors such as lifestyle, geographic factors, poor infrastructure, low health knowledge, lack of education and poverty are some causes of the high incidence of infectious and other communicable diseases in developing countries, especially among children and older people. From the get-go, Dromex focused on ensuring healthy lives and promoting well-being for all ages, collaborating in fighting communicable diseases and supporting research, development and universal access to affordable vaccines and medicines, which nicely aligns with the goal of SDG#3.b. Dromex is contemporaneous to essential biotechnology developments and has recognised its enormous potential at an early stage.

The belief in helping humanity in terms of better medicines and vaccines is entrenched in all the partners as a culture, who share similar religious and educational backgrounds are very close in age and champion the same values and ideas. The culture of helping people ranges from their overall mission to help with vaccines and health but examples of this ethos can be found in the everyday working lives of their employees – listening to family dilemmas, helping family members gain employment and an overall philosophy of doing good where they can.

The family business communicates both internally and externally their focus on SDG#3.8 (achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all), and all the stakeholders receive it well. This communication policy became one of the company's strengths. Employees are very aware of the founders' beliefs, who, even on an operational level, look after their employees' health and well-being in a paternalistic culture.

Latin-American culture has strong traditional family values that transcend professional life (Hofstede, 2001). Critically, according to one of the partners, Alec Delaney (2023): 'A further source of strength of the company is the singular family culture the partners created in the organisation, underpinned by its philosophy in helping people and benefitting the public good in relation to health and universal access to vaccines'.

In particular, when it came to the fulfilment of the COVID-19 vaccine (as will be outlined later in the chapter), under intense pressure and demand for the vaccine, Drugmex stopped filling all other orders and focused entirely on the vaccine delivery.

## **Latin American Macro Environment and Pharmaceutical Industry Context**

In terms of the pharmaceutical industry in Latin America, particularly in Mexico, some industry players argue that Mexico's health system needs to be more

articulated and receive more help from the authorities. The laboratories producing generics depend on foreign raw materials for most of their products. There is little development in innovative products and vaccines (CEPAL, 2022). Some scholars maintain that the United States-Mexico-Canada Agreement (USMCA) and the North America Free Trade Agreement (NAFTA) in enforcing patents have limited the Mexican laboratories' vaccine innovation and research and consolidated some advantages for American multinationals (Stezano et al., 2022). Thus, a lack of funding and legal restrictions generated a capacity gap between the Latin American region and other developed and even developing countries regarding vaccine research (CEPAL, 2022).

This absence of an ability to produce vaccines negatively affected the region when the COVID-19 pandemic struck. As of the end of 2021, none of the approved vaccines on the World Health Organisation (WHO) emergency list had been developed in Latin America (CEPAL, 2022). Local governments tried to source vaccines through the COVID-19 Tools Accelerator (ACT-A), and mainly its vaccine column named COVAX, which involved political and financial collaboration between donors, the WHO, Gavi The Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the United Nations Children's Fund (UNICEF). As part of COVAX, the global public health community, led by the WHO, established an 'ambitious' objective: to vaccinate at least 70% of the population in low- and middle-income countries (LMICs) against COVID-19, including those in sub-Saharan Africa (Bell et al., 2023; CEPAL, 2022).

Those multilateral arrangements (such as the COVAX and Gavi, The Vaccine Alliance) showed their limitations when Asian producers defaulted on their shipment commitments due to export restrictions in the countries of origin. To deal with the situation, many governments resorted to hasty bilateral trade agreements with the different suppliers of approved vaccines that entailed higher financial costs. In some cases, those deals also raised suspicions in public opinion concerning what they perceived or claimed was a lack of transparency in some of those operations (Silva et al., 2022).

## **Drugmex and COVID-19 Vaccine 2020**

On 8 December 2020, the Chinese manufacturer CanSino Biologics Inc. signed a contract with the Mexican government for 35 million doses of the Ad5-nCov vaccine. The contract specified that the Swiss company LATAM Pharma, an agent for CanSino, would contract a Mexican laboratory of injectables to fill and finish the vaccine in vials (this is to formulate the bulk product into a finished usable product), including obtaining the necessary approvals for the product in the Mexican territory (Silva et al., 2022; Stezano et al., 2022).



CanSino Biologics Inc. is a privately owned Chinese company established in 2009 in Tianjin, China. The company offers veterinary and human vaccines to the market of their development. Their portfolio includes 16 vaccines for the prevention of 13 infectious diseases, including the Ad5-EBOV vaccine for the prevention of Ebola and the Ad5-nCoV vaccine for the prevention of COVID-19 (Silva et al., 2022; Stezano et al., 2022).

### ***Drugmex Became the First Company to Formulate a COVID-19 Vaccine in Latin America***

In mid-2020, the Swiss company LATAM Pharma representative, on behalf of CanSino Biologics approached Drugmex. These agents intended to hire Drugmex as a contractor to fill and finish their COVID-19 vaccine. Drugmex, being a contract manufacturing organisation (CMO) with a state of the art factory, seemed a suitable candidate for the formulation of the COVID-19 vaccine because of the condition of CMO and their state of the art factory (Silva et al., 2022; Stezano et al., 2022).

An ad hoc R&D team, integrated by CanSino and Drugmex personnel, was designated for the capacitation and training of the Drugmex workers in vaccine-filling technology. After receiving the bulk active substance from China, the team in Mexico had to stabilise the antigen pH through buffers that included seven other materials (Stezano et al., 2022). Drugmex was subject to several inspections by CanSino's technicians for several weeks. Some investment in machines and devices was required, especially in quality control.

The Cofepris (the Mexican health authority) audited and approved the plant once the required changes were implemented, and the personnel duly trained to formulate the vaccine – Drugmex was the first plant in Latin America to receive authorisation to formulate a COVID-19 vaccine (Stezano et al., 2022). Drugmex had to stop all existing activity within the Mexican plant (and lost many customers in so doing) to concentrate completely on fulfilling the COVID-19 vaccine delivery.

A key issue is the type of capabilities that were demonstrated by Drugmex while filling the Convidencia® vaccine (Stezano et al., 2022), which were as follows: Drugmex was used to work by GMPs and other norms of the industry. Thanks to adjustments and investments, in 2021, Drugmex's production volume was 133% over its original capacity. In February 2021, Drugmex produced 2 million dosages of the COVID-19 vaccine (See Fig. 3). During this period, Drugmex intensified its relationship with universities and research centres. Drugmex showed critical managerial, technical and productive capabilities.

On 12 May 2021, CNN en Español reported that Mexico liberated the first batch of COVID-19 vaccines filled and finished by Drugmex in Querétaro for the emergency use of the vaccine in the country. This first batch consisted of 208,220 vaccine dosages and two retention sample packages with 720 dosages (Lemos & Gutierrez, 2021). On this day, Drugmex became the first company in Latin America to



Fig. 3. Fulfilment of the COVID-19 Vaccine at Drugmex.

formulate a COVID-19 vaccine. On 22 March 2021, the first vaccines left the Drugmex plant under armed guard (see Figs. 4 and 5). Such was the significance of the vaccine to the Mexican people at the height of the COVID-19 pandemic.



Fig. 4. The First COVID-19 Vaccines Packaged in Mexico Leave the Drugmex Plant.



Fig. 5. First Vaccines Leave DrugMex on 22 March 2021.

### **Drugmex Business Model and SDG#3 Target 3.3, Target 3.b and Target 3.d**

The Pharma industry has two ‘camps’ essentially; the developers e.g. Pfizer, and the generics, the latter of which can sell medicines for 30% of the price of original developers. The view of Drugmex in developing generics is, according to Alec Delaney (partner and head of Drugmex), ‘We help with the price of medicines. We do not sell only to certain customers, even if we are asked to do so – we want to be fair and help the public’. Also, he states, ‘Drugmex and Drugmex supply generic medicines as cheaply as possible in interests of fairness for all people’. This has been a key element and philosophy of their business over the years. Therefore, there is a strong link to SDG#3, in particular target 3.b, and target 3.d providing access to medicines for all for the management of global health risks.

Technically, the business model of Drugmex and subsequently Drugmex involves three key activities as described below. However, each of these activities had to cease to fulfil the COVID-19 vaccine completely from 2020. This loss was incurred directly by Drugmex:

- (1) Trading of drugs – reselling drugs to customers and suppliers (mostly Chinese and Indian customers). This is the most profitable part of the business, with profitability between 5–30%, averaging around 20% profitability.
- (2) The second key activity of the business is consulting, using its industry knowledge, and working with customers for product development as cheaply as possible, for example, using its small R&D lab in Buenos Aires (Innova

lab), which in turn will purchase the API for 5–6 years in payment. This element of the business is really to help and develop medicines for the benefit of the public good, aligning to *SDG#3* Target 3.b once again, ensuring affordable medicines to all.

- (3) The final activity of the business is the factory, which is the least profitable element. It is a very demanding business due to regulatory requirements. However, it has an important prestige for the business as it manufactures products for the customer.

The values, mission and overall work environment are strongly paternalistic, as is common in Latin American culture. This means that the company is quite involved in the personal family issues of employees. This, in turn, promotes a need to not just provide for, but listen to and treat employees as key stakeholders in the overall values of the business. This approach is reflected in smaller practices, such as employing family members, addressing various family problems that may arise and treating employees as part of the overall business family. These actions align not only with *SDG#3* but also have a tangible and meaningful impact on employees' everyday experiences.

In terms of major impacts, the vaccine fulfilled by Drugmex did not have the same freezing requirements as other vaccines and did not require below-temperature freezing methods. This meant that the vaccine could be distributed to very isolated and rural towns and cities in Mexico. Consequently, many everyday people benefitted, particularly in a context where wealthy people wished to pay 10,000 USD for a vaccine at this time in 2020 during the pandemic. The vaccination campaign against COVID-19 in Mexico began at the end of December 2020. Over two years later, around 76% of the country's population had been administered at least one dose of the vaccine. By that same date, more than 64% of Mexican inhabitants had received the recommended amount of doses for immunisation.

Drugmex also partners with local universities in Mexico to develop and train scientists and key employees to help develop and grow the business. However, Drugmex does not measure some of these impacts, as the activities are seen as routine and form part of Drugmex's paternalistic culture, a philosophy underpinned by the management style of the owners.

In terms of understanding the impact and goals of *SDG#3*, it is important to consider the economic context of Argentina and Latin America. In some respects, private industry competes with the government in terms of its ability to be responsive to social needs and impact on society. Many multinationals, indeed, do not enter Latin America. Drugmex (and Drugmex) give to society not only in terms of their product development at as low a cost as possible, and as evidenced by the fulfilment of the COVID-19 vaccine, as needed but it also undertakes extensive charity work in all areas of society underpinned by its social justice beliefs. This shows Drugmex's attempt to achieve *SDG#3.8*, which seeks to provide affordable essential medicines and vaccines for all. The company has extensive experience and time spent in navigating government and social needs. The ethos and values

of the three partners, which transcend the culture of the business, in this paternalistic environment, means that there was no resistance by employees or from within society to pursuing the SDG goal. Indeed, post-COVID-19 vaccine, the Drugmex plant, which had sacrificed all of its 'regular' customer base to provide 100% capacity for fulfilment of the COVID-19 vaccine, was left to pick up its business where it left off after the vaccine fulfilment was complete. This, of course, was a major challenge for the business; however, the value of working for the greater good has meant that the business remains fully capable of sustaining itself into the future.

## Next Steps for Drugmex

The role that Drugmex played during the pandemic with the COVID-19 vaccine was a boost to the prestige of the Dromex group. Nevertheless, the situation finds the four core founders of Dromex in their sixties, living in four different countries, all with adult children. Some of the offspring are interested in the pharmaceutical business and working for the group, and some are not. Latin America's economic and political situation has become more volatile than in previous times. On the other hand, the pharmaceutical industry is changing with the emergence of three new business models: (a) companies that may be active in several therapeutic areas but are quickly divesting parts of their portfolio and acquiring new ones; (b) the data-rich virtual pharmaceutical player, offering solutions through healthcare platforms and (c) the niche player focusing on a single disease looking at the entire patient pathway from prevention to cure, stressing the prevention (KPMG, 2019). Many products will become obsolete shortly as monoclonal antibody therapies replace traditional drugs of all types, from oncological to antibiotics.

Dromex and Drugmex used to presume that they could make quick decisions, avoiding the drawbacks of large pharmaceuticals. However, at this point, the company's owners are all in the early mid 60s age group and find themselves at a crossroads that will define their future and, perhaps critically, the future values of the business. Julio's son is keen to continue the business. The next generation has their views on how to run the business, not necessarily underpinned by the same values as the founders. As of July 2023, it looks as if the business may be sold.

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