2023

Health / Biopharma







Why invest in Argentina?

Argentina is the third largest economy in Latin America, with a GDP of USD 445 billion, and the third largest recipient of Foreign Direct Investment (FDI) in the region. With a population of 45 million people, 60% of which is under 35 years old, it has preferential access to the main South American markets, which altogether have about 295 million inhabitants.

At the global level, it is the eighth largest country, with over 50% of arable land. It has the second largest unconventional gas reserve and the fourth largest unconventional oil reserve in the world, as well as an extensive maritime platform of over 1.78 million km², which is rich in energy and fishing resources.

In terms of renewable resources, it is among the six countries with the highest wind consistency, with an annual average capacity factor of 20%. It also has great potential for the development of solar energy, especially in the Andean and sub-Andean regions, where global horizontal irradiation (GHI) ranges between 2,400 and 2,700 kWh/m².

Moreover, it has great potential for mining development due to its over 705,000 km² of promising mining areas, its long tradition in the production of gold, silver, lead, aluminium and copper, and its positioning as a new global leader in the exploitation of lithium—the country has the third largest global lithium reserve and is the fourth largest global producer.

Argentina is characterised by a diversified economy that produces and exports agrifood, manufactured products, minerals and energy, knowledge-based services, culture and art, among others. Throughout the country, multiple activities with a high potential for investment and growth have been developed.

The country is internationally renowned for its leadership in the production and export of products such as soybean oil, yerba mate, utility vehicles, maize and wheat grains, raw peanuts, insecticides, powdered milk, beef, lemon essential oils, black tea, shrimp, pears, sunflower oil and combed wool.

Argentina does not only stand out for its natural resources. With a dynamic scientific community, its human talent has shown its capacity in a wide range of sectors. Among Latin American countries, it ranks third in the number of academic articles published, third in patent applications and first in the Global Skills Index1 ranking for Data Science.

¹ The Global Skills Index (GSI) 2019 is the first index conducted by Coursera, an online education platform with a large skills database of 38 million students and over 3,000 courses, specialisations and undergraduate courses of the main universities available. For each country, Coursera calculates a GSI that measures the average skills expertise of the platform's students.

Economic activities by region

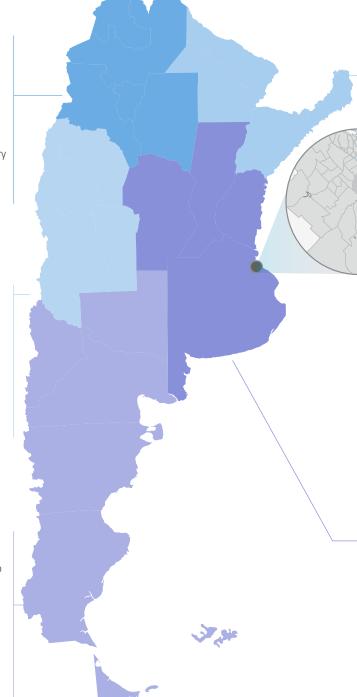
NOA • • Sugar • Tobacco • Viticulture • Bovine meat • Mining • Petroleum and refinery • Textile and metal-mechanic industry • Automotive and trucks industry • Inbound tourism

NEW CUYO •

- Viticulture
- Stone fruits peach, plum and, to a lower extent, pome fruits
- Olive
- Mining
- Manufacturing
- University education
- Inbound tourism
- Domestic tourism

PATAGONIA •

- Pome fruit, apples, and pears
- Viticulture, Alto Valle del Río Negro
- Fine fruits
- Ovine, wool, and meat
- Mining
- Textile, aluminum, and other industries
- Oil and gas, mainly
- Alternative energies
- Inbound tourism



NEA •

- Yerba mate and tea
- Citrus fruit
- Bovine meat
- Forestry and paper industry
- Oil and gas (weak)
- Inbound and domestic

AMBA

- Food industry
- Textile industry
- Automotive, metalworking
- Refinery
- Petrochemical, chemical and plastic
- Financial services
- Business services
- Logistics trading
- Software
- University education
- Inbound and domestic tourism

CENTRO •

- Cereals and oilseeds
- Beef, poultry, and pork
- Citrus fruit
- Iron and steel, automotive, metal-mechanic industries
- Refinery, petrochemical, chemical and plastic industries
- Software
- University education
- Biotechnology
- Business services
- Logistics trading

Infrastructure

Railway network	Maritime container traffic	Flight departures	Airports and ports	National and provintial routes	Ducts
17,866 km N.° 2 in LATAM N.° 13 in the world	~2 M TEU N.° 6 in LATAM	163,000 flights all over the world . N.° 4 in LATAM	Airports: 55 Ports: 101	500,000 km National routes: 37,500 km	Gas pipeline: 16,000 km Oil pipeline: 1,200 km

With longstanding policies of universal access to education and local scientific development, Argentina is the second country in the region with the highest public spending on Education (6% of GDP) and Science & Technology (0.6%). It should also be noted that Argentina is the second country in Latin America with the most unicorns (a total of 11) and the region's leading software exporter (50% of the sector's exports are destined to the USA).

The country offers benefits in terms of human resources and cultural and gender diversity policies for investors:

- The Knowledge Economy Act promotes activity in the sector through income tax reliefs (60% for micro and small companies, 40% for medium-sized companies and 20% for large companies).
- Every year, more than 150,000 professionals graduate from college.
- It is the Latin American country with the highest English language proficiency, which represents a comparative advantage in terms of service exports.
- It ranks ninth in the World Economic Forum's global ranking for leading efforts to encourage inclusiveness, equity and creativity in firms.
- It has the lowest gender gap in South America, and it ranks fifth in Latin America and the Caribbean.

Moreover, Argentina is a member of the selected group of countries that harness atomic energy for peaceful ends, building small and medium-sized modular reactors.

Thanks to these developments, Argentina can export to 170 countries around the world, achieving strong brand recognition for the quality of its products (meat, wine, oil, etc.), technology (satellites, turbines, reactors, etc.) and services (software, professionals, etc.). The country is also the main tourist destination in South America, with 7.4 million international arrivals in 2019.

Lastly, the development of maritime, aerial, rail and road infrastructure offer advantages that allow the country to access any part of the world as a competitive economy.

The AAICI has prepared these sectoral reports in order to facilitate access to essential information as well as to advantages, benefits and opportunities for those investing in Argentina—one of the countries with the greatest potential to attract FDI in the world.

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ANLIS National Administration of Laboratories and Healthcare Institutes
ANMAT National Administration of Drugs, Foods and Medical Devices

CAB Argentine Chamber of Biotechnology

CET Common external tariff

CILFA Industrial Chamber of Argentine Pharmaceutical Laboratories

CONICET National Scientific and Technical Research Council

CSB Companies specialising in biotechnology

DPCs Diversified pharma companiesFDI Foreign Direct InvestmentFONARSEC Argentine Sectorial Fund

FONCYT Fund for Scientific and Technological Research

FONTAR Argentine Technological Fund
GHI Global Horizontal Irradiance
GMP Good Manufacturing Practices
INAME National Institute of Drugs

LATAM Latin America

MINCyT Ministry of Science, Technology and Innovation

MNCs Multinational companies
NBCs New biotech companies
R&D Research and Development
S&T Science and Technology

TBCs Technology-Based Companies

USD United States dollar
VAT Value Added Tax

WHO World Health Organization

In the context of a growing demand for biotechnological drugs, the wide network of science and technology institutions and university laboratories, as well as a long tradition in R&D activities and highly qualified professionals, create a suitable environment for investments in the Argentine biopharma sector.

EXECUTIVE SUMMARY

The biopharmaceutical sector has developed significantly in Argentina thanks to numerous institutions in the field of S&T (Science and Technology), university laboratories and highly qualified professionals, as well as a wide range of public policies and instruments. Given the prospects for growth in local demand for second generation biotechnological drugs, there is an opportunity to drive capacity building and import substitution.

The biopharmaceutical sector (also known as the "biopharma sector") is part of the pharmaceutical value chain, which has a long tradition in Argentina and is one of the main manufacturing activities in terms of industrial value added, exports and creation of highly qualified employment.

In this sector, Argentina is a pioneer among emerging countries, with the start of biopharmaceutical activities dating back to the late 1980s and early 1990s. According to the Argentine Chamber of Biotechnology, the sector is made up of 72 companies producing drugs, reagents and biotechnological inputs, of which almost 90% are domestically owned and the rest are multinational companies that do not produce in the country.

In 2021, the Argentine biopharma market² was valued at around USD 1 billion, representing around 20% of the pharmaceutical market.³ In addition, exports amounted to around USD 100 million, representing almost 10% of biopharmaceutical sales and of total exports of the pharmaceutical value chain (CILFA, 2022).

Most Argentine companies are oriented towards the development of therapeutic products, first generation protein biosimilars and the provision of biotechnology services to third parties (companies or clients). Argentina's biopharmaceutical sector can expand towards the production of second generation biotech drugs, which would help meet a growing local demand that, in the face of scarce local supply, is reflected in the trade balance.

The opportunity to make progress in this field comes in an international patent cliff context. In turn, at the local level there are important capacities built and lessons learned thanks to a wide network of scientific and technological institutions, university laboratories and S&T research centres with a long tradition in R&D activities, as well as a wide range of public policies and official instruments for sectoral promotion.

² Includes local production of recombinant proteins and import of proteins, insulins and monoclonal antibodies, excluding vaccines.

³ Corresponds to sales at ex-factory price.

Highly qualified professionals

Argentina has high levels of undergraduate and postgraduate training in the disciplines associated with the development of modern biotechnology in general and the biopharma segment in particular.



These are aimed at promoting technological capabilities and financing R&D and production activities.

Argentina is a pioneer in the development of biotechnological drugs among developing countries

Pharmaceutical activities in Argentina date back to the late 1980s and early 1990s, when specialised companies emerged and the existing chemical-based pharmaceutical laboratories diversified their product portfolios.

A long tradition in R&D in university laboratories and research centres

Argentina has an important background in biotechnology research in specialised institutions (such as the Malbrán Institute, the Leloir Institute and the CONICET), with developments in cell culture and molecular biology as well as in other closely related disciplines, which facilitated the adoption and expansion of biotechnology in different sectors.



A wide network of scientific and technological institutions

The network is made up of:

- The Ministry of Science, Technology and Productive Innovation
- The Ministry of Education
- The Ministry of Health
- The Science and Technology Agency
- The CONICET and its associated institutions
- The national universities
- The National Administration of Laboratories and Healthcare Institutes (ANLIS)
- The Malbrán Institute
- Public laboratories
- The National Institute of Drugs (INAME)
 of the ANMAT

MAIN CHARACTERISTICS OF THE SECTOR

The biopharmaceutical sector,⁴ also known as the biopharma sector, is part of the pharmaceutical value chain, which has a long tradition in Argentina and is one of the main manufacturing activities in terms of industrial value added, exports and creation of highly qualified employment.

In this sector, understood as the application of modern biotechnology in the production of drugs for human and animal health care, Argentina is a pioneer among emerging countries. Pharmaceutical activities in Argentina date back to the late 1980s and early 1990s, when specialised companies emerged and the existing chemical-based pharmaceutical laboratories diversified their product portfolios.⁵ Its development was based on the exploitation of expired patents, which gave rise to the biosimilar industry.

Although relatively small in relation to other countries such as Brazil, South Korea and India, the national market for biotechnology products has grown significantly over the last 20 years, resulting in a greater relative weight in local pharmaceutical activity. In 2021, the Argentine biopharma market⁶ was valued at around USD 1 billion, representing around 20% of the pharmaceutical market.⁷ In addition, exports were around USD 100 million, representing almost 10% of biopharmaceutical sales and of total exports of the pharmaceutical value chain (CILFA, 2022).

Almost 75% of the biopharma market is supplied by imports of both active pharmaceutical ingredients and biotech drugs, which are largely provided by multinational companies. The rest is covered by local production of drugs from biotech active ingredients, mostly provided by domestically owned companies.

Companies and employment

The significant dynamism shown by the biopharmaceutical sector in the last 20 years was reflected in the entry of new companies of domestic capital, driven to some extent by public programmes aimed at promoting technology based companies (TBCs). Thus, according to the Argentine Chamber of Biotechnology, the sector is made up of 72 companies producing drugs, reagents and biotechnological inputs, of which almost 90% are domestically owned while the rest are multinational companies that do not produce in the country.

Most Argentine companies are oriented towards the development of therapeutic products, first generation protein biosimilars and the provision of biotechnology services to third parties (companies or clients). There is also a small number of companies performing in vitro diagnostics based on biotechnological techniques.

The biopharma sector in figures

72

USD 1 billon

USD 97 million

4.6%

COMPANIES

SALES

XPORTS

R&D SPENDING OVER SALES

⁴ Unlike drugs obtained by chemical synthesis. biotechnological drugs are characterised by their high molecular weight and greater structural complexity, which is very sensitive to changes in the manufacturing process. ⁵ At the global level, the emergence of biotechnology in the development and production of new therapeutic compounds in pharmaceutical production began at the end of the twentieth century. ⁶Includes local production of recombinant proteins and import of proteins, insulins and monoclonal antibodies, excluding vaccines. Orresponds to sales at exfactory price.

MAIN CHARACTERISTICS OF THE SECTOR

There are different types of domestically owned companies according to their form of organisation, productive strategy and articulation with the local infrastructure in science and technology:

- New biotech companies (NBC), which represent almost 50% of all pharmaceutical companies. They have been in operation for less than 20 years, specialise in R&D and do not have commercial production. Some of them are spin-offs⁸ from laboratories or other companies in the sector, have a high turnover rate and are usually linked to or absorbed by pharmaceutical groups that provide them with financing, distribution channels, regulatory knowledge and/ or access to markets.
- Diversified pharma companies (DPC), which account for 20% of the total. These companies used to produce drugs of chemical origin and have now entered the biotechnology segment. They are oriented towards the development of drugs from imported biopharmaceutical inputs or from other firms in the sector. Their R&D activities are geared towards expanding their knowledge base to produce biosimilars and/or acquiring capabilities to comply with regulatory requirements. Companies operating in this group include Raffo, Richmond, Delta Biotech, Syntex, Biol, Romkin and Roemmers.
- Companies specializing in biotechnology (CSB), which emerged in the 1980s and 1990s and account for 20% of the total. Companies in this segment include Biosidus; companies that are part of local pharmaceutical groups, such as Mabxience, Sinergium Biotech and Elea; and public laboratories.
- The remaining 10% is made up of subsidiaries of multinational companies (MNCs) that import biotech drugs and active biopharmaceutical ingredients, and that focus their activity on the formulation, fractionation and packaging of biotech drugs and their commercialisation in the domestic market. This group includes Gemabiotech, Amgen, Aventis (Sanofi), Roche and Chemo.

⁸ A company or organisation resulting as an extension of another by the separation of a subsidiary.

Competitiveness and market opportunities

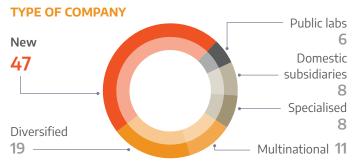
Argentina's biopharmaceutical production is distinguished from other biotechnology product markets by the presence of private domestic companies associated with large pharmaceutical groups that develop and manufacture drugs locally.

The current configuration of the sector is the result of changes in national and international regulations over the last two decades, increased competition in global markets for biological products, the different technological and organisational competencies of firms and the trajectory of the pharmaceutical industry.

It is a relatively concentrated industry with strong barriers to entry, such as access to finance, market regulations, control of distribution networks and national health regulations.

The biopharma market, by type of company and type of products

Figures in percentage of the total number of companies.





Source: Gutman et al. (2021).

MAIN CHARACTERISTICS OF THE SECTOR

Foreign trade

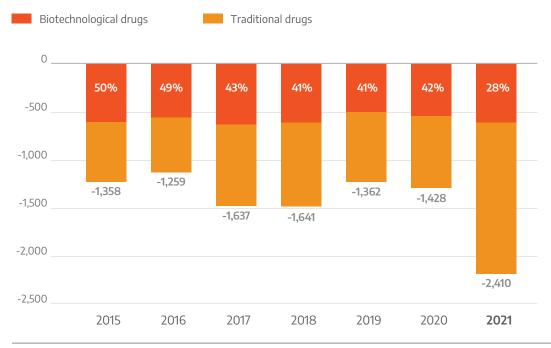
The trade balance of the pharmaceutical value chain shows an average trade deficit of around USD 1.5 billion for the 2015-2021 period, 40% of which corresponds to the biopharma sector.

The negative trade balance is due to the high price of biopharmaceuticals imported by multinational affiliates (Gutman et al., 2020). These are mostly second generation biopharmaceutical drugs used for treating complex and costly diseases—such as cancer, multiple sclerosis and rheumatoid arthritis—as well as for developing vaccines and second generation biotech drugs, to a lesser extent.⁹

⁹ From the 1990s to the 2000s, new so-called "second-generation" biodrugs, characterised by their higher molecular weight and complexity, entered the market. This generation has higher thresholds of R&D, scale, production and regulatory learning compared to the first generation (Gutman et al., 2021).

Pharma trade balance: Biotechnological and traditional drugs

Period 2015-2021. Figures in millions of USD.



Source: CILFA, 2022.

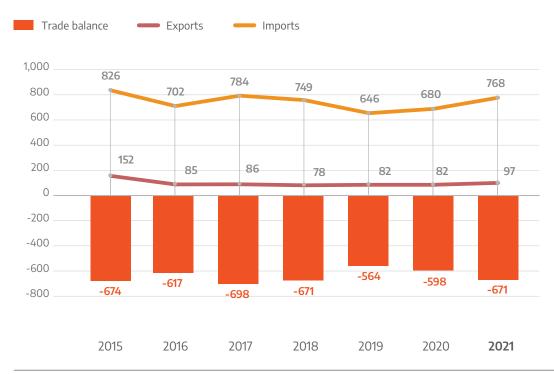
MAIN CHARACTERISTICS OF THE SECTOR

Exports are focused on the most commoditised products, such as first generation biotechnological drugs and extractive biologics, and are directed to countries in the region or to developing countries.

In recent years, the level of external sales was lower in relation to the early 2010s. This has been the result of a slowdown in purchases by Latin American countries (especially Venezuela), growing competitive pressure from multinational companies in these markets and the adoption by countries in the region, such as Chile and Brazil, of the same regulatory frameworks as developed countries, which include much more restrictive procedures and documentation practices (Gutman et al., 2020).

Biopharma trade balance

Period 2012-2021. Figures in millions of USD.



Source: CILFA.

Benefits

The biopharma sector is mainly regulated by Act No. 27,685 on the Promotion of Development and Production of Modern Biotechnology and Nanotechnology (replacing Act No. 26,270 and its amendments) and Decree No. 852/2022. The Act grants a series of tax benefits to projects that apply modern biotechnology both for R&D purposes and for the production of goods and services.

In order to benefit from the regime, beneficiaries must be registered in the Registry for the Promotion of Modern Biotechnology, on the basis of which they will be granted a certificate issued by the enforcement authority.

This regime is aimed at individuals or legal entities incorporated in Argentina that present: (i) research and development projects based on the application of modern biotechnology and/or nanotechnology, and/or (ii) projects for the application or implementation of modern biotechnology and/or nanotechnology, aimed at the production of goods and/or services or the improvement of processes and/or products.

Only projects with a "reliable technological impact" and whose holders have technical and economic and/or financial competence and comply with the biosafety requirements established by the regulations in force will be approved.

Once a tax share has been established, the enforcement authority will grant the approved projects the following benefits:

- Accelerated depreciation in income tax for capital goods, special equipment, parts or components of such goods (new and acquired for the project).
- Early refund of the value added tax (VAT) corresponding to the acquisition of the goods included in the accelerated depreciation benefit.
- Conversion into a tax credit voucher of 50% of the expenses destined to the hiring of technical assistance, research and/or development services with relevant entities of the National System of Science, Technology and Innovation. These bonds will have a duration of 10 years from their date of issue and will be registered and transferable only once.

The tax benefits for early VAT refunds, accelerated income tax depreciation and tax credit bonds totalled ARS 590 million in 2019, 2020 and 2021, a period which was distributed among 15 projects, of which 6 corresponded to companies in the biopharmaceutical sector (Biosidus, Gemabiotech, Inmunova, Terragene, Mabxience and Richmond).

Advantages

The biopharma segment has developed strongly in Argentina thanks to a network of S&T institutions and universities linked to biopharmaceutical research and development, as well as highly qualified professionals, a wide range of public policies and instruments. As a result, this sector is currently in a privileged position to overcome the technological challenges associated with the development of biotechnology and to carry out R&D activities, analytical developments and biotechnological drug production processes.

- Argentina is a pioneer in the development of biotechnological drugs among developing countries. Pharmaceutical activities in Argentina date back to the late 1980s and early 1990s, when specialised companies emerged and the existing chemical-based pharmaceutical laboratories diversified their product portfolios.
- Highly qualified professionals. Argentina has high levels of undergraduate and postgraduate training in the disciplines associated with the development of modern biotechnology in general and the biopharma segment in particular.
- A wide network of scientific and technological institutions.
 Made up of the Ministry of Science, Technology and Productive Innovation, the Ministry of Education, the Ministry of Health, the Science and Technology Agency, the CONICET and its associated institutions, the national universities, the National Administration of Laboratories and Healthcare Institutes (ANLIS), the Malbrán Institute, public laboratories and the National Institute of Drugs (INAME) of the National Administration of Drugs, Foods and Medical Devices (ANMAT).
- A long tradition in R&D in university laboratories and research centres. Argentina has an important background in biotechnology research in specialised institutions (such as the Malbrán Institute, the Leloir Institute and the CONICET), with developments in cell culture and molecular biology as well as in other closely related disciplines, which facilitated the adoption and expansion of biotechnology in different sectors.
- A wide range of public policies and instruments. These are aimed at promoting technological capabilities and financing R&D and production activities.

Main public policies and strategic lines

The Government plays a key role as a regulatory agent in the sector and as a source of funding for R&D and production activities through different programmes and instruments.

As mentioned above, the main regulatory framework for the sector is Act No. 27,685 on the Promotion of Development and Production of Modern Biotechnology and Nanotechnology (replacing Act No. 26,270 and its amendments) and Decree No. 852/2022, which grant a series of tax benefits to beneficiaries, subject to registration and compliance with requirements.

In addition, the National Agency for the Promotion of Research, Technological Development and Innovation (the RDI Agency) of the MINCyT is the governing body for a series of policies aimed at promoting the development of biopharmaceutical companies through funding:

- Fund for Scientific and Technological Research (FONCYT): It provides funding for research projects aimed at generating new scientific, technological and innovative knowledge.
- Argentine Technological Fund (FONTAR): It finances projects aimed at improving private sector productivity through technological innovation.
- Argentine Sectorial Fund (FONARSEC): It seeks to strengthen the link between the scientific and technological sector and the socio productive sector in order to contribute to the solution of social and economic problems. It has a support plan for technology based companies (EMPRETECNO), which in turn has a support programme for the creation of Technology Based Companies (EMPRETECNO PAEBT) and Project Flow Facilitators (EMPRETECNO FFP).

Public procurement is an important instrument for the growth of the pharmaceutical value chain, promoting not only the development of local capacities but also public access to healthcare. This tool has greater potential due to the expansion of the coverage of the national vaccination schedule. Over the last decade, progress has been made in import substitution which, in the first stage, focused on the transfer of formulation and fractionation technology, and then moved on to a more complex process of antigen development.

Efforts have also been made to make progress in the supply of high cost therapeutic drugs, based on technology transfer agreements between public laboratories and foreign and domestic drug companies (Lavarello et al., 2018).

Argentina has high quality standards in terms of good manufacturing practices (GMP) and drug control in line with World Health Organization (WHO) recommendations. Additionally, regulations are adapted to local requirements for compliance purposes. Since 2017, ANMAT has developed a line of support for innovation in biotechnology and advanced therapies to make it easier for local innovators to patent their products from the early stages of development.

In terms of patents, Argentina has adequate criteria that prevent the blocking of incremental innovations that favour the reduction of drug costs, which generates an adequate incentive framework for the development of local competitors (Levis, 2014).

In terms of tariff policy, through Decree 297/2021, the Government established a tariff increase from 0% to 14%, as part of the national list of exceptions to the Common External Tariff (CET), for second generation biosimilars that are produced in the country and have the capacity to replace imports, such as somatropin and its derivatives, interferon beta, etanercept, bevacizumab and rituximab.

INVESTMENT OPPORTUNITIES

Argentina's biopharma sector has the potential to expand towards second generation biotech drugs, considering several factors: the global patent cliff, the capacities created thanks to national science and technology programmes, the capacities generated by the industry from new production practices and the superior regulatory status of the country compared to most developing countries (Lavarello et al., 2017).

In Argentina, a group of companies has made progress in such drugs, based on the capabilities and advantages associated with a vast network of science and technology institutions. Similarly, the COVID-19 pandemic boosted the development of second generation vaccines at the national level, through partnerships of local groups with multinational companies, making it possible to meet the high investment costs and obtain great results in the short term.

The possibilities for growth in the second generation biotech drug segment imply a leap for companies specialising in first generation molecules, requiring higher levels of investment, mastery of new bioprocesses, greater articulation with domestic and international markets to reach minimum scale thresholds, new regulatory capacities and good laboratory and manufacturing practices.

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