A DEVELOPED SECTOR OF AN UNDERDEVELOPED COUNTRY: THE CASE OF CUBAN BIOTECHNOLOGY SECTOR

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ABSTRACT

A DEVELOPED SECTOR OF AN UNDERDEVELOPED COUNTRY:
THE CASE OF CUBAN BIOTECHNOLOGY SECTOR

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Cuba, a country with very limited resources, has attracted attention with its success in the biotechnology sector despite being subjected to US economic, trade, and financial sanctions for decades. In this study, how a developing country can be successful in a capital-intensive and high-risk sector is analysed with a mixed research method. Cuban biotechnology, in strong integration with the national health system, has set out with the aim of producing drugs and vaccines included in the country's essential drug list and national immunisation program and minimising the country's dependence on imports in a strategic area. The priority of the sector has been the development of vaccines, medicines, and early diagnosis kits in line with the current disease burden of the society in line with the preventive medicine approach. The products developed have led to a significant improvement in Cuba's health indicators. While the most important achievement of the sector is its contribution to the development of public health, a successful test was given during the COVID-19 pandemic. The sector has been increasing the country's export revenues for years through its advanced innovation capacity.

The sector, which is gathered under the umbrella of BioCubaFarma, is fully owned by the state and differs from the rest of the world with its goals, motivation, investors, and production process. The sector, characterized by a culture of cooperation rather than competition and an advanced level of integration, faces significant challenges in the supply of raw materials and intermediate materials due to the US blockade. International commercial and scientific partnerships and cooperation agreements are partially effective in solving the problems. The Cuban biotechnology case offers significant policy recommendations for developing countries due to its innovative solutions to encountered problems, its process of building adaptation and innovation capacity, and the state's role in its establishment and development.

Keywords: Biotechnology, Cuba, Innovation, Development, Integration.

ÖZ

AZ GELİŞMİŞ BİR ÜLKENİN GELİŞMİŞ BİR SEKTÖRÜ:
KÜBA BİYOTEKNOLOJİ SEKTÖRÜ OLGUSU

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Kaynakları oldukça kısıtlı bir ülke olan Küba, on yıllardır ABD'nin ekonomik, ticari ve finansal yaptırımlarına maruz kaldığı halde biyoteknoloji sektöründeki başarıları ile dikkat çekmektedir. Bu çalışmada gelişmekte olan bir ülkenin, sermaye yoğun ve yüksek riskli bir sektörde nasıl başarılı olabildiği karma araştırma metodu ile incelenmiştir. Küba biyoteknolojisi, ulusal sağlık sistemi ile güçlü bir entegrasyon içinde, ülkenin temel ilaç listesinde ve ulusal aşı takviminde yer alan ilaç ve aşıları üretmek ve stratejik bir alanda ülkenin ithalata bağımlılığını azaltmak hedefi ile yola çıkmıştır. Sektörün önceliği önleyici tıp anlayışı doğrultusunda, toplumun mevcut hastalık yüküne uygun olarak aşı, ilaç, erken tanı kitleri, vb. geliştirilmesi olmuştur. Geliştirilen ürünlerle Küba'nın sağlık göstergelerinde belirgin bir iyileşme sağlanmıştır. Sektörün en önemli başarısı toplum sağlığının gelişmesine yaptığı katkıdır; COVID-19 pandemisi döneminde başarılı bir sınav vermiştir. Sektör gelişkin inovasyon kapasitesi sayesinde yıllardır ülkenin ihracat gelirlerinin artmasını sağlamaktadır.

BioCubaFarma çatısı altında toplanan sektörün mülkiyeti tamamen devlete aittir ve hedefleri, motivasyonu, yatırımcıları, üretim süreci ile dünyanın geri kalanından

farklılaşmaktadır. Rekabetin değil işbirliği kültürünün egemen olduğu, gelişkin bir entegrasyon düzeyinin söz konusu olduğu sektörün en önemli sorunu ABD ablukası nedeniyle hammadde ve ara madde tedarikinde yaşanan sorunlardır. Uluslararası ticari ve bilimsel ortaklıklar ile işbirliği anlaşmaları sorunların çözülmesinde kısmen etkilidir. Karşılaşılan sorunlara getirilen yaratıcı çözümler, adaptasyon ve inovasyon kapasitesinin oluşturulması süreci ve kurulmasından gelişmesine devletin oynadığı rol ile Küba biyoteknolojisi olgusu gelişmekte olan ülkeler için önemli politika önerileri barındırmaktadır.

Anahtar Kelimeler: Biyoteknoloji, Küba, İnovasyon, Kalkınma, Entegrasyon

To the peoples who are creative even in their resistance…

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TABLE OF CONTENTS

PLAGIARISM iii
ABSTRACT iv
ÖZ vi
DEDICATION viii
ACKNOWLEDGMENTS ix
TABLE OF CONTENTS x
LIST OF TABLES xiii
LIST OF FIGURES xiv
LIST OF ABBREVIATIONS xv
CHAPTERS
1. INTRODUCTION 1
1.1. Motivation for the Study 1
1.2. Importance of the Biotechnology 2
1.3. Selection of the Cuban Biotechnology Case 6
1.4. Determining the Research Question 9
2. BACKGROUND AND LITERATURE REVIEW 12
2.1. Biotechnology Sector and Innovation Capacity 12
2.1.1. Emergence and Development of Biotechnology 12
2.1.2. Political Economy of Biotechnology 16
2.1.3. The Role of the State in the Biotechnology Sector and Health Innovation Systems 23
2.2. Biotechnology and Innovation In Cuba 27
2.2.1. The Early Accumulation Story of Biotechnological Researches 27
2.2.1.1. Before and right after the revolution 28
2.2.1.2. Reorganization of health care 30
2.2.1.3. Institutionalization of science 32
2.2.2. Scientific Research Meets Technology 35
2.2.3. Current Situation in Cuban Biotechnology 39

2.2.3.1. What and how does BioCubaFarma do? 39
2.2.3.2. International collaborations and health diplomacy 42
2.2.4. Uniqueness of the National Health System 45
2.2.5. The Role of Biotechnology During Pandemics 48
2.2.6. The Impact of the Blockade on the Cuban Health System and Biotechnology sector 51
3. METHODOLOGY 55
3.1. Foundations of the Research Method 56
3.2. A Case Study Design 57
3.3. Quantitative Data Collection 58
3.4. Qualitative Data Collection 61
3.4.1. Selection of Interviewers 63
3.4.2. Determination of Interview Questions 65
3.4.3. Analysing the Interviews 69
3.5. Evaluation of Quantitative Data and Qualitative Findings 71
4. ANALYSIS OF THE FINDINGS 72
4.1. Analysis of Quantitative Data on Cuban Health and Biotechnology 72
4.1.1. Descriptive Health Data of the Country Concerning the Biotechnology Sector 73
4.1.2. Human Capital Formation and Skills Development 82
4.1.3. Cuban Biotechnology and the Government Support 85
4.1.4. Quantitative Description of the Blockade's Impact on Public Health and Biotechnology 90
4.2. Interpretation of the Qualitative Findings Through the Interviews 93
4.2.1. Theme 1 Leadership 95
4.2.2. Theme 2 Public Needs 97
4.2.3. Theme 3 Central Planning 100
4.2.4. Theme 4 Human Potential 103
4.2.5. Theme 5 Integration 106
4.2.6. Theme 6 International Collaboration 109
4.2.7. Theme 7 Blockade 113
4.2.8. Theme 8 Social Values 117
4.3. Synthesis of the Quantitative Data and Qualitative Findings 119

4.3.1. Discussion from a Growth and Development Perspective 120
4.3.2. Discussion Regarding Innovation Systems and Capacity 125
4.3.2.1. Innovation systems 126
4.3.2.2. Innovation capacity 130
4.3.3. Discussion by the Impacts of the US Blockade 134
4.4. Concluding Remarks 140
5. CONCLUSIONS AND POLICY RECOMMENDATIONS 143
5.1. Policy Recommendations for Developing Countries 143
5.1.1. Prioritising State-Led Social Development 144
5.1.2. Central Planning and Priority Setting 145
5.1.3. Nationalisation of Strategic Sectors 147
5.1.4. Government Management Based on Science, Technology and İnnovation 149
5.1.5. Strategic Integration and Complementarity 152
5.1.6. Strengthening the Social Values Context of Education to Maximise Human Potential 153
5.2. Concluding Remarks 155
5.3. Limitations of the Study 159
REFERENCES 161
APPENDICES
A. APPROVAL OF THE METU HUMAN SUBJECTS ETHICS COMMITTEE 177
B. THE OPEN-ENDED QUESTIONS USED IN THE SEMI-STRUCTURED INTERVIEWS 178
C. TURKISH SUMMARY/ TÜRKÇE ÖZET 180
D. THESIS PERMISSION FORM / TEZ İZİN FORMU 192

LIST OF TABLES

Table 1. Areas of Use and Application of Biotechnology 15
Table 2. Scientific Production Centres..... 37
Table 3. Products Prominent in Export..... 41
Table 4. Institutions and Datasets Used as Quantitative Data Sources..... 59
Table 5. Summary of the Interviewees 65
Table 6. Categories, Sub-Categories, Themes and Sub-Themes of the Interviews ... 70
Table 7. Human Development Index of Cuba in 2022 74
Table 8. Basic Health Indicators of Cuba Over the Years 76
Table 9. Outcomes of the Cuban Immunisation Programme..... 77
Table 10. Cuba in Comparison with the 'First World' 81
Table 11. After Lower Secondary Schools in Cuba..... 83
Table 12. Number of Students in Higher Education Levels 84
Table 13. BioCubaFarma in Numbers 87
Table 14. Evaluation of the Interviews by Thematic Analysis..... 94
Table 15. Summary of Objectives and Tools of the Cuban Biotechnology Sector . 157

LIST OF FIGURES

Figure 1. Revenue of the Worldwide Pharmaceutical Market From 2001 to 2023 ... 20
Figure 2. Number of New Chemical or Biological Entities Developed Between 1998 and 2023, by Region of Origin *Source: (Statista, 2024d)*..... 21
Figure 3. Projected Top Therapy Areas Worldwide in 2027, by Spending (in billion U.S. dollars) *Source: (Statista, 2024e)* 22
Figure 4. Cuba's Exports: Medicament From 1995 to 2022 79
Figure 5. R&D Spending as a Share of GDP (GERD)..... 89
Figure 6. Total Annual GDP Per Capita (Current USD)..... 91

LIST OF ABBREVIATIONS

BAA	: Academy for Science and Enlightenment
BDL	: Basic Drug List
CECMED	: Cuban Regulatory Authority
CENPELAB	: National Laboratory Animal Production Centre
CIDEM	: Centre for Pharmaceutical Research and Development
CIE	: Centre for Immunoassay
CIGB	: Centre for Genetic Engineering and Biotechnology
CIM	: Centre of Molecular Immunology
CITMA	: Ministry of Science, Technology and Environment
CNEURO	: Centre for Neuroscience
ECLAC	: Economic Commission for Latin America and the Caribbean
EFPIA	: The European Federation of Pharmaceutical Industries and Associations
EGF	: Epidermal Growth Factor
ELAM	: Latin American School of Medicine
EU	: European Union
FDA	: U.S. Food and Drug Administration
FDI	: Foreign Direct Investment
GCSF	: granulocyte colony-stimulating factor
GDP	: Gross Domestic Product
GERD	: Gross Domestic Expenditure on R&D
GHIS	: Global health innovation system
HALE	: Healthy Life Expectancy
HDI	: Human Development Index
ICT	: Information and Communication Technologies
IoT	: Internet of Things
M & A	: Mergers and acquisitions

MEP	: Ministry of the Economy and Planning
MES	: Ministry of Higher Education
MINED	: Ministry of Education
MINREX	: Ministry of International Relations
MINSAP	: Ministry of Public Health
NGOs	: Non-governmental organizations
NIS	: National Innovation System
OECD	: Organization for Economic Cooperation and Development
OFAC	: Office of Foreign Assets Control
ONEI	: The National Statistics Office of Cuba
PAHO	: Pan American Health Organization
PCT	: Patent Cooperation Treaty
PNDES	: National Economic and Social Development Plan
R&D	: Research and Development
RIS	: Regional Innovation System
SDGs	: Sustainable Development Goals
SGGCI	: Government Management Based on Science, Technology and Innovation
SSTIC	: South-South and Triangular Industrial Cooperation
UK	: United Kingdom
UN	: United Nations
UNCTAD UN	: Conference on Trade and Development
UNDP	: United Nations Development Program
UNESCO	: United Nations Educational, Scientific and Cultural Organization
UNIDO	: United Nations Industrial Development Organization
USA	: United States of America
WB	: World Bank
WHO	: World Health Organization

CHAPTER 1

INTRODUCTION

1.1. Motivation for the Study

The COVID-19 pandemic has exposed the strengths and weaknesses of the health systems of countries around the world. The COVID-19 pandemic has significantly tested the crisis management and preparedness levels of countries' health infrastructures. Many countries, recognised for their advanced economies and democracies, failed these tests. Together, we witnessed a period of severe uncertainty and pessimism.

During this period, the biotechnology sector became the centre of attention for business and governments, as well as the people of the world. News about treatments and vaccines for COVID-19 was followed day by day. Amidst this news, Cuban biotechnology and the national health system once again stood out for their achievements. Cuba has not only set an example of how a country can fight a pandemic, but also provided a positive narrative of global health systems and crisis management.

Cuba's strong healthcare system and innovative biotechnology solutions, which it has not compromised despite the economic sanctions and difficulties it has been subjected to for years, have been a source of hope for humanity during the pandemic. In a world where pessimism and a sense of futility are still very much present, there is a need for more examination and sharing of positive examples.

Cuba's biotechnology sector, which produces a significant portion of the vaccines, diagnostic kits and essential medicines required by the national health system, has

also produced many innovative products that have excited the medical community around the world. This dissertation in the discipline of science and technology policy is designed to provide an accurate understanding of how a “poor” country was able to build a thriving biotechnology sector. Examining this experience, which can be a source of inspiration for developing countries, will also lead to the questioning of some conventional memorisations.

1.2. Importance of the Biotechnology

In addition to the molecular biology, genetics, and engineering sciences from which it originates, biotechnology is directly the subject of economics and political science due to its huge economic value, high innovation potential, social benefits, and investment risks it creates. Relevant to all three categories of science—natural sciences, social sciences, and formal sciences—biotechnology has marked the last four decades and has been interpreted as a technological revolution because of its impact on production processes, industrial structures, and social relations (Perez, 2002). According to Soete and Freeman (2012), biotechnology holds significant potential for economic growth and development, as it transforms existing systems, fosters the formation of new industries, initiates major innovations with significant investments, and creates new market opportunities.

The past century has seen important discoveries in biology and exciting advances in genetic engineering. Modern biotechnology, which means the transformation of new knowledge into products and processes with new technologies, is still developing at a rapid pace. These developments are followed by different segments of society, sometimes with great hope and curiosity, sometimes with anxiety and fear. Although biotechnology has the potential to solve many problems and meet many needs of humanity, from disease prevention to diagnosis and treatment processes, from increasing the yield of agricultural products to protecting the environment, the sources of this anxiety and fear created by biotechnology require scientific questioning.

We know that biotechnology is not the only area of science, technology and industry that raises concerns in people today. For example, a report published by the

Organization for Economic Cooperation and Development (OECD) in 2023 found that three-fifths of workers are concerned that they will lose their jobs or see their wages fall in the next ten years due to artificial intelligence technology (OECD, 2023). Fear and scepticism in the field of biotechnology, on the other hand, has manifested itself most widely in anti-vaccine sentiment and hesitancy, which has increased during the COVID-19 pandemic. In a study published in The Lancet, it was reported that the rate of mistrust against vaccines worldwide increased from 10-15 percent in 2019 to 25-30 percent during the pandemic (Troiano & Nardi, 2021). It can be said that underlying these concerns and scepticism towards these technologies, each of which is considered revolutionary and from which the scientific community is not exempt, is the—explicit or implicit—distrust of the subjects who own the ownership of the technology that will transform knowledge and information into a product to be offered to the market through the process of its production and sharing.

Indeed, it is not possible to say that science and technology today are developed and used in line with the collective interests and needs of humanity. The classes and political subjects in power are able to intervene in the direction and speed of scientific progress through political, ideological and economic mechanisms. The first example that comes to mind here is the atomic bombs dropped by the US on the Japanese cities of Hiroshima and Nagasaki at the end of World War II and the process of their development. But there are many more[1]. Nevertheless, within this objectivity, the scientific and academic community should not approach developments in science and technology with a fearful conspiratorialism or pure optimistic enthusiasm.

Biotechnology is defined as any technological application in which biological systems, living organisms or their derivatives are used to create or modify products

[1] The US has a long track record in this regard: The Tuskegee syphilis test on the African-American population in the US is a well-known example of the unethical use of science (Cuerda-Galindo, Sierra-Valenti, González-López, & López-Muñoz, 2014). Gynecomastia in Haitian immigrant men has been blamed on injections given upon entry into the US. In addition, the US has been repeatedly accused of using biological weapons in China, Vietnam, Cambodia and Laos. There is strong evidence that the outbreak of Dengue Fever in Cuba in 1981 was initiated by the CIA (Erkekoğlu & Koçer-Gümüşel, 2018). There are countless such examples over the past century.

and processes for a specific use (Secretariat of the Convention on Biological Diversity, 2001). The expression “specific use” in this definition means that when it comes to a profit-oriented market economy, products and innovations are aimed at maximizing the market shares and profits of companies, regardless of the fact that they are aimed at the needs of people. It is precisely for this reason that the biotechnology sector, which is a capital-intensive sector, is a sector in which monopolies usually invest or have a strong tendency to monopolise, and monopolies tend to reap the rewards of their investments as quickly as possible in the form of profitability. In other words, the main motivation for large capital investments is not to meet people's needs or to solve social problems (BAA, 2020). For sure, the problems of humanity cannot be solved by science or technology alone. However, humanity is evolving towards an increasingly knowledge-based society, and both knowledge itself and the process of its production are being privatised through intellectual property rights, patents, numerous laws and contracts. Knowledge and the process of its production are increasingly concentrated in the hands of fewer individuals and/or companies, which can be detrimental to the quality and scope of knowledge. In this context, capitalism itself becomes an obstacle to the production of new knowledge by preventing the accumulation of knowledge (Dávila, 2006). In the field of biotechnology, the COVID-19 pandemic provides us with endless data in this respect.

Life expectancy at birth increased globally after the two world wars in the first half of the last century. An evaluation of the first period of the 21st century reveals a 6-year increase in life expectancy at birth between 2000 and 2019. Life expectancy increased from 66.8 years in 2000 to 73.1 years in 2019, and healthy life expectancy (HALE)[2] increased from 58.1 to 63.5 for the same years (WHO, 2021). These increases have undoubtedly been driven by biotechnological innovations and new diagnostic and therapeutic methods, pharmaceutical products and rehabilitation technologies. However, during the COVID-19 pandemic, there has been a 10-year drop in these very basic health parameters in just two years. Global life expectancy fell to 71.4 years, and HALE to 61.9 years in two years (WHO, 2021). The first

[2] HALE is defined as the avarage number of years that a person can expect to live "full health" from birth and also used for monitoring the health policies (WHO, 2023).

reasons that come to mind in this rapid regression are the virulence of the new virus, overload in the health system, and problems in access to care and treatment. However, the dominant treatment-oriented and marketized health systems in the world, along with the biotechnology sector that focuses on research and production to meet these systems' demands or create supply, could potentially impact this rapid regression.

Research and production activities for the protection of health only enter the agenda of the biotechnology industry when the expectation of profit is too high. The biotechnology industry, oriented towards production in accordance with the understanding of personal medicine rather than communitarian medicine, directs research and development studies based on the disease load of high-income countries. For instance, long before the COVID-19 pandemic, it terminated some coronavirus vaccine studies, some of which had come a long way, because they did not generate profit[3]. However, one of the most important issues that accelerates the process of developing a new vaccine is previous vaccine studies against the same or similar viruses. The question of how much the sharp decline in life expectancy at birth has been impacted by the failure of biotechnology monopolies to prioritise collaboration over competition during the pandemic deserves thorough investigation. This questioning should also include the time lost as multiple companies worked simultaneously on vaccines with identical technologies and the delays in mass production caused by patent protections on the developed vaccines.

In short, although humanity has the knowledge and technological know-how to develop a much faster and more effective fight against the pandemic, the ownership of this knowledge and technology by individuals and companies, not society, and the profit maximisation focus of the sector have weakened the fight against the pandemic[4]. On the other hand, it is biotechnology that has ensured the regression in

[3] In the 2000s and early 2010s, vaccine studies were initiated for Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). However, these vaccine projects were terminated as SARS and MERS did not become widespread epidemics, and their commercial markets were considered limited.

[4] There is no study in the literature that demonstrates my hypothesis here with quantifiable evidence. However, arguments for this hypothesis include the COVAX project itself, which the World Health

global life expectancy during the pandemic was limited to a decade rather than a twenty- or thirty-year regression. The development, production and administration of COVID-19 vaccines has been the most effective weapon in the fight against the pandemic. The contradiction here is not inherent in the field of biotechnology itself, but in the private ownership of knowledge as a means of production and of the production process. What is more advanced for humanity is not only the development of science, but also its direct connection to social life and needs. If this can be achieved, the field of biotechnology will no longer be an insecure field that inspires fear, but a field of work for all disciplines of science that offers excitement and hope, which we would like to witness every moment of.

1.3. Selection of the Cuban Biotechnology Case

The most important distinguishing feature of Cuban biotechnology, whose goals, motivation, investors and production process are completely different from biotechnologies of other countries, is the way in which science is integrated into the economy while preserving its social character (Dávila, 2006).

Cuba produces 8 of the 11 vaccines in the national vaccination program and supplies 70 percent[5] of the medicines it needs through domestic production (Martínez-Díaz et al., 2024). With the vaccines and biotechnological products it produces, it not only saves money on medical supplies but also contributes significantly to the national economy by exporting these products to dozens of countries. It has also developed many innovative biotechnological products that have attracted a tremendous deal of attention around the world. Among these, VA-MENGOC-BC (the first vaccine developed against meningitis types B and C), Heberon Alpha R (an interferon alpha 2b-based drug used in the treatment of hepatitis C and B), Heberprot-P (a drug effective in reducing amputations in the treatment of diabetic foot ulcers), CIMAvax-

Organization (WHO) had to launch during the COVID-19 pandemic due to large inequalities in access to vaccines between countries, and the fact that the industry has still not produced a vaccine against the Ebola outbreak, which has caused thousands of deaths in poor African countries.

[5] This rate, which has dropped from 80 percent to 70 percent in the face of severe economic, trade and financial sanctions, depends on Cuba's ability to solve the problem of raw material and material supply (Martínez-Díaz et al., 2024).

EGF (one of the world's first therapeutic cancer vaccines used in lung cancer) are the best known. It also developed five vaccine candidates during the COVID-19 pandemic, licensed three of them in a short period of time and vaccinated the population over 2 years of age in a short period of time (Villanueva & Espiñeira, 2023).

Biotechnology is a sector that requires high capital investments due to the intensive emphasis on research and development activities; therefore, it takes time for investments to turn into products and profits. On the other hand, investment in R&D activities rarely results in innovation and a profitable product for the market. Due to this high capital risk, the biotechnology sector, in which only large monopolies and countries with an advanced level of development can generally afford to invest, is concentrated in high-income countries. Today, the United States of America (USA), India, the United Kingdom (UK), Germany and Canada stand out among the countries that invest the most in biotechnology. While North America continues to lead in terms of investment rates, there have been significant government incentives in this sector in India and China in recent years. The largest companies operating in the sector are Johnson & Johnson, Pfizer, Amgen, Merck & Co., Gilead Sciences (USA), Novartis, and Roche (Switzerland), which specialize in pharmaceuticals and have a high market capitalization (StartUs, 2024). Scientific work in the field is also often funded by these large companies. Cuba is the only country in its income category to have an independent and consistent biotech sector. The only investor in the Cuban biotech sector is the Cuban state, which guarantees the coherent policy, long-term planning and infrastructure investments that the sector needs (Özkan, 2019).

Another important feature of Cuban biotechnology is its ability to maintain continuity in research, development, innovation, and production despite the increasingly severe US economic, commercial, and financial sanctions[6] that began in the early years of the revolution. These sanctions are aimed not only at terminating

[6] International law and literature define these sanctions as an embargo, but the Cuban State defines them as an economic war that aims to overthrow the political regime in Cuba by leaving the people impoverished and hungry. They prefer the definition of blockade, which encompasses a political and military threat and isolation, over the economic concept of embargo (Erdemol, 2022).

relations between the United States and Cuba, but also at preventing all commercial activities and cooperation with other countries and international companies. Even during a global crisis such as the COVID-19 pandemic, US sanctions prevented Cuba from purchasing mechanical ventilator equipment and maintenance services and importing oxygen from third countries. These sanctions, which have been voted to end 32 times by the United Nations (UN) General Assembly, are causing a crisis in all strategic sectors of Cuba, such as energy, health, education, agriculture, as well as restricting access to vital products such as food, fuel and medicine. On the one hand, Cuban biotechnology is forced to develop further in order to increase the country's potential to manage this state of poverty and crisis, and on the other hand, its development in this field is hindered as it is prevented from having the latest technology, important reagents, and some software necessary for the biotechnology sector.

In short, the Cuban biotechnology sector has made dramatic improvements in the country's health indicators and has also become an important economic force for the country through the export of biotechnological products. Tourism, sugar, tobacco, and biotechnology are among the sectors that contribute the most to the country's economy (ONEI, 2022). In the world ranking of Gross Domestic Product (GDP), which is accepted as one of the economic development indicators of countries, Cuba ranked 65th in 2023 (Global Finance, 2023).

Another characteristic of Cuban biotechnology is that, contrary to common assumptions in the world, it derives its innovation and production capability not from competition between institutions and individuals but from effective communication and cooperation within and between institutions. The processes of R&D, innovation, production, distribution, and marketing have all been brought together under the same governance structure, thus ensuring that scientists have a voice and say in the whole process. By removing artificial barriers between science centres and factories, the alienation of scientists from the product and the production process was prevented. This production process, called the closed-loop approach, enables rapid improvements to be made in the products produced and increases innovation capability. For instance, these features enabled scientific institutions to swiftly

organise themselves based on their capabilities and equipment during extraordinary circumstances like a pandemic, leading to the rapid development of five COVID-19 vaccines. Additionally, due to the robust integration of scientific centres with the central state, Cuba has been the country capable of vaccinating its population aged more than 2 against COVID-19 in the most extensive and rapid manner (Díaz-Canel Bermúdez, 2022).

Cuba has created a population that approaches science with confidence rather than scepticism; it also provides an experience from which underdeveloped and developing countries can benefit. The Cuban biotechnology case can motivate many countries, hesitant to establish an advanced national industry out of a sense of tardiness, to take the path to progress and development. In a context where scientists and academia are increasingly distanced from the society and problems they live in, where they are forced to develop their production under the shadow of imposed performance and academic criteria, where alienation is rapidly destroying quality scientific production, where young people have no motivation for the future, and where hope is sought in emigration abroad, Cuba's game-changing biotechnology experience can be an inspiration.

1.4. Determining the Research Question

As an archipelagic country, Cuba has a small and open economy with no international land borders and limited underground and above-ground resources; therefore, it is dependent on international trade by air and sea. Moreover, it has been fighting an economic war for more than sixty years under increasingly severe economic, trade and financial sanctions imposed by the United States. Nevertheless, Cuba is ranked in the 'high' category of the UN Human Development Index (HDI). It is a country with an advanced level of development in the fields of education and health and a developed capacity for scientific research (UNDP, 2022). Its success in the field of biotechnology has largely been realised after the dissolution of the Soviet Union, which had earlier provided Cuba substantial economic and technological support. All this justifies the question “How did Cuba achieve this and what conclusions can other countries draw from it?” (Giles, 2005).

The research topic of this study is to understand how Cuba was able to achieve this unique success in the field of biotechnology. Being a country capable of producing its own vaccines, supplying pharmaceuticals and biotechnological products through domestic industry, and managing crisis periods such as pandemics without relying on foreign countries is a crucial capability for many developing countries with fragile economies today.

In this regard, this study aims to comprehend how Cuba, a developing country, has achieved an advanced level of innovation and production capacity in biotechnology, a strategic sector in many aspects. To address this, a literature review on the biotechnology sector and Cuban biotechnology was first conducted. Accordingly, the first section of the second chapter provides a basis for understanding the factors affecting the emergence, development, and innovation capacity of biotechnology. The second section includes a review of a diverse range of literature on the biotechnology sector in Cuba, from its founding objectives to its current production potential, from the challenges faced to the methods used to overcome these challenges.

The third chapter provides information on the methodology of the study. This chapter outlines the methods used to obtain the necessary data for the study, utilizing both quantitative and qualitative research strategies. For the quantitative data, statistics and data related to Cuban biotechnology from the Cuban State and international organisations such as the World Bank (WB), UN, OECD, etc., are analysed, while for the qualitative data, semi-structured interviews with employees of important scientific centres such as CIBG (Genetic Engineering and Biotechnology Centre), CIM (Molecular Immunology Centre), IFV (Finlay Institute), and other relevant people directly involved in the biotechnological research, development, and innovation process in Cuba are used.

Thus, in this study, where the quantitative and qualitative data collected are evaluated with a mixed methodology, the data and findings obtained in the fourth chapter are analysed in order to find holistic and in-depth answers to the research question. The same section discusses these data and findings from a growth and

development perspective, focusing on innovation systems and capacity, as well as the impacts of the US blockade.

The final chapter contains the conclusions of the study and some policy recommendations. This study found that a national economy that focuses on meeting social needs requires central planning and a high level of integration. It is emphasised that a communitarian approach, which is not market- and profit-orientated, has positive effects on the growth of developing countries and that competition is not a necessity in order to progress and innovate in a targeted area. In addition, the importance of nationalisation in strategic sectors and the benefits of science, technology, and innovation-based management of the country are mentioned.

In an objectivity where scientists and the academic community are increasingly distanced from the society and problems they live in, where they are forced to make their productions under the shadow of some performance and academic criteria, where alienation is rapidly destroying qualified scientific production, where young people have no motivation for the future and hope is sought in emigration abroad, Cuba's ground breaking biotechnology experience has a truly inspiring character.

CHAPTER 2

BACKGROUND AND LITERATURE REVIEW

2.1. Biotechnology Sector and Innovation Capacity

2.1.1. Emergence and Development of Biotechnology

"The bourgeoisie cannot survive without a permanent revolution in the means of production."

Karl Marx and Friedrich Engels

Biotechnology, which first appeared as a term in the book "Biotechnology of Meat, Fat, and Milk Production in an Agricultural Large-Scale Farm" written in 1919 by a Hungarian agricultural engineer, Károly Ereky, has much older roots (Fári & Kralovánszky, 2006).

The Neolithic Period, in which human societies passed from the primitive communal period based on hunter-gathering and nomadic life to settled life with the invention of agriculture, is an era in which we know that biotechnology[7] has many practices. This era, which marked the emergence of the surplus product, is a historical interval in which people began to accumulate and pass on a lot of experience and knowledge through observation and experimentation in order to breed plants and animals. Producing durable foodstuffs such as bread, beer, cheese, and wine by using yeast and using mules that were crossbred between a male donkey and a female horse in transport and agriculture were the first examples that come to mind (Verma et al., 2011).

[7] Beyond the definition of the technology, including the process of transforming inputs into outputs, it should be remembered that the concept of technology has historically had the meaning of making a tool, doing an action with a tool, or making a thing or object (Türkcan, 2016).

It is known that the Sumerians and Babylonians brewed beer in 6000 BC, and the Egyptians used fermented bread in 4000 BC. In this sense, it is necessary to know that biotechnology is not something new and that people have been using microorganisms experimentally for many years without realising it, that making beer, bread, yoghurt, cheese with fermentation, oriental foods, and sewage treatment are biotechnological practices (Smith, 2012). Following this period, which Türkcan (2016) calls the era of anonymous inventions, the era of individual and later the era of collective and institutional inventions began. Molecular biology and genetics, which form the core of today's modern biotechnology, emerged in the light of the discoveries made by scientists such as Brown, Koch, Pasteur, and Mendel, whose names are well known today. Such scientific developments as the comprehension of the structure of the cell, the development of vaccines against rabies and smallpox, and the discovery of the laws of heredity led to the modern molecular biology and genetics of the 20th century. In short, biotechnology is not a discovery that suddenly emerged at a moment in history, but an accumulation (Verma, et al, 2011).

A milestone for modern biotechnology was the development of recombinant DNA technology in the 1970s, following the discovery of the DNA structure in 1953. Recombinant DNA technology, which means the insertion of cut DNA into the DNA of another organism, forms the basis of genetic engineering. The production of insulin and other therapeutic proteins with this technology are significant breakthroughs for medical science. In the first quarter of the 21st century, there were two important developments in the field of biotechnology. One is the Human Genome Project (HGP)[8], completed in 2003, and the other is the CRISPR-Cas9[9] (Clustered Regularly Interspaced Short Palindromic Repeats) technology developed in the 2010s. These technologies have raised great excitement as they have opened up fast and cost-effective ways of modifying the genes of living organisms to eliminate diseases, create more resilient plants, eradicate pathogens, and much more. On the other hand, some researchers and scientists have been concerned about the

[8] The HGP, started in 1990, focused on sequencing the approximately 3 billion base pairs in the human genome and determining which genes these base pairs encode (Evrim Ağacı, 2021).

[9] Using this groundbreaking method in gene editing technology, the desired DNA region can be cut using the enzyme Cas9. Thus, DNA sequences can be cut, modified, or deleted very precisely (Ledford, 2015).

manipulation of hereditary material through these developments. The potential of this technology to produce risky genomes and disrupt ecosystems has raised some ethical questions (Ledford, 2015).

The general principles of biotechnology are based on genetic and bioprocess engineering, microbiology, cell and tissue cultures. Genetic engineering, which involves changing the genetic material of organisms and thus their properties, has led, for example, to the use of genetically modified organisms (GMOs) in agriculture to increase crop yields and microorganisms to reduce environmental pollutants (bioremediation). The use of new molecules with new functions by changing the structure and function of proteins in the field of medicine and the use of various biological systems in industrial production processes can be included in the above. Nevertheless, biotechnology is not just about the most popular recombinant DNA technology and genetic modification by fusion techniques.

Bioprocessing technology, which is historically the most important field of biotechnology, is today still traditionally used in the production of foods such as beer, cheese, and wine and in the manufacture of medical products such as antibiotics and cell culture. Although it is the oldest field of biotechnology, the related sectors continue to carry out R&D studies and use the new fermentation process innovations to increase production. New polysaccharides, important drugs, solvents, and protein-enhanced foods have been added to the products produced by this technology. *Waste technology,* another historical biotechnological field, is gaining importance due to the necessity of conserving resources and recycling, and biofuels, foods, and fertilisers produced in this way promise for the future. Within this field of *environmental technologies* developed for the solution of environmental problems, pollution control, and elimination of toxic wastes, projects on metal extraction from waste mines and ores of low quality are also ongoing. The European Union (EU) aims to produce less waste, consume less energy, and reduce greenhouse gas emissions with these environmentally friendly biotechnologies defined as “white technology”. In addition, L-amino acids, semi-synthetic penicillin, starch, cellulose, etc. are produced with *enzyme technologies* used to create special molecular converters (bioreactors), and *genetic and recombinant DNA technology* are used increasingly in plant and

animal agriculture to boost productivity. This technology is used to modify taste and flavour as well as to improve the quality and safety of food. One of the consequences of the comprehension of the human genome is the prominence of individualised medicine and the increasing number of laboratories working on personalised treatments. “Smart” drugs, developed with these technologies, which only affect the diseased area and protect healthy cells, keep creating excitement in the medical community (Smith, 2012).

A former editor of Bio/Technology magazine said, “There is no such thing as biotechnology; there are biotechnologies. There is no biotechnology industry; there are industries that depend on biotechnologies for new products and competitive advantage” (McCormick, 1996). Indeed, the use areas, production processes, and products of biotechnology are gradually becoming more complex, and countless goods are produced or different production processes are emerging by using biotechnologies in agriculture, health, the environment, energy, and many other fields. These numerous uses in various sectors have even led to debates on the definition of biotechnology (Arundel et al., 2007). This is because when the definition is incomplete or incorrect, the relevant industries cannot be identified correctly. It has been pointed out that this situation would lead to inaccurate estimation of R&D, employment, and sector revenues, reduce the comparability and quality of statistics, and thus lead to misinterpretation of relevant economic parameters (Miller, 2007).

Table 1. Areas of Use and Application of Biotechnology

Sector	**Areas of use**	**Application areas**
Health and Medicine	Developing drugs	Healthy long life and treatment
	Genetical tests	Targeted therapy applications with personalized medicine
	Development of vaccines	Preventing diseases
	Clinical research and screening methods	Early diagnosis

Table 1. (continued)

Agriculture	GMOs	Increasing productivity, durability and nutritional value
	Biopesticides	Fighting diseases and pests
	Sustainable Agriculture	Reduced chemical use and soil health
Environment and energy	Bioremediation	Cleaning dirty environments
	Renewable energy	Energy production from biological resources
	Waste and recycling	Recycling and biodegradation of waste
	Carbon footprint reduction	Reducing carbon emissions
Food industry	Fermentation	Use of microorganisms in food production
	Food safety	Improving food quality and safety
Industry and Production	Bioprocesses	Production methods using microorganisms and enzymes
	Renewable energy	Use of biofuels instead of fossil fuels and energy security
	Production of materials and chemicals	Utilizing bioplastics and biosynthetic products

Source: Designed by the author

In brief, the field of biotechnology covers many sectors, varying from the production of nutritionally enhanced foods to biofuel production, from pharmacy and medicine to environmental pollution control. Biotechnology, whose areas of use and application are summarised in Table 1, is still mostly a pharmaceutical industry, but a growing number of start-ups are operating in food and environmental monitoring materials. In this study, we will focus on the health and pharmaceutical sector of biotechnology, which has a high potential for both social benefit and economic income generation.

2.1.2. Political Economy of Biotechnology

According to the Russian economist Kondratieff, capitalist economies go through long cycles of expansion, stagnation, and crisis. These cycles, which last about 40 to 60 years, are triggered by major technological innovations and industrial

breakthroughs. According to this approach, the era of steam and railways, which was the first period after the industrial revolution, was followed by the era of steel and electricity. Focusing on the dominant technological applications of the period, the technological paradigm after the 1970s is considered to be the information and communication technologies (ICTs) (Perez, 2002). The intervals of these cycles are getting shorter with the rapid developments in science and technology. As of the 2000s, the Internet of Things (IoT), artificial intelligence, biotechnology, and the technologies of sustainable energy solutions have become important technologies that shape society and the economy and have an impact on sectors other than their own.

The 1970s, when biotechnology started to develop rapidly, was also a period of severe capitalist crisis, with waves of high inflation and unemployment emerging in the world in general. During these long years of economic stagnation, which is also called the Oil Crisis, as in other crises of the system, there was a decline in profit rates and a blockage of capital accumulation processes. The rapid increase in energy prices, the rise in production costs, and the slowdown in economic growth deeply affected many national economies. As a solution, governments implemented neoliberal policies in the process of restructuring their economies. Hence, the free-market economy was encouraged by limiting the role of the state in the economy through large-scale privatisation and the reduction of public services and real wages. The rise of biotechnology coincides with this period. The fact that the reserves of fossil fuels, a non-renewable energy source, would run out after some time has led to an increased interest in new raw materials and new biotechnological methods as alternative ways of revitalising economies on a local, regional, national, and even global basis (Smith, 2012). These were the years in which states started to formulate technology policies rather than confining themselves to science policies, based on the effect of technological development on economic growth and development (Taymaz, 2016). At this point, it is noteworthy that the countries called the Asian Tigers—South Korea, Taiwan, Singapore, and Hong Kong—caught up[10] with the growth

[10] This has been addressed in the economic literature with catch-up and leapfrogging theories and suggests some latecomers can bypass outdated technologies, skip big investments in prior systems, and catch up with advanced economies (Lee & Lim, 2001).

rates of developed countries through technology transfer, human capital investments, export-led growth strategies, and strong government interventions. Likewise, new countries were added to the world's strong economies in sectors such as electronics, automotive, software, petrochemicals, etc. However, in the biotechnology sector, which grew rapidly in the 1980s and started to be used in many industrial fields, the technological and commercial dominance of the USA and the UK continued for many years. It took quite a long time for biotechnology to transcend the borders of these two countries. Today, although countries such as Canada, Switzerland, China, India, Argentina, and Brazil have included biotechnology in agriculture, energy products, and pharmaceutical sectors, the hegemony of the USA still dominates the global market (Niosi, 2014). The key characteristics of the biotechnology sector, which have an impact on this, can be listed as follows:

1. A high level of capital investment is required. It needs high-cost and advanced scientific and technological knowledge such as molecular biology, genetic engineering, and bioinformatics. Furthermore, R&D studies, clinical trials, and regulatory approval processes are also very costly.
2. It is a risky investment area with a higher uncertainty. R&D activities do not guarantee scientific and technical success. Besides, strict regulatory approval processes must be completed for the quality and reliability of the products. In the meantime, rapid changes and developments in the field may result in one product being immediately replaced by another. Adapting to new technologies incurs additional costs.
3. It carries a high innovation potential. Technology-orientated and multidisciplinary structure and links with practical applications increase the innovation potential (Smith, 2012).
4. It requires a long-term investment perspective. Since the duration of the process from the R&D stage to the emergence of a commercial product is quite long for the reasons mentioned above, a patient investment approach is needed.
5. Being a capital- and labour-intensive sector, having high innovation potential, investment diversity, and a wide market provide opportunity for high profit rates (Statista, 2024a). In turn, high profit rates lead to high competition and monopolisation tendencies.

When these fundamental characteristics are taken into consideration, it is not surprising that the biotechnology sector, which accounts for more than 30 percent of the global economy (Smith, 2012), has been concentrated in high-income countries. According to the OECD Emerging Technology Indicators, there are 2840 active biotechnology companies in the USA, 1860 in France, 1738 in Canada, 1348 in Spain, and 1025 in Korea in 2021 (OECD, 2021a). The USA has led the world in biotechnology research and trade for fifty years. The USA has a global biotechnology value share of approximately 59 percent (Statista, 2024b), and this status is mainly due to the large biotechnology companies and research centres that have been operating for many years in California (Bay Area, Los Angeles, San Diego) and the Northeast Region of the USA (Boston Area, New York, New Jersey), as well as universities such as Harvard and MIT (Niosi, 2014).

The biotechnology sector is one in which the process of transforming R&D research into a commodity is quite long. Moreover, for instance, in the pharmaceutical industry, out of every 10.000 substances synthesised in the laboratory, only one to two of them pass all the research and development stages and become a marketable medicine (EFPIA, 2024). Nevertheless, being one of the dominant sectors of biotechnology, the health and pharmaceutical industry[11] continues to grow steadily, as seen in Figure 1. While the USA has more than half of the global pharmaceutical market size, which reached approximately USD 1.6 trillion in 2023, China, entering the biotechnology market for the first time in 1997 with a single drug, increased its share in this market to 11 percent in a short period of time. The USA and China are also the world's largest national pharmaceutical markets. The USA accounts for 44 percent of total pharmaceutical expenditure worldwide (including Canada, 53 percent in North America), China for 7 percent (for hospital expenditure only), and Japan for 4 percent. This ratio is approximately 23 percent for Europe as a whole (including Belarus, Russia, Türkiye, and Ukraine) (IQVIA, 2024). The global health

[11] It is very difficult to define whether a company in the pharmaceutical sector is a classical pharmaceutical company or a biotechnology company. Indeed, almost all of the giant pharmaceutical monopolies have increasing revenues from biotechnology-derived drugs in their total revenues. For example, Pfizer, one of the world's leading pharmaceutical companies, generated most of its post-pandemic revenue from the COVID-19 vaccine, which is a biotechnological product. Amgen, another US company, is the world's largest pure biotechnology company. However, Swiss-based Roche is the company with the world's highest biotechnological revenue, although it also produces pharmaceuticals in addition to biotechnology (Statista, 2024c).

expenditures have increased by 35 percent in the last five years. Global usage of pharmaceuticals, which increased by 14 percent between 2018 and 2023, is also expected to increase by 12 percent in the next five years. Such increases are effective in the continuation of investments and R&D activities in the sector (Evaluate Pharma, 2024).

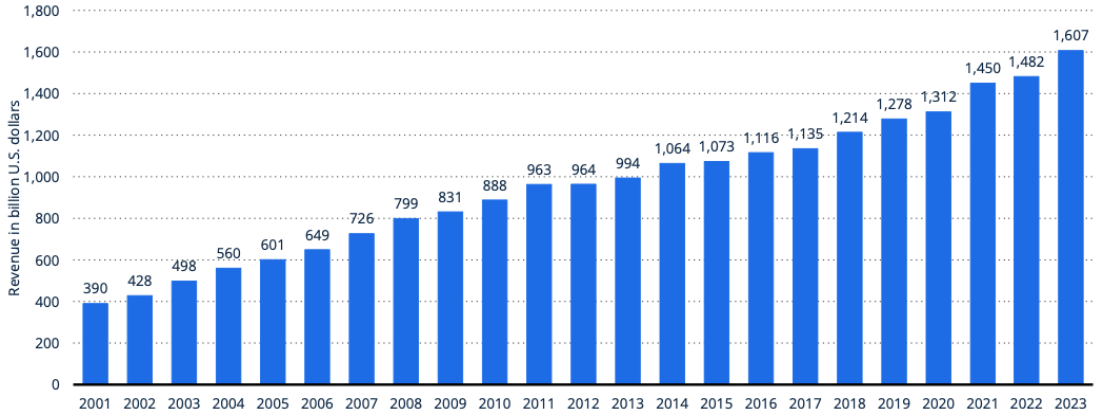

Figure 1. Revenue of the Worldwide Pharmaceutical Market From 2001 to 2023

Source: (Statista, 2024a).

Biotechnology companies worldwide allocate 27 percent of their revenues to R&D activities. A business company's annual review report for 2023 predicts a decline in this ratio to 21 percent in 2030. The reasons for this expected decline include the global macroeconomic recession, the global increase in genericising bluckbusters due to patent expiry, the US biosafety laws, and the tendency to restrict contracts with Chinese companies. On the other hand, it is asserted that these risks significantly influence the growing number of mergers and acquisitions (M&A)[12] in the sector (Evaluate Pharma, 2024). The US companies carried out 39 percent of all worldwide R&D activities in 2023, compared to 43 percent in the previous year. China's R&D rates are rising in tandem with the USA's declining R&D rates. The proportion of China-based companies involved in biopharmaceutical R&D increased from 13 percent in 2023 to 16 percent in 2024. A similar upward trend is observed in the proportion of total drugs developed worldwide. While 51.1 percent of the total

[12] As an example, in 2024, Novartis, one of the world's pharmaceutical monopolies, acquired Calypso Biotech, while Merck, another monopoly, announced that it strengthened its research in the field of oncology by acquiring Harpoon Therapeutics (Evaluate Pharma, 2024).

drugs developed worldwide in 2023 were developed with US R&D, this rate decreased to 49.1 percent in 2024. For China, this rate increased from 23.6 percent to 26.7 percent. The UK, another country with the highest number of biopharmaceutical products developed in the world, fell to fourth place, with Korea taking third place (Pharma R&D, 2024). Figure 2 shows a graph of the number of newly developed chemical and biological substances by regional origin between 1998 and 2023. These ratios and graphs indicate that the biotechnology and pharmaceutical industry continues to grow in terms of trade volume, R&D activities, and the number of drugs developed. However, although the USA maintains its position as the country that benefits the most from this growth, its growth rate is slowing down due to Far Eastern countries' increasing investments, market shares, and incomes in the sector.

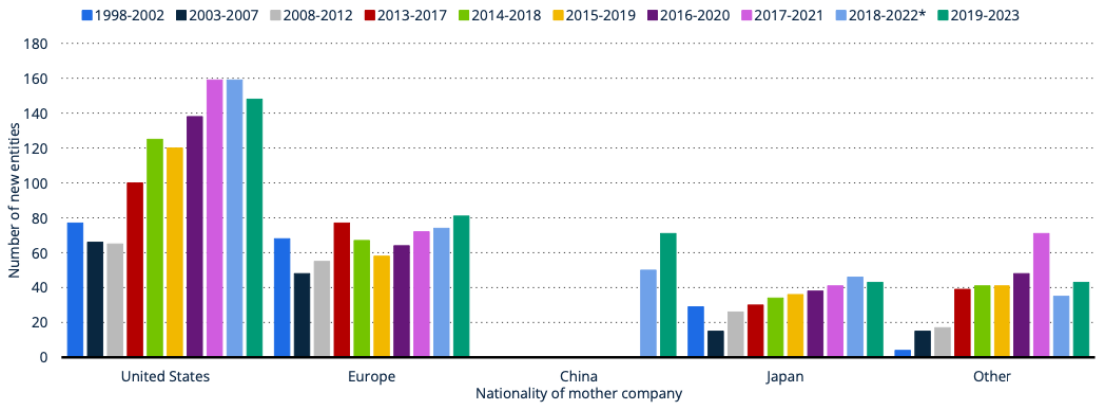

Figure 2. Number of New Chemical or Biological Entities Developed Between 1998 and 2023, by Region of Origin *Source: (Statista, 2024d)*

Along with the COVID-19 pandemic, the biotechnology sector has become the focus of attention of the whole world in 2020-2021. Having a great variety of products ranging from small molecular chemical pharmaceuticals with a centuries-old history (the use of biological processes is limited in this group; they are mostly based on chemical synthesis processes) to large complex biomolecules, R&D studies in the biopharmaceutical sector, especially in the fields of oncology, immunology, and endocrinology, have been increasing in recent years. Out of the total 608 novel active substances launched worldwide between 2014 and 2023, 201 are in the field of oncology (including supportive therapy), 68 in neurology, and 35 in endocrinology (IQVIA, 2024). Figure 3 shows that in 2027, the highest treatment expenditures

worldwide are expected to be again in these three areas. Currently, companies are focusing on breast, lung, and colon cancers, which are the most frequently seen cancers in society, while obesity and metabolic diseases, which affect 1 billion people in the world—more than 50 percent of the US population—are another important focus in R&D. In addition, the R&D studies targeting the rare diseases are increasing in number. As of 2023, the number of drug development studies on rare diseases increased to 761 from 389 in 2013. The interest in the development of anti-infective treatments varies from year to year. The growth in both R&D studies and the number of new products observed in the field of infectious diseases during the COVID-19 pandemic has almost completely halted (Pharma R&D, 2024). It is, of course, quite logical that research and new products for anti-infective treatments increase during pandemics. However, the sector's focus on areas with high profit rates, including very rare diseases, instead of taking into account the large population affected by infectious diseases, especially in poor countries, except for the pandemics, once again reveals the market-orientated structure of the sector rather than social needs.

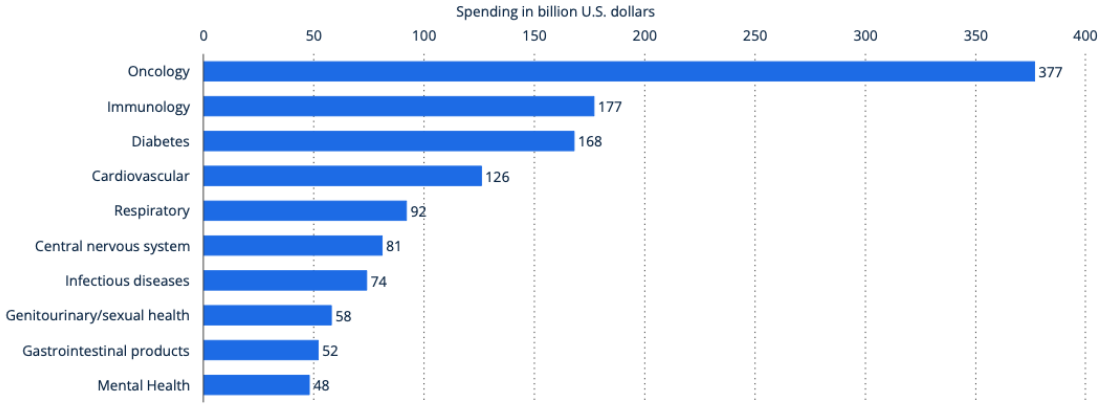

Figure 3. Projected Top Therapy Areas Worldwide in 2027, by Spending (in billion U.S. dollars) *Source: (Statista, 2024e)*

The diversity of biopharmaceutical products in the biotechnology sector, which is gradually increasing with the use of high technology and R&D studies, is predicted to increase further with the use of big data and artificial intelligence. The access and use of these highly clinically efficient medicines are gradually increasing despite their high costs, even in Latin American and Asian countries. However, in spite of

this and the growing research and trading facilities of emerging economies[13] such as China, India, and Brazil, inequalities are deepening in the production and consumption of biotechnological products. Therefore, it is of great importance for developing countries to gain the capacity to integrate biotechnology into their own research and innovation systems in line with their own needs and priorities.

2.1.3. The Role of the State in the Biotechnology Sector and Health Innovation Systems

Strategic sectors such as the biotechnology industry, which require large infrastructural and capital investments but also involve high capital risk, are often initially driven by state-sponsored programs. It is reported that the entrepreneurial role of the state in this initial phase enables a better learning process and technological orientation. On the other hand, it is a matter of debate whether the state can sustain its investments in the long term due to the intensive investments required by the sector and the long-term economic returns (Zhang et al., 2011).

Biotechnology is an industrial field that harbours high potential as well as high risk. For this reason, biotechnology has been one of the primary sectors in the efforts of states such as India, China, and the Republic of Korea to catch up with developed countries by using developmental state models. The ability of the sector to absorb high risk has been one of the reasons why East and Southeast Asian countries have not refrained from investing in biotechnology. China, a country with a large population, initially invested in the biotechnology sector to meet its food needs, but it quickly transitioned into one focused on endogenous sectoral growth and subsequently became an export-orientated sector. Asian countries' plans to catch up with developed countries are not uniform; there exist different experiences and interactions. For example, while Japan's catch-up plan is a direct “state-guided coordination”, South Korea's is more of a “state-organised” plan. Singapore, which established its biotechnology sector with very intensive state support, acted with the

[13] Brazil, China, and Indian markets grew, respectively, by 12.3%, 5.4%, and 9.9% in the 2018-2023 period. In comparison, the average market growth for the top five European Union markets was 7.4 percent, and for the USA, 8.4 percent (EFPIA, 2024).

aim of establishing a collaborative culture among institutions in addition to the massive R&D support of the state (Zhang et al., 2011).

The biotechnology sector, where innovations are quite decisive in sectoral growth and development, requires a well-developed and high-quality research infrastructure. This high technology required infrastructure also requires high investment. It is generally accepted that the state should support strategic sectors such as biotechnology with a strong science policy and R&D support. However, there are also approaches that state financial (through grants, funds, credit, and tax incentives) or legal (science-industry cooperation, patent laws) support will not be adequate to encourage this sector, as it has both high risks and high potential, and that the state should act proactively with a strategic plan. As a proof of this, the experiences of countries where the biotechnology sector has been successful in terms of knowledge transfer, technological learning, assimilation, and innovation development under a state-supported R&D model are shown (Zhang et al., 2011). However, it is known that it is not simple to maintain the production sustainability of the sector in a country where there is no economic stability, the supply of raw materials and intermediate materials is unstable, and costs are high.

In sectors such as biotechnology, which are knowledge-based rather than manufacturing-based, it is necessary to innovate in order to be competitive in the market. The innovation capacity and speed of this deep and knowledge-intensive industrial production are adversely affected by the scattering of resources such as knowledge, technology, and technical equipment among different organisations (Kang & Park, 2012). At this point, we see policy recommendations suggesting that the state should be an interface between the private sector and academia. It is stated that national and regional university, industry, and state collaborations will increase success and also reduce costs, provide technological development, and industrial deepening in high-risk and R&D-orientated sectors such as biotechnology. Etzkowitz (2002) discusses university, industry, and government cooperation with three main models. Of the models he defines as statist, liberal, and triple helix models, he claims that the last[14] one he developed is the most effective model. In all these models,

[14] The triple helix model, a model in which the state, university, and industry assume the role of each other, is closer to the model applied in the industrialised European countries (Tiryakioğlu, 2016).

where the role of the state is to regulate, support or supervise, the main objective is actually to increase added value (Tiryakioğlu, 2016).

In time, national, regional, and sectoral innovation systems have been described as more systematic and interactive models. These systems, which have different functions and importance for developed and developing countries, have come to the agenda again after the COVID-19 pandemic, especially with the content of health innovation systems.

The concept of innovation, which is included with the terms 'technological development' in classical economics and 'new combinations' in evolutionary economics, has positive content in both theoretical approaches. New technological developments (innovations in today's sense) are attributed importance for the development of social production and historical progress. According to the OECD Oslo Guidelines, innovation is a new or improved product or process (or combination thereof) that differs significantly from the unit's[15] previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process) (OECD, 2018). Unlike invention, innovation produces an economic output by being put on the market and occurs not only in the product but also in processes, marketing and organisational methods (Schumpeter, 1939).

Freeman and Perez (1988), classified innovations as incremental innovations, radical innovations, changes in the technology system, and changes in the technoeconomic paradigm (technological revolutions) according to their magnitude and effects. According to this definition, biotechnology is a sector that creates changes in the technological system by affecting more than one sector with incremental and radical innovations and enabling the emergence of new sectors. According to the evolutionary economics approach, innovation is the main driving force for the growth and competitiveness of this rapidly developing new sector of modern economies, while competition is the driving force of innovation (Schumpeter, 1942).

[15] In this definition, the firm is taken as the unit, and in this respect, it is a definition closer to the evolutionary economics approach, which points out that technology does not spread homogeneously rather than the assumption that everyone has full information as claimed by classical economics.

Various strategies have been proposed for enhancing innovation capability or capacity. These macro- and meso-level strategies vary from development-orientated national approaches to entrepreneur-orientated firm growth targets. These approaches, which can be listed as national innovation system (NIS), regional innovation system (RIS), endogenous regional development, university, industry, government cooperation, etc., can be differentiated or intertwined in practice[16].

Defined as open, evolving, systematic, and interactive modelling of institutions and economic structures, NIS have different functions and importance for developed and developing countries (Lundvall, 2015). With the concept of health after the COVID-19 pandemic, these innovation systems are back on the agenda.

Innovations in the health sector (medicines, medical devices, digital health technologies, etc.) often occur at the intersection of biotechnology, information technologies, and medical sciences. Health innovations depend not only on technological developments but also on the institutional structures and regulatory frameworks. Health innovation systems are defined as the set of structures, policies, and processes that encourage and enable the implementation of innovations in a country's health sector. They can play an important role in improving public health by increasing the quality, accessibility, and efficiency of health services if they focus on preventing diseases, improving treatment processes, and improving general health services through innovations. It is suggested that health innovation systems established through the interaction of multiple actors (governments, hospitals, pharmaceutical companies, research institutes, NGOs, and patients) have the potential to reduce health inequalities as well as increase them (Consoli & Mina, 2009). Reports assessing the performance of different countries in the development and distribution of COVID-19 vaccines have examined how innovations against COVID-19 have affected the resilience of countries' health systems (OECD, 2021b). The report discusses what needs to be done to make countries' health innovation systems more resilient to crises and emphasises the importance of the capacity to innovate rapidly in times of crisis.

[16] For example, despite the strong role of the state, the Chinese biotechnology innovation system is characterized by hybrid policy approaches and practices, such as public-private partnerships, regional innovation systems, etc., rather than a purely developmentalist state model (Zhang et al., 2011).

It has been noted that the state plays a leading role in health innovations; basic research and development investments are mostly made by the public sector, and important innovations in the field of health (vaccines, new treatment methods, etc.) are usually financed by the state (Mazzucato & Li, 2019). However, in terms of the integration of the innovations developed by health innovation systems into the worldwide health system, the concept of the global health innovation system (GHIS) has been used. GHIS comprises not only the development of innovations such as new drugs, vaccines, medical devices, and health service delivery models but also making these innovations accessible and sustainable. Moreover, it has been pointed out that beyond national health innovation systems, strong cooperation and coordination between different countries and international institutions are needed to deal with global health challenges (Mahoney & Morel, 2006).

2.2. Biotechnology and Innovation In Cuba

"Cuba's future must, by necessity, be a future of scientists." Fidel Castro, 1960.

2.2.1. The Early Accumulation Story of Biotechnological Researches

Cuba's success in biotechnology and the pharmaceutical industry today is recognised not only by scientific authorities and industry circles but also by non-socialist political actors. Cuba produces more than 60 percent[17] of the country's Basic Drug List (BDL) and many of the medical supplies and diagnostic kits it needs (BioCubaFarma, 2018), exporting its medical products to many countries and thus not only saving considerable money but also financing its own public health system (Evenson, 2007).

The biotechnology sector, which is a risky investment area requiring intensive capital flows, is generally an industrial area where large monopolies can carry out R&D and innovation-orientated studies. Cuba's biotechnological industrial trade balance has

[17] This rate varies between 60 and 80 percent in different sources and in different years. As mentioned earlier, the variation seems to depend on Cuba's ability to circumvent US sanctions and thus the amount of raw materials, reagents, and consumables it is able to procure (Martínez-Díaz et al., 2024; Evenson, 2007).

garnered significant attention due to its consistent positive performance from 1995 to 2015, despite the destabilization of even the world's strongest national economies (O'Farrill, 2018). Being an island country with limited surface and underground resources and subjected to various economic, commercial, and financial sanctions by the United States since the early years of the Revolution, Cuba is an exceptional academic case of how an underdeveloped country can develop. Although factors such as raw material resources, industrial infrastructure, human resources, science, technology and innovation policies, and the state's governance system play complex roles in a country's economic development, the Cuban state has another fundamental approach that significantly determines and influences all of these: As a socialist country since 1959, social needs and public interest are the determining factors in all policies developed by Cuba. In line with this approach, scientific work and production in Cuba are not carried out under the determination of a profit-orientated market and in competition, but in solidarity and cooperation focusing on public health and the needs of the country (Reed, 2009).

Despite its shortcomings in many sectors today, Cuba's success in biotechnology is primarily rooted in centrally planned public healthcare designed to meet the health needs of all citizens, a universally free education system at all levels, and, directly linked to these, its health, education, and science policies.

2.2.1.1. Before and right after the revolution

Discovered in the 15th century as one of the first islands of the American continent, Cuba was a Spanish colony until the beginning of the 20th century. Beginning in the second half of the 19th century, Cuba's struggle for independence included two important wars, one lasting ten years and the other three years. The struggle for independence finally culminated in the establishment of the Republic of Cuba in 1902, but this time the country was largely dominated politically and economically by the United States. Cuba's strategic geographical position in maritime trade and its large sugar plantations, which account for a significant share of the world's sugar quota, were important to the US, and the US used Cuba's struggle against Spanish

colonialism to its advantage in what historians call the “ripe fruit” theory (Navarro, 2015).

From the foundation of the Republic until the revolution in 1959, Cuba underwent many elections and coups, and the government changed nineteen times. Batista, who passed into history as an oppressive dictator, came to power with a military coup in 1952. Batista's *coup d'état* and oppressive character, as well as his being a loyal implementer of US policies that disregarded the independence of the country and the deepening of social inequalities day by day, paved the way for the gradual strengthening of social opposition in the country. In a short period of time, various organisations, especially composed of well-educated young cadres, gained social legitimacy with a discourse of independence, development, and radical democracy. One of these organisations was the 26th of July Movement led by Fidel Castro, which led to the Cuban Revolution that culminated in the escape of dictator Batista on 1 January 1959 (Navarro, 2015).

On January 1, 1959, the revolutionary government[18] that came to power identified the six most important problems in the country for priority early public intervention: land distribution, industrialisation, housing, unemployment, and the delivery of health care and education (WHO, 2015). Therefore, in all these areas, with a holistic approach, it rapidly takes action to ensure economic and social transformation. The revolution, which did not have a socialist character at the beginning, acquired a socialist character while trying to carry out these transformations. One of the first acts of the revolutionary government, which declared in 1961 that the new regime was socialism, was land reform. This was followed by the nationalisation of many companies and sectors and a literacy campaign organised through a national mobilisation. This literacy campaign in 1961, which has a very significant impact on the country's history, was not only a move towards enlightenment but also a significant move towards development. Due to the insufficient number of teachers needed for the campaign to yield the desired results, 120,000 volunteers, including middle and high school students, responded to the government's appeal (Ünlü, 2021).

[18] Today, the revolutionary government headed by Miguel Mario Díaz-Canel Bermúdez is still in power.

At the end of this year-long campaign, which brought together thousands of young educators and the rural poor, Cuba was declared a country free of illiteracy by UNESCO. The volunteer educators of this campaign, mostly young women, were encouraged to continue their education through post-campaign training programs and scholarships (Documentary, 2012). This campaign, which had important ideological consequences, from the construction of equality between the sexes to the creation of a patriotic and socialist youth, also laid the groundwork for Cuba's foray into biotechnology. Other important first actions in this respect include the activation of the Cuban Academy of Science in 1962 and the establishment of the Public Health Institutes (Villanueva, 2021).

2.2.1.2. Reorganization of health care

After the revolution, three main objectives were prioritized in the field of health (Chaple, 2005). These were;

- Expansion of state institutions related to public health
- Building rural health systems
- Reorientation of research on societal needs with medical education.

Before January 1959, health care in Cuba was provided through private, public, and public-private partnerships. There were many well-trained physicians in the country, but they mostly worked in private practices and clinics in the big cities. While some clinics operated on a monthly fee subscription system, others financed themselves through contributions from bosses and workers. The only hospitals providing free health care were located in major cities. Only one third of the total number of hospital beds in the country were under the Ministry of Health and Social Welfare, while only 23 percent of physicians were employed by the state (Belek, 2021). Under these conditions, access to health care was both geographically and economically difficult for the poor rural peasant population engaged in agriculture. Following the revolution, the government opened numerous state-owned polyclinics and implemented measures to prevent the closure of private practices and the establishment of new ones. All private clinics were incorporated into the public sector by the 1970s (Fitz, 2018).

Before the revolution, Cuba was able to produce some basic vaccines such as rabies, smallpox, typhoid and BCG. However, this did not imply that Cuba was building up and progressing in the field of applied research and laboratories (Truslow, 1951). Established in the 1950s, local companies producing some generic medicines and biological products had 30 percent of the national pharmaceutical market. The remaining 50 percent of the market was controlled by subsidiaries of foreign companies (Abbott, Squib) and 20 percent by importers (O'Farrill, 2018).

The revolutionary government's first practices in the health industry were to cut the prices of pharmaceutical products by 15 percent for domestic products and 20 percent for imported products. Following these practices, which led to conflicts of interest with foreign companies and issues with product supply, fifteen local pharmaceutical companies merged under the Consolidated Pharmaceutical Company and became affiliated with the Ministry of Public Health[19]. The nationalization campaigns carried out throughout the country resulted in foreign companies closing down their plants and leaving the country (WHO, 2015).

Among those who left Cuba after the revolution were foreign and local company executives, as well as some professionals and skilled laborers. From 1959 to 1967, 3000 of the 6300 physicians in the country—excluding young graduates—left the country. Only 22 medical professors and one medical faculty remained (O'Farrill, 2018). For the new healthcare system, in which preventive healthcare practices came to the forefront, it was essential to ensure the continuity, dissemination, and quality of medical education. Firstly, a direct relationship between medical education and the field was established. Thus, a new approach enabled both the provision of health services in rural areas and the integration of medical education with practice. This practice, just like the literacy campaign, enabled newly graduated physicians to work in rural areas with socialist and patriotic ideals. During this period, socialist countries, especially Czechoslovakia, made significant contributions to the opening of new medical faculties and the acceleration of the process of training new physicians (Roemer, 1976).

[19] After the revolution, the name of the Ministry of Health and Social Welfare was changed to the Ministry of Public Health in 1961.

With a focus on centralizing planning and decentralizing management, the health service quickly achieved significant successes. Cuba eradicated infectious diseases like polio (1963), malaria (1968), and diphtheria (1971), and its health indicators rapidly improved (Belek, 2021). However, there was another important requirement to ensure the continuity of socialized healthcare services: the supply of medical equipment, diagnostic kits, and medicines. Although Cuba alleviated the economic and commercial sanctions of the United States, which had started immediately after the revolution, with cheap commercial agreements with socialist countries (Lévesque, 1977), it had become a necessity to invest in the pharmaceutical industry in order to protect and improve the health of the people[20].

2.2.1.3. Institutionalization of science

Institutions established before the revolution, such as the Cuban Academy of Sciences, the Cancer Institute, the Institute of Tropical Medicine, and the Finlay Institute, remained largely idle; the post-revolutionary emigration of most of the researchers and administrators working in these institutions deepened the country's problem of having an experienced and qualified labour force. The Cuban Academy of Sciences, which was activated in 1962, was not sufficient to overcome this problem. In this sense, the first scientific institution established after the revolution was the National Centre for Scientific Research (CNIC). The CNIC, a non-profit organisation whose sole purpose was to integrate scientific research into public health, served as a kind of incubator for all the other scientific institutes established after 1980 that were responsible for the country's breakthroughs in biotechnology. In 1965, following the government's appeal to young physicians to devote themselves to biomedical research, thirteen young physicians began their work at CNIC, primarily aiming to deepen the researchers' knowledge of science and mathematics. In addition to physicians, the institution also employed chemists and engineers, and its young scientists soon won scholarships to study at prestigious universities such as the

[20] The economic war, which began in June 1959 with the cancellation of Cuba's sugar quota in the US market, continues with the enactment of thecelli Act in 1992, the Helms-Burton Act in 1996 and new sanctions that have been added recently. (Erdemol, 2022). At the end of this chapter, the implications for biotechnology of these laws and resolutions imposed by the US on Cuba, which have been repeatedly voted down at the UN, will be discussed separately.

Pasteur Institute, Harvard University, and Heidelberg University. The Unit of Microbial Genetics, which is part of the CNIC, started working on the recombination of genetic materials as early as 1978. Its unit of neurophysiology was later transformed into the Centre for Neuroscience (CNEURO), which has been responsible for many innovations around the world. The institution was for many years the national centre for biochemical research and education and today has trained many researchers working in the field of biotechnology (Baracca & Franconi, 2016).

By the 1980s, Cuba's greatest asset was its well-educated, highly qualified labour force. Cuba's biotechnology adventure also began in these years. Cuba's first known biotechnological product was human leukocyte interferon alpha, produced by the Biological Research Centre (CIB) in 1981. Interferon was seen as a hope in the treatment of cancer, which was increasing worldwide in those years. President Fidel Castro took a personal interest in the production of interferon, and the State Council sent six scientists to Finland for training. After a short period of training, the researchers set up a small laboratory in a state protocol house and within a year had developed the ability to produce large quantities of interferon. This small laboratory, which Castro regularly visited almost every night, became CIB and then CIBG (Centre for Genetic Engineering and Biotechnology), which today is home to many innovative discoveries (Whitefield, 2017). Interferon, which over the years proved to be not as effective as expected in cancer treatment, was used in the 1981 epidemic of dengue fever[21] in Cuba, which killed 158 people, and was found to be effective in the early stages of the disease. This renewed function of interferon has been a significant contribution to the medical community.

After the revolution, Cuba traded with Latin America and especially with the socialist countries in order to obtain the raw materials and supplies it needed in most areas. The full opening of the Eastern European socialist countries' market to Cuba in

[21] The 1981 outbreak of dengue fever in Cuba was the first laboratory-confirmed and clinically diagnosed outbreak of dengue hemorrhagic fever in the Americas. It has killed 158 people, including 101 children. Genetic laboratory studies of the outbreak, which began simultaneously in the east, west, and centre of the country, provided strong evidence that the virus was deliberately introduced into the country by the United States (Prensa Latina, 2016).

the 1960s provided, in addition to basic medicines and vaccines, the raw materials and supplies necessary for the few nationalised pharmaceutical companies to produce medicines. The quality control system established in Havana for the quality control of the medicines produced in these companies at that time has evolved into CECMED (Centre for State Control of Drugs, Equipment, and Medical Devices), which today is an important authority regulating the control of drugs, equipment, and medical devices, as well as clinical trials and imports, with the development of the national pharmaceutical industry over time (WHO, 2015).

The Finlay Institute (IFV)[22], which was restructured after the revolution to produce some basic vaccines (smallpox, typhoid, tetanus, rabies, and tuberculosis) that did not require advanced technology, produced human albumin and immunoglobulin. Domestic production of blood products, which led to a significant reduction in import costs, enabled Cuba to safely produce its own blood products at a time when HIV infection and AIDS were on the rise. This process, which Cuban citizens participated in by donating their blood, is a good example of weaving health care with social participation. Another important biotechnological product developed by IFV is the meningitis vaccine, which was started in the 80s due to the meningococcemia epidemic, which was a major public health problem in Cuba and in the world. The vaccine developed by Cuba for the first time was included in child vaccination programs in many Latin American countries and played an important role in controlling the epidemic in the region (WHO, 2015). The vaccine, trade name VA-MENGOC-BC®, received the World Intellectual Property Organisation (WIPO) gold medal in 1989. Twenty-four years later, however, Novartis applied for EU and US Food and Drug Administration (FDA) approval and then launched Bexsero, a meningococcal vaccine, which was marketed to the public as a first vaccine (O'Farrill, 2018). This case epitomises the ignoring of Cuban science and biotechnology.

The most critical component of preventive health services and a healthy society is maternal and child health. Cuba is a country that has been followed with interest by

[22] IFV was founded from the beginning in 1991 as an organisation that uses high technology in its R&D and innovation work.

public health specialists for years due to its low maternal and infant mortality rates. Routine screening tests during pregnancy and the postnatal period are effective in contributing to Cuba's success. In 1987, Cuba established the Centre for Immunoassay (CIE) to domestically produce these screening tests and develop more advanced rapid diagnosis and screening methods. Today, the CIE produces prenatal and postnatal diagnostic tests and equipment for the early detection of treatable diseases in pregnant women and newborns, as well as some infection and cancer screening equipment (Reed, 2009).

In 1982, Cuba established the National Laboratory Animal Production Centre (CENPELAB) to produce the laboratory animals and their food needed for various pharmaceutical and biotechnology studies. After 1980, Cuba gradually increased its research and production potential with the establishment of many scientific centres and institutes in the field of biotechnology, and from the beginning, Cuba has attached importance to developing effective communication and cooperation between these institutions (WHO, 2015).

2.2.2. Scientific Research Meets Technology

One of the best features of the Cuban health system is its ability to combine a public health system with high technology (Dávila, 2019). The establishment of CIGB in 1986 was one of Cuba's most important steps in the field of biotechnology. The centre, which was also planned to carry out research on animal, plant, and industrial biotechnology in addition to pharmaceuticals, vaccines, and immunodiagnostics, was equipped with high-tech equipment worth approximately 100 million dollars (De la Fuente, 2001). These investments, described in an article in Nature as “Cuba's million-dollar gamble” (Kaiser, 1998), were made with the private encouragement of Fidel Castro himself.

Cuba has holistic policies that aim to ensure that scientific endeavours go hand in hand with the promotion of public health and social development. In this direction, the first organizational structure in the biotechnology sector was established in 1981, aiming to develop innovation capability with an approach that does not only consist

of the production and marketing of biopharmaceutical products. The Biologic Front, established as a high-level policy-making body, accelerated investment processes in the biotechnology sector (De la Fuente, 2001). Having a large number of institutions under its umbrella has facilitated the implementation of interdisciplinary pilots, which has served to enhance the system's ability to innovate.

Considered a third world country with a low GDP, Cuba became a country with the basic health problems of developed countries only a decade after the revolution: Thanks to its preventive health-oriented approach, cardiovascular diseases and cancers have become the leading causes of death (Belek, 2021). It therefore quickly focuses on developing a strategy and plan for the prevention of non-infectious diseases. CIBG started to carry out R&D activities for the treatment of these diseases. In a short period of time, it began to develop and produce products such as recombinant interferon, Hepatitis B vaccine, streptokinase, granulocyte colony-stimulating factor (GCSF), epidermal growth factor (EGF) and erythropoietin, which are sold quite expensively on the international market. Some of these products are also precursors of some of the original highly effective molecules that Cuba has gifted to medical science and the peoples of the world (WHO, 2015).

The fall of socialist governments in Eastern Europe in 1989 and the collapse of the USSR in 1991 caused raw material supply problems in Cuba, not only in biotechnology but also in the country's few other sectors. Cuba's economy, which has no underground resources other than rich nickel deposits, consists of an agricultural economy based on sugar and tobacco. With the dissolution of the Soviet Union, in an instant, the sources of Cuba's basic needs disappeared. The country was left without raw materials, fuel and foodstuffs, in addition to losing its international export market (Ramonet, 2006). During this special period (1989-1995), there was a food shortage due to the lack of fuel, animal feed and fertilizer as a result of the US blockade, infectious diseases started to increase due to the lack of hygiene products, milk distribution to children was reduced from 7 years old to 5 years old, and laboratory and imaging examinations were limited (Kuntz, 1994). The country loses 35 percent of its GDP, 85 percent of its exports and more than 75 percent of its fuel supply (Dávila, 2024).

Despite these challenges, investments in biotechnology and research and development activities continued during the special period. Fidel Castro recognizes that Cuba's educated and highly qualified workforce is the country's most important capital. In addition, the capacity and ability to produce indigenous medicines and vaccines not only lightens the country's economic burden, but is also an important part of the national development and defence strategy.[23] At its 4th Congress in 1991, the Cuban Communist Party emphasized that the long-term strategy of using science and technology in the socioeconomic development of the country remains valid (Peritore & Galve-Peritore, 1995). Accordingly, some new scientific centres were established, while others were restructured. The Finlay Institute for Vaccines (IFV) was established in 1991, the National Bioproduct Centre (BIOCEN) in 1992 and the Centre for Molecule Immunology (CIM) in 1994. Over time, CNIC functions as a commercial state enterprise, focusing on product development (Sáenz, 2005). Table 2 below shows some of the scientific production centres that have been instrumental in the development of the country's biotechnology sector and are now part of BioCubaFarma[24] in their current institutional form, and some of their salient features.

Table 2. Scientific Production Centres

Institutions & Centres	**Foundation date**	**Key products & innovations or Main activities & functionalities**
ICIDCA (Research Institute for Sugar Cane Derivatives)	1963	Animal feed, bioproducts, energy efficiency, wax and waste reuse.
CNIC (National Centre for Scientific Research)	1965	Functioned as a science incubation centre
CENSA (National Centre for Agricultural Health)	1969	Re-founded in 1980
CIB (Centre for Biological Research)	1981	Produced the first biotechnological product, Interferon B
CENPALAB (National Centre for Production of Laboratory Animals)	1982	Domestic production of laboratory animals and their feeds for R&D

[23] Vaccines are vital. Foreign dependence on products that are vital for public health weakens a country's security and defense strategy. For Cuba, it is also critical to counter the biological attacks to which it has been repeatedly exposed.

[24] The following sections will provide information about this large state-owned biotechnology company.

Table 2. (continued)

CIBG (Genetic Engineering and Biotechnology Centre)	1986	Recombinant Hepatitis B vaccine and many other innovations
CIE (Immunoassay Centre)	1987	Diagnostic kits, screening materials. Reduced infant mortality rates
CECMED (Centre for State Control of Medicines and Medical Devices)	1989	Product safety, arrangement of clinical trials, regulations for import and export
CNEURO (Cuban Neuroscience Centre)	1990	Recognised worldwide by quantitative electroencephalography (qEEG)
IFV (Finlay Institute)	1991	Developed the first vaccine in the world against Meningitis B
BIOCEN (National Bioproducts Centre)	1992	Participate in the development of COVID-19 vaccines
CIM (Molecular Immunology Centre)	1994	Focused on cancer treatments, therapeutic vaccines
CIDEM (Centre for Drug Research and Development)	1994	Researches and development of pharmaceuticals
IPK (Tropical Medicine Institute)	Re-founded in 1993	Researches in infection disease, epidemiology, vaccine trials

Source: Designed from WHO (2015) and Evenson (2007).

Created in 1981, the Biologic Front was transformed into the Scientific Pole in 1992. Located in West Havana, this science park includes more than fifty academic and medical institutions (including important innovative centres such as CIBG, IFV, CIM, IPK) and employs more than ten thousand people. It aims to facilitate the export of biotechnological products by enabling its institutions and facilities to set up their own companies (Villanueva, 2021). In short, the Cuban State took many new steps during this period to turn science into an economic power.

Technological investments of millions of dollars in the biotechnology sector resulted in impressive results in less than a decade from projects carried out by centres such as CIBG, CIM and IFV. As these investments become profitable, new centres are established and equipped with state-of-the-art technology, this time costing more than 1 billion dollars (De la Fuente, 2001). Biotechnology has become the country's

second most important export earning sector, with Cuban scientists and researchers creating numerous innovative products (Belek, 2015).

2.2.3. Current Situation in Cuban Biotechnology

Biotechnology is a strategic sector for the multifaceted objectives of Cuba's National Economic and Social Development Plan (PNDES)[25] until 2030. The sector has a long history of training human capital and promoting scientific developments in the country. The creation of CNIC in 1965, the Biologic Front in 1981, the West Havana Science Pole in 1992, QUIFEMA in 2001 and BioCubaFarma in 2012 are important milestones for Cuban biotechnology. QUIFEMA is a business group created in 2001 by the Ministry of Public Health (MINSAP) to bring together factories that produce domestic generic medicines. In 2012, the biotechnology companies of the Ministry of Science, Technology and Environment (CITMA) and the pharmaceutical companies of QUIFEMA were merged into a single state-owned enterprise. BioCubaFarma is the giant conglomerate that manages this integration and coordination of biotechnology and pharmaceutical industries with different scientific and technical sophistication, regulatory standards and business cultures. Today, BioCubaFarma, which includes 7 of the 8 companies in Cuba that have been certified as high-tech companies, plays a key role in making the country's biotechnology globally recognized and increasing exports (Martínez-Díaz et al., 2024).

2.2.3.1. What and how does BioCubaFarma do?

When BioCubaFarma was created in December 2012, it encompassed pharmaceutical and biotechnology companies not only in Havana, but in all 15 provinces across the country. Under its umbrella were 16 major manufacturing companies, 8 marketing companies, 11 companies based abroad and 3 service companies (Villanueva, 2021). Today, it consists of 47 companies, 65 business units, 164 production lines and 21 scientific units. It has more than 16,000 employees,

[25] The PNDES is Cuba's current national economic and social development plan, which includes strategic priorities such as increasing Cuba's productive capacity, improving social services and ensuring economic sustainability (Presidensia y Gobierno de Cuba, 2018).

including 15,000 specialists, technicians and operators. On its website, the holding company defines its mission as “BioCubaFarma is a sustainable, efficient and competitive business organization that researches, develops, manufactures and markets pharmaceuticals, diagnostic systems, equipment and high-tech services based on scientific and technical development to improve the health of the population, produce exportable goods and services and advanced technologies in food production” (BioCubaFarma, 2024).

BioCubaFarma has saved more than 10 billion dollars for the national economy over the last decade with its pharmaceuticals, medical technology and biotechnological products for the national health system. But more importantly, it has contributed to the improvement of the country's health indicators thanks to the vaccines, diagnostic kits and treatments it produces. BioCubaFarma, which produces 8 of the 11 vaccines[26] in the national vaccination program and many screening kits, plays an important role in the country's preventive health services. BioCubaFarma has focused its product pipeline on the development of innovative products in many fields such as cancer, cardiovascular diseases, neurology, biosimilar and generic medicines, medical equipment and diagnostic reagents in line with the needs of the national health system and the country's main health problems. Another indirect contribution to public health is its R&D and production activities on products and methods to increase agricultural production and productivity in a country facing a food crisis due to the US blockade.

BioCubaFarma has established extensive technological networks and strengthened its innovation ecosystem through international collaborations and numerous agreements with the country's main universities and scientific institutions. By consolidating its scientific and technical research base, it has produced 85 innovative products and more than 2,500 scientific articles in the field of health and agriculture in the last decade. Today, it exports more than 300 products to 74 countries (Martínez-Díaz et al., 2024). This state-owned enterprise, which has around 2,500 patents registered

[26] In August 2024, after the publication of this reference article in January-March 2004, Cuban authorities announced that the newly developed pneumococcal vaccine, Pneumosil 10 Valente, was included in the island's national vaccination program. This brings the total number of vaccines produced by Cuba to 17, 12 of which are used domestically (Ballaga, 2024).

outside Cuba, sells abroad vaccines for human health, biopharmaceuticals, drugs for cancer treatment, diagnostic kits (some prominent products are shown in Table 3), as well as agricultural biotechnology products (BioCubaFarma, 2018).

Table 3. Products Prominent in Export

	Product	**Use area**
Vaccines	HEBERBIOVAC-HB	Preventive Hepatitis B vaccine
	Heberpenta	Pentavalent childhood vaccine
	VA-MENGOC-BC	Preventive Meningococcal vaccine
	Quimi-Hib	Preventive Haemophilus influenzae B vac
	Soberana 2 & Plus	COVID-19 vaccine
	Abdala	COVID-19 vaccine
Cancer Treatments	CIMAvax-EGF	Therapeutic lung cancer vaccine
	Nimotuzumab	Head and neck tumours, colorectal cancers
	HeberFERON	Basal cell carcinoma
Biopharmaceuticals	Heberon Alfa R	Cancers, viral infections
	Heberprot-P	Diabetic ulcerative lesions
	Hebervital	Chronic renal failure
	Streptokinase	Acute myocardial infarction
	Policosanal	Cholesterol-lowering medicine
	TROFIN	Nutritional supplements for immunity
Diagnostic Tools	SUMA	Ultra micro analytical system
	UMELISA	Reagent kits
	DIRAMIC	Rapid microbiological diagnosis
	PCR kits	Microbiological diagnosis
	Glucometers	Blood glucose measurement

Sources: Designed by the author

BioCubaFarma uses 58 percent of its operating revenues for the development of its companies (infrastructure, R&D, training activities) and the remaining 42 percent for the benefit of employees (personal income and personal/collective incentives). A program called “Project Life” has been established to protect and develop a skilled workforce. In addition to educational support, this program includes different topics

such as providing healthy food and housing, increasing workers' salaries (Martínez-Díaz et al., 2024).

One of the most important features that distinguishes Cuban biotechnology, namely BioCubaFarma, is its “closed loop” approach. The closed-loop approach, based on the inclusion of research, development, production and marketing activities under the same institutional roof, began to be discussed with the Biologic Front experience created in 1981 and was further developed with the Scientific Pole experience. It is a cycle in which science centres and researchers not only produce scientific results, but also follow the entire process of transforming the research results into a product, proving and registering the product's beneficial efficacy, and then taking it through the production line to society, producing both a social benefit and an economic output. It creates an obstacle to the alienation of scientists from the product and production, and encourages them to be part of the whole process from beginning to end and to feel and take responsibility at every stage. This increases the potential and speed of development of new products and makes it possible to make better investment forecasts. In short, scientific research creates its own economic engine and encourages sectoral growth (Dávila, 2007).

During the COVID-19 pandemic, BioCubaFarma played a crucial role in helping the country's healthcare system overcome this crisis with vaccines, devices and new forms of treatment. The sector's future plans include increasing research into food production to overcome another current crisis: the food crisis (León, 2023).

2.2.3.2. International collaborations and health diplomacy

BioCubaFarma contributes to the economic development of the country through the export of goods and services, as well as meeting the demands of the national health system. However, the irregularity in the supply of raw materials and reactive agents due to the blockade is the most important obstacle on stable production and exports. For this reason, international cooperation and health diplomacy are particularly important.

BioCubaFarma realizes its international business plans through partnerships or based solely on Cuban capital. As of 2024, it has a total of 12 foreign companies, 6 of which are mixed and 6 of which are entirely Cuban. It has companies with mixed capital in China, Spain, Thailand and Singapore, and companies with Cuban capital in Venezuela, Ecuador, Brazil and Mexico. In addition, it has a representative office in China and a branch office in Colombia. In the last decade, it has obtained 769 health registrations abroad and more than 2,000 registered patents.

Among the countries where biotechnology is transferred from Cuba are “southern” countries such as China, Vietnam, Malaysia, Thailand, Singapore, India, Iran, Venezuela, Ecuador, Mexico, Argentina, Brazil, Jamaica, South Africa, Algeria. Technology transfer to these developing countries takes place at the formulation, active pharmaceutical ingredient and packaging stages of production. In particular, biotechnological production in China through the China-Cuba joint venture makes a significant contribution to meeting Cuba's foreign exchange needs in relation to the size of the Chinese market (BioCubaFarma, 2018; Martínez-Díaz et al., 2024; WHO, 2015).

One of the first examples of south-south cooperation was the training of Cuban technicians in a generic pharmaceutical manufacturing plant in India in the late 1970s through a UNIDO (United Nations Industrial Development Organization) project, which resulted in the opening of a pharmaceutical factory in Havana that by 1986 was capable of producing 15 generic drugs (UNIDO, 2016). Another important south-south cooperation was established through health diplomacy between the public institutions of both countries to reduce Brazil's dependence on imports. Cuba's technology transfer increased Brazil's capacity to produce pharmaceuticals, prompting the WHO to request the partnership to produce AC meningitis vaccine for African countries. Between 2007 and 2009, 19 million doses of Cuban meningitis vaccine produced in Brazil were distributed by WHO to Burkina Faso, Ethiopia, Mali and Nigeria (Sáenz et al., 2010).

Cuba is not only building south-south but also south-north cooperation. It has signed bilateral and trilateral scientific and commercial agreements in the biotechnology

field with Canada, Australia, some European countries, and even the USA. Among these important agreements, the brain mapping project with China and Canada in 2016 stands out. CIM and US Roswell Park Comprehensive Cancer Centre established another significant scientific collaboration. CIMAvax-EGF, a highly effective immunotherapeutic vaccine developed by CIM for the treatment of lung cancer, has aroused interest in the scientific community, and US scientists have requested that US health authorities authorize clinical trials for this medicine due to its potential benefits. As a result of diplomatic and scientific insistence that Cuba's biotechnological products should be considered outside the scope of US sanctions, the US blockade was loosened for some medical products with certain exceptions. Thus, clinical trials of CIMAvax-EGF began in the US in 2016 with FDA regulatory approval. In 2018, this scientific collaboration evolved into the foundation of a manufacturing and marketing joint venture called Innovative Immune Alliance (Torres, 2018).

BioCubaFarma, a subsidiary of CITMA, has been opened to foreign investment in line with the country's new economic regulations. One such agreement was signed with a Spanish company to provide engineering services in Cuba and abroad. A similar foreign partnership has been built between Russia and Cuba to address neurodegenerative diseases. In 2020, a South-South and Triangular Industrial Cooperation (SSTIC) was established between the governments of Cuba and Slovenia, also through UNIDO (Martínez-Díaz et al., 2024; Sáenz et al., 2010; UNIDO, 2021).

The Cuban State's health diplomacy goes beyond BioCubaFarma's international scientific and commercial collaborations and partnerships in the field of biotechnology. Cuba, which has a well-developed health system and a large number of qualified health personnel, has been sending health personnel and medical aid to various countries and conducting various health education activities for decades. Since the early years of the revolution, Cuba has sent thousands of medical personnel and physicians to hundreds of countries, particularly poor Latin American and African countries. It has contributed to the establishment of nine medical schools in Yemen, Guyana, Ethiopia, Guinea-Bissau, Uganda, Ghana, Gambia, Equatorial

Guinea and Haiti. At the Latin American Medical School (ELAM), founded in Havana in 1999, some 30,000 young people from more than a hundred countries have received free medical training and returned home as doctors. Cuba also has an association of physicians that offers international medical solidarity in times of disaster and serious epidemics. Called the Henry Reeve Medical Brigade[27], it is an association of medics that mobilizes quickly to provide medical assistance in extraordinary situations such as floods, earthquakes, hurricanes and epidemics. He has provided health services to millions of people in countries such as Sierra Leone, Guinea and Liberia during the Ebola outbreak in Africa in 2014, in Italy, Jamaica and Andorra during the COVID-19 pandemic, in Haiti in 2010 and in Turkey in 2023. In 2017, the Brigade received the WHO's Public Health Award for its fight against the Ebola outbreak in Africa (JMKDD, 2017).

The Cuban health system responds to international demand not only for emergencies but also for some specialised treatments. Health care is provided in Cuba, or abroad through the legal intermediation of Cuban embassies or consulates, through some health companies, institutions or universities in thirty countries. The content of the health services provided varies from country to country, but generally, products of Cuban biotechnology with high clinical impact are in demand. Heberprot-B for the treatment of diabetic foot, therapeutic cancer vaccines, Cuban products for vitiligo and psoriasis are the most frequently requested treatments. Ophthalmology, orthopaedics and dental services are also highly appreciated (Hernández, 2023).

2.2.4. Uniqueness of the National Health System

According to Article 72 of the Cuban Constitution, “Public health is a right of all people, and it is the State's responsibility to guarantee access to quality medical attention, protection, and recovery services, free of charge. The State, in order to effectuate this right, institutes a healthcare system at all levels that is accessible to the population and develops prevention and education programs, in which the society

[27] It was first created in 2005 to respond to Hurricane Katrina, which hit the United States. However, the US government did not accept Cuba's offer of assistance. Since then, the brigade has been providing medical support to disaster areas around the world.

and families contribute" (Constitute Cuba, 2019). In addition to Article 72 of the Constitution, the concept of health is also included in articles related to rights such as "healthy environment", "healthy housing", "healthy nutrition", "health at work". The Cuban health system is also shaped around these fundamental human rights.

Cuba's health indicators, which are unparalleled in the third world and compared to those of the most developed countries, have been praised by international organizations such as the WHO, the Pan American Health Organization (PAHO), the World Bank, as well as the world's most renowned scientific journals such as The Lancet, Science and The New England Journal of Medicine (Lamrani, 2021). According to the WHO report, the main principles of the Cuban national health system are that it is state-provided, universal and free of charge, guarantees full coverage and access, has a preventive health focus, is based on primary health care, is regional, is based on social and community practice, and has an intersectoral approach (WHO, 2015).

Cuban health services are organized around three main objectives. These are; (1) centralization of planning and decentralization of management, (2) participation of community organizations in health promotion efforts, and (3) integration of preventive and curative health services as a whole (Belek, 2021). Accordingly, the Cuban health system is organized at the national, provincial and municipal levels, under the Cuban Ministry of Public Health. Health services corresponding to the municipal level are provided by family physicians and nurse practitioners in polyclinics and clinics. Approximately 80 percent of health services are provided at this level. The main function of the secondary level, corresponding to the state level, is to prevent complications and provide emergency rehabilitation. This service is provided in hospitals in the states and covers about 15 percent of all health problems. Tertiary care covers health problems related to sequelae or complications, accounting for about 5 percent of all health problems in the country. Specialized hospitals or national coordinating institutes provide this service (Domínguez-Alonso & Zacea, 2011).

In contrast to the regional delivery of health services, centralization of information obtained from the field enables rapid identification of the most important health

problems of the community. A holistic health strategy is developed with the information collected at the centre. The strategy includes planning not only to solve the problems identified but also to prevent diseases from occurring. Preventive health services are not limited to vaccinations by health professionals, health screenings for early diagnosis, follow-up of chronic diseases or education. As stated in the Constitution, direct community participation in health delivery is open to, and even encouraged. This participation takes place at different levels, from local committees to national coordination boards.

The popularly elected assemblies of each state and municipality also elect their local public health councils. These councils meet with local health centres, family doctors and community representatives to consider public health requests and recommendations. Local public health councils work directly with mass organizations. Among these mass organizations, the Cuban Women's Federation, the Committees for the Defence of the Revolution, the Farmers' Union and trade unions have the largest and most widespread organizations. Together they carry out a wide range of activities, from educational activities and street cleaning to maintenance and repair of schools and housing, blood donations and vaccination campaigns (Belek, 2021).

Another specificity of the Cuban health system is its integration across sectors and institutions. In addition to the Ministry of Public Health, several central government agencies, such as the Ministry of Labour, Social Security and Welfare, the Ministry of Food Industry, the Ministry of Housing and Urban Regulation, the Ministry of Higher Education, the Institute of Sports, Physical Education and Recreation, and of course the Ministry of Science, Technology and Environment, have different responsibilities for the protection and promotion of public health.

Cuba's unique health system has played an important role in Cuba's biotechnology achievements. Today, the domestic production of a significant portion of the vaccines included in the national vaccination program, rapid diagnostic kits used in pregnant and new born monitoring and screening, and more than 60 percent of the medicines included in the national list of essential medicines has been made possible

by the task and motivation of the biotechnology sector to respond to the demands of the health system. The relationship between Cuban biotechnology and the health system is mutually reinforcing and complementary. As the population ages, the biotechnology sector focuses on R&D for cardiovascular diseases, cancer and neurodegenerative diseases, while the health system is capable of providing rapid feedback on the impact of the sector's products on public health. During the COVID-19 pandemic, this dual interaction and integration enabled the biotechnology sector to rapidly develop vaccines and vaccination rates quickly exceeded 90 percent.

2.2.5. The Role of Biotechnology During Pandemics

The COVID-19 pandemic has plunged health systems around the world, including in developed countries, into a deep crisis. Beyond being a medical crisis, the crisis has turned into a socioeconomic and humanitarian crisis, deepening existing inequalities. It has been observed that national health systems, in which states have withdrawn from public services, the public's access to health services has been limited, and national health systems focused on treatment and individual medicine are highly resistant to such a complicated situation (PAHO, 2021). In contrast, free, inclusive, accessible, planned and integrated health systems have been found to respond better to the pandemic. In a report published by PAHO (Pan American Health Organization) before the pandemic, it was reported that the Cuban health system's methods and approaches to the prevention and control of infectious diseases offer lessons that can guide other countries in the region (PAHO, 2018).

The first case of COVID-19 in Cuba was registered on March 11, 2020. Before the first case, on January 20, the Cuban State had drawn up a prevention and control plan. On February 12, it created the COVID-19 Fighting Scientific Group, on February 17, the COVID-19 Health Observatory, and on February 26, the COVID-19 Innovation Committee (Bermúdez & Jover, 2020). Just a few weeks after the first case was detected, more than 28,000 medical students were running active screening programs (Burki, 2021).

Cuba's COVID-19 incidence and mortality rates remained below global rates due to the systematic leadership and early action of its government, the integration of

different organizations and social sectors, direct links between scientists and the government, public involvement in pandemic control, and effective social communication (Martínez-Díaz et al., 2020). But another positive factor was the key role played by Cuban biotechnology in the pandemic. BioCubaFarma produced 85 percent of the drugs used in COVID-19 treatment protocols, all of the COVID-19 vaccines used to immunize the population against coronavirus, and medical equipment such as mechanical ventilators (Martínez-Díaz et al., 2024). In this respect, Cuban biotechnology has achieved what no other country has been able to achieve in the pandemic, proving that it has an innovation potential similar to that of developed countries.

The COVID-19 Response Science Group was created by MINSAP and BioCubaFarma. It consisted of four groups: the innovation committee, the clinical expert group, the modelling and epidemiology group, and the psychology and scientific knowledge group. The innovation committee played an important role in the conduct of clinical research and the creation of innovative products. BioCubaFarma worked on 16 projects for new treatments and medical technologies to combat COVID-19. Of these, 11 were aimed at patients and at-risk groups, while 5 were preventive vaccine projects. The research was aimed at preventing infection, preventing the onset of severe disease in at-risk groups, controlling viremia in moderate disease, and reducing systemic hyperinflammation in severe disease. There were also studies aimed at reducing sequelae in recovered patients.

Some products under development before the pandemic were re-evaluated and repositioned for COVID-19. Biopharmaceuticals such as Nasalferon, Biomodulin-T, Hebertrans were used preventively in high-risk groups, while interferons such as Hebron, Heberferon R were used to reduce viremia. Immunomodulators such as Jusvinza and Itolizumab were an option to suppress the hyperinflammatory response in severe disease. The use of these biotechnological products resulted in a 7 percent reduction in the number of severely and critically ill patients, while the country's mortality rate was one tenth of the global average (Martínez-Díaz et al., 2020).

Soberana 02 and Abdala vaccines, two of the 5 vaccines developed against COVID-19, are the vaccines used in the mass vaccination of the country. Just like other

biotech companies around the world, Cuba has primarily used existing vaccine study platforms[28] to get quick results from vaccine studies, thus shortening the vaccine production timeline. As a result, Cuba has produced vaccines that have been found to have a high efficacy of over 92 percent in preventing severe illness and death due to COVID-19 under real-life conditions. Apart from Soberana 02 and Abdala, other COVID-19 vaccines produced are Soberana 01, Soberana plus and Mambisa. Mambisa is the first nasal vaccine developed against coronavirus. These vaccines have been found to be very safe compared to other COVID-19 vaccines in the world. Cuba is the only country where children between the ages of 2-18 are vaccinated and scientific studies have reported that vaccine side effects are very rare and mild, including in this age group. Another important feature of Cuban vaccines is their higher thermostability, which means more flexible storage conditions (Reardon, 2021).

Despite all these advantages, the WHO has not recognized Cuban vaccines. However, vaccine studies have been carried out according to recommended procedures and more than twenty articles on Cuban vaccines have been published in major journals. This situation has resulted in the failure to utilize COVID-19 vaccines, which could have become an opportunity to solve the economic problems caused by the arrival of only 80,000 tourists in 2020 and the 11 percent decrease in GDP in the country, which receives 4 million tourists every year. Through an agreement with Iran on Phase 3 studies of the Soberana 02 vaccine, Cuban vaccines have been used in Iran, while other exports have been limited to Vietnam and Venezuela. Although the CIBG-Mariel Biotechnology Complex, where Abdala is produced on an industrial scale, is active, the WHO has been unable to recognize Cuban vaccines due to delays in the start-up of the production line for recombinant products. The reason for this is the US blockade, which has never been relaxed, including during the pandemic (Aljazeera, 2021; Burki, 2021; Villanueva & Espiñeira, 2023).

[28] The Receptor Binding Domain (RBD) is a critical region in the spike protein of viruses such as COVID-19 that allows the virus to enter the cell. The conjugate vaccine technology that Cuba has been using for years to produce meningitis and typhoid vaccines also targeted these proteins (Reardon, 2021).

2.2.6. The Impact of the Blockade on the Cuban Health System and Biotechnology sector

As mentioned in the previous section, Cuba's export of COVID-19 vaccines has been limited or even prevented by the US blockade. Financial sanctions imposed by the United States make it very difficult for Cuba to transfer money through banks. CIBG was unable to find a bank that would honour the transfer of funds to pay for some of the materials and equipment it ordered to increase its vaccine production capacity in the pandemic, and the start-up delay resulted in the WHO not recognizing Cuban vaccines (Villanueva & Espiñeira, 2023). In this period alone, the estimated loss of revenue caused by the blockade in the biotech sector due to export losses is USD 142,886,200 between March 2022 and February 2024 (MINREX, 2023).

Under Trump (2017-2021), new financial sanctions were added to the US economic and trade sanctions that Cuba has been subjected to since the beginning of the revolution. In January 2021, the inclusion of Cuba on the list of countries supporting terrorism[29] was added to the more than 240 “preventive measures” against Cuba. As a result, the economic, commercial and financial sanctions imposed have brought Cuba's international trade, both inward and outward, to a standstill. For years, the Cuban state has been trying to mitigate this problem through numerous diplomatic negotiations and agreements with third countries and companies (MINREX, 2024).

One of the key US laws restricting the main sources of income for Cuban biotechnology is the Toricelli law[30], which prohibits ships calling at Cuban ports to

[29] Between 2012 and 2016, peace talks between the Colombian government and the Revolutionary Armed People's Forces (FARC) took place in Cuba. In addition to Cuba, other mediators included Norway, Chile, Venezuela and even the Vatican. After the talks were concluded, when Colombia demanded the extradition of one of the parties to the talks, Cuba, as a guarantor country, refused. Using this as an excuse, nine days before handing over power to the Biden administration, the Trump administration included Cuba in the list of countries that support terrorism. Since then, many companies and financial institutions around the world have refused to work with Cuba, fearing retaliation from the US Treasury Department. Dozens of banks have suspended their activities with Cuba, including transfers for the purchase of food, medicine, fuel, consumables and other goods (SoL, 2024).

[30] The Torricelli Act, officially known as the Cuban Democracy Act of 1992, is a US law that took advantage of the dissolution of the USSR to limit Cuba's international trade and financing. The key components ot the act that restrict Cuba’s trade are: (1) It prohibits U.S. subsidiaries in third countries from trading with Cuba (2) Any ship that docks in Cuba is prohibited from docking in a U.S. port for 180 days (MINREX, 2023).

pick up or drop off goods from calling at US ports for 180 days after leaving Cuba (US Archive, 2001a). For Cuba, which has no land borders, maritime trade is essential. However, due to this 1992 law, Cuban biotechnology is struggling to find new markets for the medical devices and medicines it produces. Another major impediment to the sector's commercial dynamism is that Venezuela, one of BioCubaFarma's most important trading partners, which already has few trade agreements, has also been subjected to US sanctions. As a result, the economic collapse in Venezuela has had a very negative impact on Cuba's pharmaceutical exports (Villanueva & Espiñeira, 2023).

The severity of the US blockade has increased since the collapse of the USSR, including during the pandemic[31]. In fact, the supply of medical supplies and equipment needed by Cuban biotechnology was blocked even during the pandemic. During the COVID-19 pandemic, the use of oxygen and mechanical ventilators increased in the treatment of critically ill patients worldwide. During the pandemic, it was not possible for Cuba to urgently supply oxygen from the USA, which is only 90 miles away, after a malfunction in oxygen tanks. Cuba had to procure oxygen from transatlantic countries at prices far above its cost. In addition, it was unable to receive maintenance services for its existing artificial respiration devices and was prevented from purchasing new mechanical ventilators. This is because two Swiss companies supplying mechanical ventilators were bought by the US. A similar supply problem was experienced in Cuba's increasing supply of injectors for treatment and mass vaccination during the pandemic. Japanese, German and Indian companies producing injectors did not sell Cuba the injectors it needed due to their trade relations with the US. In short, the US sanctions in question hinder not only Cuba's relations with the US, but also its commercial activities with third countries and companies (Erdemol, 2022).

Aware that foreign biotechnology companies would not have access to the drugs and vaccines they would develop against COVID-19 due to the US blockade, the Cuban

[31] During his election campaign, Obama said that sanctions against Cuba were not working and that it was in the US interest to re-establish diplomatic relations. When he came to power, Cuban-Americans were allowed to transfer money to Cuba and travel to the country for religious or educational purposes. This period was the only one with some relaxation (Erdemol, 2022).

State and people have relied on the Cuban health system and biotechnology in the fight against the pandemic. BioCubaFarma has proven to be an important pillar of national sovereignty, both in the development of the country's COVID-19 vaccines and in the repositioning of its products developed for different situations in COVID-19. Another critical contribution of the sector was the development of mechanical ventilators required by the health system during the pandemic. Cuba, which was prevented from purchasing mechanical ventilator devices due to the US blockade, overcame this problem thanks to the country's biotechnology sector with its highly qualified workforce and high innovation potential (Martínez-Díaz et al., 2024; MINREX, 2023). Cuban President Díaz-Canel has described the country's ability to find innovative and scientific solutions to the US blockade and economic problems as "creative resistance"[32]. In this sense, it can be said that creative resistance was present from the very beginning of the process of building the biotechnology sector.

US sanctions[33] began immediately after the revolution. Its nature and scope have changed from time to time. From the early years of the revolution until the collapse of the Socialist Bloc (1959-1990), measures such as the Trade with the Enemy Act of 1917, the Foreign Assistance Act of 1961, the Cuban Assets Control Regulations of 1963, which mainly restricted the export of food and medicine to Cuba, were implemented (Ciano, 2024). During this period, Cuba took steps to produce its own pharmaceuticals. Procuring the necessary raw materials from the socialist countries, Sweden and Spain, Cuba was able to produce 83 percent of the medicines it needed by the 1980s. However, US sanctions acquired a cross-border character after the collapse of the socialist bloc. In 1992, the Torricelli Act authorized the US to impose sanctions on third countries and companies that trade with Cuba. This makes it imperative for Cuba to take steps to preserve the country's independence in pharmaceutical production. Cuba's access to medicines has become very limited, and

[32] This concept has been used frequently since the pandemic by President Miguel Díaz-Canel, state authorities, scientists and other opinion leaders in society. https://www.cumhuriyet.com.tr/dunya/kuba-devlet-baskani-miguel-diaz-canel-turkiyede-kuba-dostlariyla-bulustu-2005599

[33] In a secret memorandum dated April 6, 1960, prepared by Lester D. Mallory, US Assistant Secretary of State for the Americas, the strategy for the fight against the Cuban revolution was defined as follows: To deprive the country of material and financial resources, to create hunger, suffering and despair among the population, to trigger social unrest and to subjugate the revolution (MINREX, 2023).

instead of aiming for generic drug production, Cuba has turned to biotechnology with its high scientific capacity and number of trained scientists, which has been a more effective and rational option for drug production (Belek, 2021; Dávila, 2011). The US blockade was exacerbated by the Helms-Burton Act of 1996 (US Archive, 2001b) and the Trade Sanctions Reform and Export Promotion Act of 2000 (OFAC, 2000). This prevented the sale to Cuba of goods and technologies containing more than 10 percent of US components (Lamrani, 2013).

As a result, Socialist Cuba, which was left alone with the collapse of the socialist bloc and was in a kind of economic war due to the trade sanctions of the USA for decades, has invested in the biotechnology sector by using its most important resource, qualified manpower, in order to survive. Its contribution to the country's development and independence, notably its positive impact on public health, has made Cuban biotechnology the sector of which the country is most proud. The sector's future plans include increasing research activities, this time to address the food crisis, another consequence of the blockade (León, 2023).

CHAPTER 3

METHODOLOGY

Historians of science say that science begins with man's curiosity to understand how things happen. Observing the processes that are already taking place and conducting some experiments, man uses the knowledge he gains and accumulates from these observations and experiments to understand and make sense of his existence. However, this is not the only use of knowledge. As a social being, humans also need knowledge for survival (Sheptulin, 1978).

In today's social production process, knowledge is as important and decisive a means of production as machinery, raw materials, energy, land and labour power. It contributes to the process of capital accumulation by increasing the efficiency of the production process. However, under capitalism, a class society based on private ownership of the means of production, knowledge is commodified. It is reduced to an economic value rather than a social value. However, unlike other goods, knowledge is a commodity whose value increases as it is consumed (Akçomak et al., 2016). The reproduction, distribution and consumption of knowledge is determined by the class that dominates the existing relations of production, and for this very reason it cannot be detached from the process and dealt with independently.

Based on the brief conceptual introduction above, it should be kept in mind that focusing only on observations and the measurable, or taking the existing as absolute and unchanging, in explaining processes and cases can lead to misleading conclusions. Cuba's globally recognized success in the biotechnology sector is unique to be explained by popular assumptions and parameters in the field of science, technology and innovation. Cuba, a 'third world country', has built its own sector with a high innovative capacity in the capital-intensive field of biotechnology,

where only countries with advanced levels of development and large monopolies can invest. This thesis seeks to answer the question: “How was Cuba able to achieve this unique success in biotechnology?”. The aim of this chapter is to describe the methodology used to collect and analyse the data that will be used to answer this research question.

3.1. Foundations of the Research Method

The research question is “How did Cuba, a developing country, reach an advanced level in the field of biotechnology?”. In this direction, the data collected will be analysed in order to evaluate the factors affecting the development of biotechnology in Cuba, its science and technology policies and innovation strategy.

Before attempting to understand, explain and describe the reality in the field of study, researchers should make a plan of action. This plan of action is defined as a research strategy, according to which research is organised through a qualitative, quantitative or mixed strategy (Bryman, 2016). Quantitative research is usually aimed at testing a hypothesis and is based on the collection and analysis of numerical data. The data obtained are used to examine the relationships between variables and to make generalizations. Qualitative research, on the other hand, focuses on understanding the experiences and perspectives of participants in a selected sample group through interviews and observations. It provides a contextualized relationship and is more flexible. A mixed methods strategy combines both qualitative and quantitative research methods. Thus, it is possible to provide more comprehensive and in-depth answers to the research question.

In this research, as an unusual phenomenon; the biotechnology sector of an island country with very limited raw material resources, which is incomparably more developed than the size of its national economy, will be analysed. Moreover, this country remains under a blockade for more than 60 years and is subjected to numerous economic sanctions. Therefore, in order to provide a clear answer to the research question by contextualising it properly, a more comprehensive and in-depth assessment is needed. Accordingly, in this research, it was thought that it would be

better to collect both quantitative and qualitative data and to use a mixed research strategy.

3.2. A Case Study Design

A case study is based on selecting, examining and evaluating a specific event, process, institution, person or group to understand reality. It is a powerful and systematic research method to understand a particular phenomenon in a unique context and to develop an in-depth understanding and approach. Yin describes a case study as "an in-depth investigation of a contemporary phenomenon in a real-life context, especially when the boundaries between phenomenon and context are not clear" (Yin, 2018). Cuban biotechnology is a unique case that differs from the rest of the world in terms of development motivation, investment capital, innovation process and institutional organization. Despite not having a strong national economy, Cuba has achieved success in a capital-intensive sector. In this sense, the case study design will be used to establish the contextual relationships between Cuba as a phenomenon and its success in biotechnology. Identifying these contexts can also provide a perspective for developing countries to make moves in the pharmaceutical sector, which is a strategic sector in terms of public health and national security.

One of the basic steps of case studies is to identify research questions and objectives. Yin often focuses on why and how questions in case studies. She emphasizes that the phenomenon should not be studied in isolation, but in the social, cultural, economic and political context in which it occurs (Yin, 2018). This study will investigate why Cuba, which is among the middle high-income countries but does not have a strong national economy, has nevertheless invested in biotechnology, a capital-intensive sector, and how it has achieved success in this field, which has a large amount of risk capital.

The use of multiple data sources in case studies makes the analysis and conclusions more comprehensive. In this respect, in addition to national and international reports, statistics and literature that provide quantitative data, it is important to consult interviews that provide qualitative data and document observations. This provides a

multidimensional perspective and increases the reliability of the data set. In this study, both quantitative and qualitative data will be used. For quantitative data, data from Cuban government reports, international organization reports and literature will be reviewed. Qualitative data will be obtained from interviews with managers of institutions working in the field of biotechnology in Cuba, relevant academics and public authorities.

3.3. Quantitative Data Collection

In quantitative research, the researcher collects data, draws conclusions and tests hypotheses by observing reality outside the researcher (Guba & Lincoln, 1994). In this study, first of all, data that can be used to evaluate Cuba's biotechnology should be obtained. Only in the light of these data can an objective assessment be made on whether Cuba is successful in the field of biotechnology.

Various methods can be followed to collect quantitative data. The most important of these is the examination of electronic databases. International institutional reports and databases, which researchers, investors and politicians consult to monitor economic and technological developments in the world, understand sectoral trends, make investment decisions and develop innovation strategies, provide a large amount of data. Moreover, some data sets make it possible to make comparisons according to selected variables. There are also numerous international business monitors that provide comprehensive data. However, this study prioritizes the use of data from international organizations and official government statistics, assuming that they provide more accurate data and use a reliable methodology.

Within the scope of this thesis, in order to obtain quantitative data on the biotechnology sector in Cuba, the reports of these international organizations and directly accessible reports prepared by the Cuban government were analysed. Table 4 below shows the international organizations and Cuban Institutions whose reports and datasets in the field of science, technology and economy were examined, and the links to their websites and databases.

Table 4. Institutions and Datasets Used as Quantitative Data Sources

Organizations and institutions	**Database links**
OECD	https://www.oecd.org/en/data/datasets
United Nations Institutions UNDP UNCTAD UNIDO ECLAC	 https://hdr.undp.org/data-center https://unctad.org/statistics https://www.unido.org/ https://www.cepal.org/en
World Bank	https://data.worldbank.org/
WIPO	https://www.wipo.int/portal/en/index.html
UNESCO UIS	https://uis.unesco.org/
WHO	https://www.who.int/data
PAHO (Pan American Health Organization)	https://www.paho.org/en
EFPIA (The European Federation of Pharmaceutical Industries and Associations)	https://www.efpia.eu/
ONEI (National Statistics Office of Cuba)*	http://onei.cu/
BioCubaFarma	https://www.biocubafarma.cu/
Cuba Health Network	https://www.sld.cu/

*Due to problems with internet access to this organisation's website, the data was pulled from the ONEI Telegram channel.

One of the distinguishing features of Cuban biotechnology is its motivation for research and production focused on the needs of the country's national health system. In this respect, the data of the reports obtained as a result of the searches made by typing the words “science, health, biotechnology, Cuba” into the search engines on the websites of the international institutions listed above, which may be related to the world in general and Cuban biotechnology, were evaluated.

Within the scope of the research question, it is not always possible to access the most up-to-date data in databases. In such cases, some statistical databases that provide

more generalized data were rarely used. These include Statista (https://www.statista.com/) and CEIC (https://www.ceicdata.com/en). In general, their statistics are based on data provided by the international organizations mentioned above.

In order to understand the contribution of Cuban biotechnology to the country's economy and how it has been affected by the blockade, the databases also examined some key economic indicators. Reports to the UN General Assembly on the costs of the blockade and Cuban Foreign Ministry (MINREX) reports were also utilized. In addition to data research with this grey literature[34] outside of traditional academic publishing channels, another source of data is the literature review. In addition to the theoretical framework, historical and social background, the literature review provided meaningful statistics and data for this study. For the literature review, google scholar, web of science and METU Library electronic databases were used.

When evaluating a sector, the sector's production and productivity, financial performance and contribution to the national economy are generally determined. In addition, R&D expenditures and the potential for new product development are determined. There are some difficulties in evaluating Cuban biotechnology with all these parameters and quantitative data. Underlying this is the fact that the sector is not owned by a private company or conglomerate, but has been 100% state-owned since its establishment. During its establishment, all investment was made by the state and R&D activities were prioritized according to the needs of the national health system in line with a central planning. Therefore, for example, measuring the financial performance of the sector and its contribution to the national economy requires the collection of a large amount of data and a holistic data analysis. The database and literature review conducted for this thesis did not find quantitative data covering all of these multifaceted outcomes. The quantitative data collected was used to understand some of the defining characteristics of the sector. Product diversity, number of patents, innovation capability, export capacity, trade balance,

[34] Grey literature refers to information and documents not published in traditional academic journals. Conference proceedings, government documents, policy documents, technical reports, interviews are examples of gray literature. Such documents can be an important source of information in scientific studies.

employment rates were interpreted using these descriptive quantitative data. In addition, the country's health, education and some economic data were used to understand Cuba's reasons for investing in this sector and its subsequent achievements in this sector.

Since Cuban biotechnology is not market- and profit-oriented, but social needs-oriented, and was established with a prioritized approach to health protection, data on some health indicators were used to assess the performance of the sector. In addition, some basic economic indicators were used to understand how the country's scarce resources and being a blockaded country have affected Cuban biotechnology since its establishment. The quantitative data used in this thesis can be categorized as follows:

- Descriptive data on the sector (number of products, number of R&D projects, number of patents, infrastructure, employment rates, export revenues, trade balance)
- Key parameters of the health system (mortality rates, life expectancy, health expenditures, human resources, infrastructure)
- Key indicators of the country's economy (GDP rates, HDI, R&D investments).

3.4. Qualitative Data Collection

Quantitative data is very useful in describing phenomena, and when the right methodology is used, it also enables comparisons to be made. However, case studies aim not only to describe and compare phenomena, but also to examine them in depth in their context. In this sense, descriptive data is not enough to make meaningful conclusions and inferences about the phenomenon. For this, it is also necessary to understand the objectivity, environmental factors, historical and social conditions in which the phenomenon emerged, and other elements with which it interacted. In cases where this is not done, investigations may remain superficial and may even lead to incomplete or incorrect conclusions. In short, the development of a holistic understanding of the phenomenon, the explanation of causal relationships, the generalizability of the phenomenon, and therefore its functionality in developing a

theory or testing existing theories can only be possible by examining the phenomenon in its context (Yin, 2018).

There is much important information in the literature on the achievements of Cuban biotechnology, the case of this thesis. However, this thesis is not about the achievements, but rather about understanding how these achievements were achieved. A study whose research question is based on the question of "how" naturally tends to understand and explain the concrete situation defined by quantitative data in a causal relationship by establishing the right contexts. When it comes to the public sector, it is particularly important to understand the economic, political and cultural factors that influence its emergence and development. However, understanding the changes the sector is going through and its plans for the future also helps to establish the causal relationship in a coherent and continuous manner.

In this study, we have tried to understand why Cuba, which differs from other countries in that it is an island country, ruled by a socialist regime and has been subjected to US sanctions since its establishment, decided to invest in a field with such a high level of risk capital, how it turned this decision into a success, the difficulties encountered and the motivation to overcome these difficulties. The relationships and interactions established throughout all these processes were analysed. The qualitative information required for these analyses was obtained from qualitative semi-structured interviews with employees and managers of scientific centres and institutions operating in the field of biotechnology in Cuba, as well as relevant public authorities.

Qualitative interviews are a form of qualitative research that is increasingly used in social research with the widespread use of the internet. The format of the interviews depends on the aims of the research, the researcher's questions and the situation of the participants. The qualitative interview format used in this thesis is the semi-structured interview. In other words, although the interview questions are determined before the interviews are conducted, the order of the questions can be changed or additional questions can be asked according to the answers received from the

interviewer during the interview. Thus, it is possible to remain flexible in the interviews and get more detailed information about the subject. The ability to ask additional questions to the participant in case new and unexpected information emerges during semi-structured interviews increases the diversity, depth and reliability of the qualitative data obtained. The disadvantage of such interviews is that it is difficult to analyse the data.

Within the scope of this thesis, after the semi-structured interview questions and possible interviewees were determined, approval for the research was obtained by applying to METU Human Research Ethics Committee.

3.4.1. Selection of Interviewers

Who to conduct qualitative interviews with is determined according to the purpose of the research and the research question. In order to enrich the data and deepen the study in this sense, people or institutions with the capacity to answer the research question should be identified first. One of the important criteria is that the interviewers have expertise in the subject or have direct knowledge and experience on the subject. In addition, the potential of the interviewee to provide new and unexpected information should also be taken into consideration (Patton, 2014).

Accordingly, scientific centres and institutions that make significant contributions to the development of biotechnological products and innovations in Cuba were identified. Cuban biotechnology is managed by a state-owned business group called BioCubaFarma. There are numerous companies and scientific centres affiliated to this entity. One of the unique features of its scientific centres is that they also have their own production lines. Accordingly, it was decided to establish a relationship with some of these scientific centres under the umbrella of BioCubaFarma in order to conduct interviews.

One of these scientific organisations with which meetings are planned was IFV, one of the centres that developed vaccines during the COVID-19 pandemic. Another was CIGB, which has many innovative products and patents and has a significant

contribution to the export revenues of the sector with its WIPO gold medal-winning product Heberprot-P. A meeting has been planned with CIM, which stands out with its cancer research and has established a scientific partnership with a US company through CIMAvax-EGF, a therapeutic cancer vaccine developed despite the US blockade. It was also planned to contact the management of BioCubaFarma, to which all these institutions are affiliated, and the Ministry of Science, Technology, and Environment (CITMA), to which the sector is affiliated. In addition, it was decided to determine academics from universities who could be interviewed on the subject.

The fact that the case analysed in this thesis is biotechnology in Cuba made another criterion more important in determining the interviewees: accessibility of the interviewees. The internet could have helped overcome the challenges posed by Cuba's transoceanic location in relation to Turkey and the time difference between the two countries during qualitative interviews. However, during the planned period of the thesis, the country experienced three major hurricanes, and due to the collapse of the country's energy system, Cuba experienced widespread power outages that lasted for days and recurred from time to time. This significantly limited the number of qualitative interviews that were scheduled. Initially, the ambassador of the Republic of Cuba in Ankara was interviewed, as he is a person with an academic background and has experience in establishing international collaborations in the field of biotechnology. It was also important to be able to establish a direct dialogue with the biotechnology institutes through the embassy and to overcome some of the challenges more quickly.

The first semi-structured interview was conducted face-to-face with the Cuban Ambassador at the embassy residence. After the interview, the ambassador was asked to provide guidance and assistance in contacting the institutions that were to be interviewed for this thesis. Accordingly, in addition to the Ambassador of the Republic of Cuba to Turkey, online interviews were conducted with individuals working and/or managing IFV, CIBG, and CIM organizations. Unfortunately, the planned face-to-face and online interviews with senior executives of BioCubaFarma could not be completed. The planned interview from academia was conducted face-to-face with a professor of economics who was in Turkey for a symposium. As a

result, despite all limiting factors, 5 semi-structured interviews were completed with the organisations and individuals listed in Table 5:

Table 5. Summary of the Interviewees

ID	**Institution**	**Age Range**	**Gender**	**Job Title**
A	Cuban Embassy	50-60	Male	The ambassador, a professor in political sciences
B	University of Havana	40-50	Male	A professor in the Faculty of Economics
C	IFV	40-50	Male	A project leader, manager and chemist
D	CIM	50-60	Female	An investigator studying tumour immunology
E	CIBG	50-60	Female	An engineer and a business development director

3.4.2. Determination of Interview Questions

The reports and databases of international organizations consulted for the collection of quantitative data in this thesis define countries, sectors and services based on certain indicators and make comparisons based on these indicators. However, these indicators can sometimes be misleading or inadequate due to the specific characteristics or unique dynamics of countries, sectors and services. The fact that the country analysed in this thesis is Cuba and the sector is biotechnology increases this possibility. Because Cuba is a country where it is difficult to access up-to-date data, while biotechnology is a sector whose scope has changed over the years. Therefore, it is important to interpret quantitative data together with qualitative data. Only in this way can quantitative data be placed in the right context. In short, findings from qualitative interviews are important for increasing the strength of the study.

Bryman (2016) states that qualitative research is more flexible and explanatory than quantitative research. In this context, the questions determined for semi-structured

interviews where qualitative findings are collected should be prepared to understand the special and unknown aspects of the phenomenon and to find in-depth answers to the research question in a causal way. Yin (2018) argues that interview questions should be structured to support the "why" and "how" questions of the research.

In line with these recommendations, the interview questions were structured in a form that could be expanded when necessary and allowed the interviewer to share more information. Thus, in line with the case study methodology suggested by Yin and Bryman, it was aimed to collect contextual and in-depth data and to obtain broad and detailed answers. In addition, after each interview, the questions were reviewed in order to obtain more in-depth and broad information in the next interview.

This thesis seeks to answer the question "How did Cuba, a developing country, reach an advanced point in the field of biotechnology?". With its different characteristics (island country, ruled by a socialist regime, under US blockade for 65 years), it is tried to understand why Cuba decided to invest in a field with such a high level of risk capital, how it turned this decision into a success, the challenges it faced and its motivation to overcome these challenges. Throughout all these processes, the relationships and interactions established and the imagination of the future have been tried to be informed. The 10 questions prepared in this direction were constructed with different qualities. Questions that question contextual causality, questions that allow detailed answers with their flexible structure, and 10 open-ended questions that aim for clearer and clearer information with thematic focuses were structured. These questions were used to obtain basic and contextual information and to understand the organizational dynamics of the sector. Information and data were collected on the historical and social developments that paved the way for the development of the Cuban biotechnology sector, the historical and current development dynamics of the sector, the challenges it faced, its motivation to overcome these challenges, the relationships and interactions it established.

The 10 open-ended questions used in the semi-structured interviews conducted within the scope of this dissertation and the contextual content criterias that were attempted to comprehend within are as follows:

Question 1. *Cuba's biotechnology achievements, despite limited material resources and years of blockade, have garnered widespread recognition. In addition to essential medicines and medical equipment, Cuba has developed five vaccine candidates with proven national and international effectiveness during the COVID-19 pandemic. Does Cuba have a science policy that makes these achievements possible? If so, is the policy being updated, and how?*

Historical background, dynamics of change and development, politics

Question 2. *Can we say Cuba has a holistic national strategic approach to biotechnology and innovations? If so, can you give information about it?*

Background, policy and strategy

Question 3. *What is the planning process for biotechnology production in Cuba? Did Cuba establish inter-institutional or inter-sectoral relations in this sphere?*

Planning, relationship, interaction, corporate culture

Question 4. *Does Cuba establish or consider the development of international cooperation on research and development in biotechnology important? What international collaborations in biotechnology has Cuba established so far, if any?*

Planning, relationship, interaction

Question 5. *Cuba is known for its internationalism in the field of health. Several countries dispatch international medical brigades during extraordinary circumstances, disasters, or emergencies. Does Cuba retain this kind of internationalist orientation both in the development of biotechnological innovations and in the process of manufacturing such products?*

Interaction, motivation

Question 6. *What are the challenges your country encounters in the field of innovation and the manufacturing of biotechnological products? How do you*

overcome the problem of sourcing raw materials in a country with minimal surface and underground resources?

Obstacles, challenges, adaptation

Question 7. *What are the government's endeavours in the Cuban State in terms of specialising and developing skills in the biotechnology sector? Which institutions other than universities is Cuba working with, and with what kind of cooperation and planning?*

Relationship, interaction, change and development

Question 8. *During the COVID-19 pandemic, even large pharmaceutical monopolies had some difficulties developing an effective vaccine. However, Cuba developed five different vaccines, three of which received licenses and went into use quickly. How do you think Cuba achieved this in such an extraordinary period and under such difficult circumstances?*

Challenges, adaptation, change and development

Question 9. *The Cuban government is grappling with significant economic challenges that have intensified in recent times. Do you only produce vaccines, medicines, and equipment to meet national needs? Isn't it possible to alleviate economic distress by exporting domestic products in the field of biotechnology, especially vaccines?*

Challenges, adaptation

Question 10. *Cuba submits various reports to the international public, highlighting the severe economic and social consequences of the blockade against the island. Under such circumstances, the highly educated population may be particularly likely to emigrate. How are the working lives and living standards of scientists, workers,*

and managers working in the field of biotechnology affected by this situation? What motivates and demotivates you to continue innovation and scientific productivity?

Challenges, Adaptation, Motivation, Culture

3.4.3. Analysing the Interviews

The study question of this thesis requires a contextual analysis rather than a descriptive analysis. The qualitative data required for this contextual analysis was obtained from 5 semi-structured interviews. The analysis of the semi-structured interviews presents a number of challenges. First of all, the open-ended nature of the questions carries the risk of distracting the focus during the interview. In such cases, the questions are reformulated in a different way. In addition, even if each question posed to the participants has a different focus, the answers may be closely related and transitive. Or the answers to questions that are flexibly structured in order to obtain deep and broad information may become complicated. Although all these create an opportunity for deepening the study, they make the evaluation process and the identification of keywords for thematic analysis more difficult.

In this study, the thematic analysis method was used to analyse the qualitative interviews. This approach allows the data to be systematically organized and interpreted within the framework of specific categories and themes (Braun & Clarke, 2006). After consecutive readings of the transcripts obtained from the interviews conducted within the scope of this thesis, 3 main categories and 8 themes were identified. In determining the categories, we focused on three main elements (government, institutional capabilities and adaptability) that have decisive effects on countries' technological development and innovation systems. The interview transcripts were evaluated in accordance with these 3 categories and 8 themes, and the relevant sub-themes were grouped under each theme while preserving the contextual meaning of the statements during this evaluation. Table 5 shows the categories, themes and sub-themes of the qualitative interviews. The themes have a significant interaction with each other and with sub-themes. This interaction is further enhanced by the fact that Cuba is socialist, the means of production are

socially owned and all sectors, including biotechnology, are state sectors. In this sense, some themes, sub-themes and categories are intertwined or closely related to each other.

Table 6. Categories, Sub-Categories, Themes and Sub-Themes of the Interviews

Categories	**Sub-Categories**	**Themes**	**Sub-Themes**
The state (prioritising the interests of society)	Revolution	Leadership	Revolution Independence Foresightfulness
	Policy and the strategy	Public Needs (social benefits)	National health system Priorities Economic development Social development Innovation
	Organisation	Central Planning	Priorities in R&D Central budget and investments Institutionalisation Technological sovereignty
Capabilities (of an island state with few resources)	Supporting policies, institutional structures, and qualified human resources as the infrastructure	Human potential	Learning process Education system Development Values Migration
		Integration	National health system Complementarity Efficiency Closed loop system Innovation Interphases
		Collaboration	Internationalist solidarity Technology transfer Export capacity Blockade
Adaptability	Resourcefulness	Blockade	Supply chains Export barriers Technology transfer Scientific development Innovation capability Creative resistance
	Motivation	Social values	Collective responsibility Trust Organisation culture Resistance

3.5. Evaluation of Quantitative Data and Qualitative Findings

Bryman (2016) points out that quantitative data and qualitative findings obtained through mixed study method can be analysed within the framework of a concordance model. According to this method, also called the convergence model, qualitative and quantitative data are first analysed independently of each other. After these independent analyses, common themes and inferences between the two are sought. This method provides a basis for discussing whether the findings obtained from different types of data complement each other, if so, how they complement each other, and if not, the reasons for this. Thus, a more comprehensive understanding of the case is developed. The reliability of the research increases when qualitative and quantitative data are in harmony with each other and point to the same thing. If incompatible results are obtained, new research questions arise.

Within the scope of this thesis, the quantitative data related to the Cuban biotechnology sector and the qualitative findings obtained from the interviews were evaluated separately and then the fit between the data was evaluated.

With all these findings, Cuban biotechnology is discussed in terms of state-based development models, innovation capacity and systems, and blockade.

CHAPTER 4

ANALYSIS OF THE FINDINGS

In this chapter, in order to find an answer to the research question, quantitative and qualitative findings will be inspected, and their relationship with one another will be discussed in light of the literature. The first section includes Cuba's health indicators, its human resources, statistics and values related to the biotechnology sector. The relationship of these data with each other and with Cuba's economic parameters are being inspected. In the second section, completed 5 interviews on chosen 8 topics in order to find an in depth and contextual answer to the research question will be analysed. Then in the third part, quantitative and qualitative findings will be synthesized and discussed on the topic of Cuba's biotechnology sector from three distinct perspectives. This section includes a discussion of Cuban biotechnology from a growth and development perspective, regarding innovation systems and by the effects of the US blockade.

4.1. Analysis of Quantitative Data on Cuban Health and Biotechnology

Cuba is an archipelago country, situated inside the Caribbean Sea. The total area of the Caribbean's biggest island, Cuba, is 110,860 square kilometres. Cuba, which has no land borders with any country, has its closest neighbours by sea as the United States, Haiti, Jamaica, Mexico, and the Bahamas. Governed by the socialist democracy since 1959, it is only 145 km (90 miles) away from the USA.

The population of Cuba is 11,194,44 where the urban population ratio is 77 percent. The recent annual population growth rate is -0.39. This decline is mainly due to the country's low total fertility rate (live births per woman). A total fertility rate of 2.1 represents replacement fertility, but for Cuba, this rate has been under 2 since the

1980s and recently decreased to 1.4 in 2022. Besides the net migration rate is -0.6/1000 in 2021. The median age of the Cuban population is 41.9 years whereas 73.9 percent is between 15 and 64 years old (UNICEF, 2023; WHO Data, 2023; World Bank Group Data, 2022; Worldometers, 2024). Cuba, whose population pyramid's bottom is shrinking, shows similarities with high income countries. Said shrinking has effects on labour force, pension systems, health parameters and social service organizations.

4.1.1. Descriptive Health Data of the Country Concerning the Biotechnology Sector

Since the missing properties of the official statistics in the biotechnological sector (R&D funds, exportation income, investment expenses, etc.) are quite high, defining the basic attributes of the sector is hard. Additionally, due to the ever-growing nature of biotechnology and its effects in various kinds of industries, making a country-to-country comparison is complicated. This thesis will identify and quantitatively analyse the biotechnology sector, primarily focusing on its relationship with Cuba's health system indicators.

UNDP (1999) identified Cuba as a country that has achieved a good level of human development (HDI) through its achievements in education and health in its report. HDI[35], is a more comprehensive indicator compared to GDP. It defines the basic human development of countries by incorporating indexes such as citizens' long and healthy lives, access to information, and living standards. Table 7 displays the results based on life expectancy at birth, expected years of schooling, mean years of schooling, and gross national income (GNI) per capita. In 2022, the HDI world listing ranked Cuba 85th out of 193 countries, with a score of 0.764. However, in previous years, Cuba achieved higher scores and rankings, including an HDI score of 0.784 in 2008 and 2009, and a higher ranking of 48th in 2006 (UNDP, 2024). Up until 2013, UNDP has also shared the results of HDI values of countries without including the GNI values, and in these listings, Cuba's world ranking in terms of

[35] HDI values above 0.800 are categorised as very high, values between 0.700-0.799 as high, 0.550-0.699 as medium, and values below 0.550 as low.

human development is higher. In 2012, despite being ranked 104th in the GNI world ranking, Cuba secured the 25th position (HDI: 0.894) in the HDI world ranking that excludes income. According to this result, Cuba's performance point was +79. In the same year, the USA had the score of +2 (Belek, 2021).

Table 7. Human Development Index of Cuba in 2022

Cuba in 2022	**Female**	**Male**	**Gender Gap**
HDI Value	0.750	0.771	-0.021
Life expectancy at birth	80,6 years	75.8 years	4.8 years
Expected years of schooling	15.3 years	13.7 years	1.5 years
Mean years of schooling	10.6 years	10.4 years	0.2 years
Gross national income per capita*	5.571 USD	10.373 USD	-4.802 USD

Source: UNDP Data Centre (UNDP, 2024)

**Purchasing power parity in 2017*

For many years, Cuba has exhibited superior indicators in terms of education and health parameters when compared to other Latin American and Caribbean countries in its region, as well as countries at a similar level of development and income. For instance, compared to the Dominican Republic, which is another middle-income Latin American country, Cuba's life expectancy was 76.18 in 2000, compared to 69.42 in the Dominican Republic. Moreover, the expected years of schooling is 12,445 in Cuba and 11,121 in the Dominican Republic, while the means of schooling is 9,999 in Cuba and 6,464 in the Dominican Republic. In the 2022 dataset for Cuba, the life expectancy stands at 78.15, the expected years of schooling at 14.409, and the means of schooling at 10.548, while in the Dominican Republic, these figures stand at 74.17, 13.557, and 9.151, respectively (UNDP, 2022). According to The State of the World's Children 2019 UNICEF Report, mortality in children aged < 5 years (per 1000 live births) is 4 in Cuba, whereas this rate for the Dominican Republic is 29, Mexico is 13, the USA is 7, Canada is 5, and the UK is 4. Again, according to the same report, infant mortality rate (per 1000 live births) is 4 in Cuba, 24 in the Dominican Republic, 11 in Mexico, 6 in Canada, and 4 in the UK (UNICEF, 2019).

Infant and children mortality rates are affected by various parameters. Since the 1980s, all deliveries in Cuba have taken place in hospitals. The rate of pregnant women between 15 and 49 years old getting antenatal care with at least four visits is over 98 percent. The national immunization program also includes a high completion rate of vaccinations. In Cuba, this rate is over 99 percent for all vaccines, while in Canada it varies between 71 and 95 percent depending on the vaccine (UNICEF, 2023). Polio, malaria, diphtheria, measles, tuberculosis, meningitis, new-born tetanus, whooping cough, and mumps have already been eradicated in Cuba (Ambrón et al., 2018).

Another developmental indicator of Cuba's health parameters is that the most common cause of mortality in children under 5 years is congenital anomalies, whereas in middle-income countries, preventable infectious diseases are usually among the causes of under-5 mortality (WHO Data, 2023). The most common causes of infant mortality in the country are, in order, (1) perinatal (2.7 per 1000), (2) malformations and chromosomal abnormalities (0.8 per 1000), and (3) influenza and pneumonia (0.1 per 1000). The third cause, influenza and pneumonia, which are preventable infectious diseases with a rate of only 0.1 per 1000, also serves as indicators of health development. Despite Cuba's food crises due to multiple reasons, the malnutrition rate in children is not high. In 2015, low weight rates under the age of 5 have been dropped to around 3 percent. This is largely due to increased breastfeeding rates and the government's provision of weekly essential nutrients for every child (Belek, 2021; UNICEF, 2016).

Table 8 shows the changes in Cuba's basic health indicators in some selected years. The year 1980 has been chosen in order to monitor the impact of the biotechnological sector (since the sector's establishment is in 1980) on the health parameters, and the year 1990 has been chosen to understand the effects of the dissolution of the Soviet Union and the ongoing Special Period, respectively. While 2010 was chosen as a year that the domestic biotechnology sector started to make measurable differences in public health, the years 2019, 2021, and 2023 were determined to evaluate health indicators just before, during, and after the pandemic.

Table 8. Basic Health Indicators of Cuba Over the Years

Indicators	**2023**	**2021**	**2019**	**2010**	**1990**	**1980**
Infant mortality (per 1000 live births)	7,1	7.6	5.0	4.5	10.7	19.6
Mortality in children aged < 5 years (per 1000 live births)*	8.8	9.2	6.6	5.7	13.2	24.3
Maternal mortality (per 100.000 live births)	38.7	176.6	37.4	43.1	31.6	52.6
Crude mortality rate (per 1000)	10	15	10	8	7	6
Low birth weight (per 100 live births)	7.6	6.6	5.4	5.4	7.6	9.7
Life expectancy at birth	78	74	78	78	74	73
Survival to 65 years (%)	88*	82	87	87	81	-
Current health expenditure (% of GDP)	-	13.79	11.08	10.69	-	-
GDP per capita (Current USD)	-	7.291	9,139	5,275	2,695	2,030

Source: Prepared from World Bank and WHO Data and Cuban National Statistics Institute (ONEI) 2023 reports (ONEI, 2024a; WHO Data, 2023).

** In WHO and UNESCO reports, mortality under 5 years values are better estimates based on data from previous years. In this table, ONEI's values published in 2024, which are more negative than the estimated values, are used.*

Mother and child health, is one of the most important elements of public health. As can be seen in Table 8, up until 2019, Cuba's basic health indicators has been growing positively. The fact that Cuba, which has lower GDP and health expenditures per capita compared to developed countries, has equally advanced health indicators proves that the preventive, health-orientated public medicine approach of the Cuban health system has been successful (the USA, with a GDP per capita level 6 times higher than Cuba, has an infant mortality rate of 5 per thousand, and life expectancy at birth is 78.5 in 2019). The decline in maternal and child mortality year by year is due to the organisation of the health system that guarantees pregnancy controls, as well as the use of antenatal and perinatal early diagnosis kits produced by Cuban biotechnology and, of course, childhood vaccinations. The alpha-

fetoprotein test developed by CIE is used (since 1982) to detect birth defects, and tests to detect ectopic pregnancy and trophoblastic disease (since 1992) are used in pregnancy screenings; tests for the early detection of congenital hypothyroidism (1986), phenylketonuria (2000), congenital adrenal hyperplasia (2005), biotinase deficiency, and galactosemia are used in new born (WHO, 2015). Cuban biotechnology is producing 9 out of 12 vaccines that are presented in the national immunisation program. With vaccination rates closing in to 100 percent, infectious diseases have been mostly eradicated or severe disease, mortality and morbidity rates has been dropped substantially. In Table 9, outcomes of the vaccination program in Cuba can be seen.

Table 9. Outcomes of the Cuban Immunisation Programme

Vaccines*	**Diseases**	**Year of intervention**	**Year of impact**	**Final impact**
IPV, OPVb	Poliomyelitis	1962	1962	Eradicated
TT DT DPT	Neonatal tetanus Diphtheria Tetanus Whooping cough	1962	1972 1979 1987 1979	Eradicated Eradicated Eradicated Eradicated
Measles, Mumps and Rubella MMR	Measles Rubella Mumps Congenital Rubella Syndrome Post mumps meningitis	1971 1982 1986 1986 1986	1993 1995 1995 1989 1989	Eradicated Eradicated Eradicated Eradicated Eradicated
BCG	Severe tuberculosis Tuberculous meningitis	1962	1972	Eradicated
Quimi-Hib Heberpenta-L (DPT, HB, Hib)	Hemophilus influenzae type B (Hib) meningitis. Diphtheria, whooping cough, tetanus, hepatitis B, and Hib	1999	2001	Rate <0.1 per 100 thousand population
Hepatitis B	Hepatitis B Hepatitis B in persons aged <20	1992	2001	Rate <0.1 per 100 thousand population

Table 9. (continued)

Vax-TyVi	Typhoid fever	1962	2000	Rate <0.1 per 100 thousand population
Va-mengoc-BC	Meningococcal B and C diseases	1988	1993	Mortality<98% morbidity<93%

Source: Prepared from PAHO 2018 Special Report (Ambrón et al., 2018).
[*]Some vaccines used against some diseases have been reproduced with different technologies and combinations over the years.

Despite the severe recession in the country's economy during the Special Period between 1989 and 1995, the state's decisiveness to keep funding biotechnology ended up with the ability to generate and locally produce vaccines and pharmaceuticals needs by itself. Losing most of its international market and supply chain during the Special Period, a deterioration in health indicators of Cuba could be expected by 1990. However, the strengthening biotechnology sector in the country provided a meaningful positive trend in the health indicators. Moreover, the sector has not only produced medicines and medical supplies essential for society's health, but has also enhanced its export capabilities, significantly contributing to the country's revenue. In 1995, the export of medical products generated a revenue of 125 million USD, which was 15 million more than the previous year. This revenue was further enhanced by the addition of health tourism, which generated an additional 40 million USD. Hence, during the Special Period, the problems of financing of the nationwide health system have been solved. During the same period, Cuba's health expenditures in foreign currency decreased significantly. From 1989 to 1993, said expense has dropped from 227.3 million USD to 66.9 million (Ciano, 2024).

With the advancements in biotechnology and medicine industries, Cuba became the largest exporter of pharmaceuticals in Latin America in 2004. In 2010, Cuba's largest source of export revenue after nickel was the biotechnology sector (Ciano, 2024). During this period, health indicators improved every year so that in 2013, the infant mortality rate reached its lowest value ever in the country's history, with 4.2 in 1000.

The downside observed in Table 8, as of 2019, excluding the impact of the pandemic, is closely related to the worsening of the US blockade since 2017, which we will discuss later. The problem of supplying raw materials, reactive agents, and some equipment in good enough quantities and with stability for the biotechnological industry is directly related to the aggravated economic, commercial, and financial sanctions imposed by the US. The blockade is one the most crucially damaging conditions that significantly hinder the sector's production capacity and export revenues. Due to the blockade, Cuban biotechnology is unable to manufacture some of the drugs on the country's essential national drug list, even though it has the potential to do so, and is unable to enter into foreign trade agreements (Martínez Díaz et al., 2020). UN Conference on Trade and Development (UNCTAD) reported that, between 1995 and 2022, Cuba’s medicament export income has reached its peak value in 2011 (623,198.662 USD), the lowest value in 1998 (5,401.993 USD), and after 2016 it sank below 200,000.000 USD (CEICDATA, 2023). Figure 4 shows the changes in the sector's export revenues over the years.

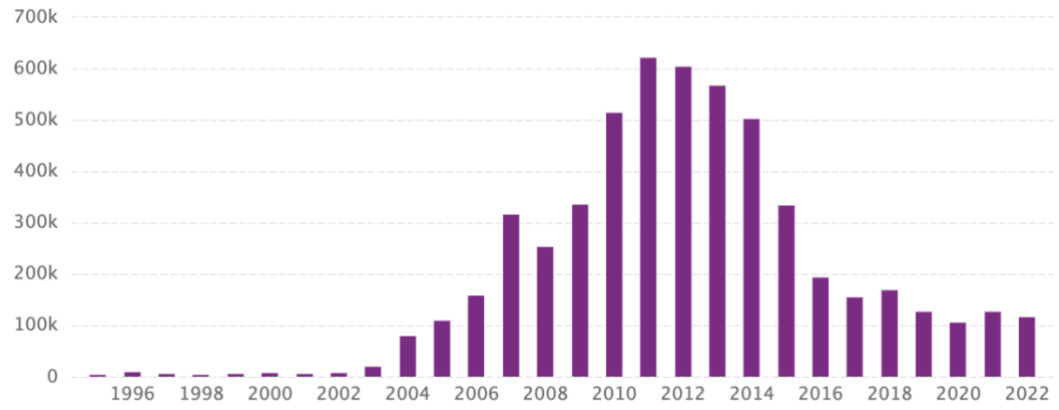

Figure 4. Cuba's Exports: Medicament From 1995 to 2022

Source: CEICDATA using data from UNCTAD

The World Health Statistics Report for monitoring the sustainable development goals (SDGs) reported that life expectancy at birth, which had declined in countries during the pandemic, has started to improve again worldwide (WHO, 2023). According to this report, life expectancy at birth for Cuba is 80.3 for women and 75.4 for men (in both sexes, 77.8), while healthy life expectancy at birth (HALE) is 66.6 for women and 69.2 for men (in both sexes, 67.8). The most common causes of mortality in

Cuba are, respectively, (1) heart disease, (2) cancer, (3) cerebrovascular diseases, (4) influenza and pneumonia, and (5) accidents (ONEI, 2024a). Such a ranking, being an indicator of health development, is the same with countries such as the UK, USA and Canada, whose country incomes and per capita health expenditures are quite high. Preventable and infectious diseases, such as lower respiratory tract infections, stroke, premature birth, malaria, and tuberculosis, which were among the causes of death in low- and middle-income countries (WHO Data Platform, 2024) disappeared as the main health problems in Cuba ten years after the revolution. The next five causes of mortality in Cuba are (6) lower respiratory chronic diseases, (7) vascular diseases, (8) diabetes, (9) cirrhosis and liver diseases and (10) intentional self-mutilation (ONEI, 2024a). Since its establishment, Cuban biotechnology has prioritised research and development (R&D) and product development to combat the country's leading causes of disease. Policosanol, which lowers cholesterol levels to prevent heart diseases, and streptokinase which is used in the treatment of acute myocardial infarction exemplify Cuba's biomedical innovations. The CIMAvax-EGF therapeutic vaccine for lung cancer, the most common cancer in men due to high tobacco consumption[36] in the society, can be added to this list. Heberprot-P, developed for diabetes complications, is the most effective medication for the prevention of limb loss due to diabetic ulcers worldwide. The Hepatitis B vaccine, which significantly reduces the incidence of cirrhosis and liver cancer, has been included in the national vaccination schedule since 1992. Recently, in 2024, the pneumococcal vaccine has been added to the national vaccination programme and will be probably effective in reducing the incidence of the only infectious disease that is among the most common causes of mortality. These and many other similar products with the directly traceable positive trends in the country’s health indicators are the most concrete evidence of the success of the Cuban biotechnology sector.

In short, the most important achievement of Cuban biotechnology is the integration of technological development with public health. In fact, a dual relation is present in this sense. While Cuban biotechnology directs its research for the needs of the public, it also uses centralised data of the national health system directly coming

[36] According to WHO Data, the rate of tobacco use in people over the age of 15 in Cuba is approximately 20 percent (WHO Data, 2023).

from the health units of the country. Thus, it is possible to get information more quickly about the effect of the products and the aspects of the products that need to be improved. In this sense, the contribution of primary health care units to the scientific studies and product development is enormous. Therefore, primary health care units do not only provide healthcare, but also generate science. MINSAP has a total of 12,918 health care units, 489 of which are social welfare units, including elderly care centres, grandparents' homes, and psychopedagogical medical centres. There are 11,222 family physician units, 251 polyclinics, 153 maternity homes, 113 dental clinics, 29 blood banks, and 12 research institutes. Out of the 149 total number of hospitals, 54 of them are general, 27 of them are surgical, 12 of them are gynaecological, 4 of them are mother-child, 22 of them are paediatric, and 30 of them are specialised hospitals (ONEI, 2024a).

One of the health indicators used to monitor countries' SDGs is the ratio of hospital beds to population. In Cuba, the ratio of hospital beds is 4.2 (per 1000), which is above of the developed countries and world average. The total number of hospital beds in 149 hospitals and clinical centres that provide inpatient health services is 62.825[37]. The research institutes have also 752 hospital beds (ONEI, 2024a). In the Table 10 below, Cuba is compared to the two important countries of world biotechnology sector the USA and the UK, including some health parameters related to SDGs of the countries. The EU and global averages are also included.

Table 10. Cuba in Comparison with the 'First World'

	Cuba	**USA**	**UK**	**EU**	**Global**
Density of doctors*	84.3	35.6	31.7	36.6	16.3
Density of nurses and midwifery*	75.7	124.7	91.7	83.4	39.4
Density of dentists*	16.7	6	5.2	6.2	3.3
Number of hospital beds**	4.2	2.7	2.4	5.3	3.3
GGHE-D /GGE (%)***	16.4	22.4	19.5	12.6	10.7
Human Development Index 2022	0.764	0.927	0.940	-	-

[37] According to ONEI statistics, 15,123 of these beds are social assistance beds (ONEI, 2024a).

Source: UNDP Data; World Bank Data, WHO 2023
[*]Between the years 2013-2021, per 10.000 population
[**]In 2021, per 1.000 population
[***]Domestic General Government Health Expenditure as a percentage of General Government Expenditure in 2020

Cuba's national income, who is behind the USA and the UK in terms of the share of the government budget allocated to general health expenditures, certainly cannot be compared with 'first world countries'. Nevertheless, the public health and education have always been a priority to Cuban Government, and even in most economically difficult times, the necessary expenditures and investments in these areas were not abandoned[38]. In the table above, it can be seen that Cuba is in a better position than not only world average, but also UK and USA in terms of number of doctors and dentists per population, and the number of hospital beds. According to the statistics of ONEI (2024a), when these rates are reversed, population per doctor is 127, and the population per dentist is 705. It can be predicted that such a high numbers of health staff and physician will also increase the quality of health services. The data show that the Cuba's biggest asset is its human capital. The high number of qualified and educated people, which is influential in the Cuba's health indicators that can compete with developed countries, is also one of the most important pillars of the success of the biotechnology sector, working integrated with national health system.

4.1.2. Human Capital Formation and Skills Development

Since 1959, the Cuban State has allocated a significant portion of the country's revenues to the education of human resources. This investment in human capital has been instrumental in making Cuba, a developing country, known for its advanced health indicators and biotechnology in the 21st century. The primary goal of the democratization of education that began immediately after the revolution was to ensure access to education for everyone. Today, for every 100,000 inhabitants, there are 644 enrolments in primary education, 296 in secondary education, 109 in pre-university schools, 175 in technical and professional schools (147 for intermediate

[38] Despite the huge deficits created by the blockade in the country's economy, health expenditures, which were 11,193 million USD (987 USD / per capita) in 2018, increased to 12,124 million USD (1072 USD / per capita) in 2022 (World Bank).

technical education, 28 for qualified workers), and 257 for universities (ONEI, 2024c).

In Cuba, almost all of the population completed the 9 years of primary and lower secondary education. Pre-university schools, which are the next stage after the lower secondary education, are divided into two as basic sciences and medical sciences schools in Cuba. In the country, higher education is the responsibility of more than just one institution. While the universities of medical sciences are affiliated to MINSAP, the rest is affiliated to Ministry of Education (MINED), Ministry of Higher Education (MES) and National Institute of Sports, Physical Education and Recreation. These institutions (with the exception of the schools of medical sciences, which are affiliated to MINSAP) have been gradually integrated to improve the quality of education (WHO, 2015). Table 11 shows the Cuban upper secondary and the higher education schools in numbers.

Table 11. After Lower Secondary Schools in Cuba

Education level	**Number of schools**	**Teaching Staff**
Preuniversity Urban Rural Exact sciences	307 in total 259 32 16	15.930 in total
Technical and professional	410	27.466
Adult schools for peasants	473	4.515
Art schools	37	3.293
Sport schools	35	3.576
Superior MES affiliated MINSAP affiliated Others	50 in total 22 16 12	50.293 in total 17.145 32.943 210
Municipality university	122	-

Source: *Designed from the Education Reports of the Cuban National Statistical Institute (ONEI, 2024c)*

Today Cuba has 13 university of medicines across the country, while this number was just 1 in the early 1960's. Additionally, there are 25 schools of medical sciences,

4 schools of dentistry, 4 schools of nursing, 4 schools of health technology, 26 centres affiliated with medical sciences, 46 centres affiliated with municipal universities (WHO, 2015). As a result of this, as of 2023, the country has 80.763 doctors, 14.542 dentists, 73.284 nurses and 79.933 other health personnel (ONEI, 2024a).

Being related mainly with health, biotechnology sector also has numerous engineers, chemists, physicists, mathematicians etc. working in. The sector requires high and medium expertise level technical personnel as well as researchers with advanced education in the production process. In Cuba in 2023, total number of people who are working in science and technology areas is 91.310. The ones who have higher levels of education are 54.503 people, 19.685 of them also has PhDs. Also one another striking factor is, according to ONEI stats, more than half of the people who are working in the fields of science and technology are woman (50.633 out of 91.130) (ONEI, 2024b). This is in line with the country's statistics on the level of higher education. As can be seen in Table 12, out of people who are initially enrolled, graduated or post-graduated from higher education, number of women is higher, especially in the natural sciences, mathematics and medicine (ONEI, 2024c).

Table 12. Number of Students in Higher Education Levels

2022-2023	**Initial enrolment**		**Graduates**		**Postgraduate***	
	Total	Women	Total	Women	Total	Women
Higher Education	265.086	174.502	36.770	24.380	322.547	175.204
Technical sciences	30.121	11.219	4205	1.782		
Natural sciences and mathematics	4.143	2.474	473	307		
Medicine	77.288	56.247	13.456	9.249		

Source: Data from the Cuban National Institute of Statistics is used (ONEI, 2024)

**43.210 of the postgraduate students are at the master's level, while 6.133 are at the doctorate level.*

In 2001, in a study led by the World Bank, countries were categorized based on their scientific prowess as, (1) developed, (2) proficient, (3) developing, (4) lagging. In this list, from Latin America countries only Cuba and the Brazil was placed in proficient category. A decision by the CITMA, created in the mid-1990s, to establish a series of science centres in the national interest was instrumental in this. As an example of these centres, National Institute of Agricultural Science against the food crisis of the country or Institute of Meteorology against the hurricane problems of the country can be counted. However, what really shines out is the foundation and reconstruction of 21 scientific centres, which today are gathered under the roof of BioCubaFarma, the company that manages and directs the country's research and production in the field of biotechnology (Arxer, 2010).

Today in Cuba, there are 143 research centres, 30 scientific and technical service centres, 74 development and innovation units, 2 science and technology parks, 7 science and technology companies which act as interphases, 1 innovation and development institution, 9 high technology companies. Numbers of science, technology and innovation entities are increases year after year (ONEI, 2024c).

4.1.3. Cuban Biotechnology and the Government Support

BioCubaFarma, which gathers all components of Cuba's biotechnology sector under its roof, is a state-owned enterprise that produces pharmaceuticals, medical technology and biotechnological products for the improvement of human health and agriculture. There exist 47 companies, 21 science, technology and innovation institutions and 8 high technology companies which are affiliated to BioCubaFarma. Furthermore, it has 65 work units and 164 production lines. The company which has over 16.000 workers, stood out with having 6.048 employees who are involved in the research, development and innovation areas, this coincides with more than 30 percent of its human capital. In BioCubaFarma, 1.265 employees have acquired master’s degrees while 265 have acquired PhD degrees.

Cuban biotechnology has advanced beyond the national borders with international scientific agreements and joint research centres. 12 of 47 companies in the

BioCubaFarma are international. 6 of these are run by Cuban capital solely, whereas other 6 are partnerships[39]. The main products produced are drugs and biopharmaceuticals for the prevention of oncological, cardiovascular, diabetic and infectious diseases in accordance with the needs of the national health system. Generic medicines, diagnostic reagents and medical equipment are also produced[40]. National Health System is supplying 795 products from BioCubaFarma as of 2024. These products include medicines for hospitals and pharmacies, diagnostic kits, clinical chemical reactive, medical equipment and devices, and some medical care items. BioCubaFarma produces more than 60 percent of the drugs on the national basic drug list, which currently stands at 395 drugs. The total number of products produced for the domestic market is 1,600. Its R&D&I system has more than 80 technological platforms, and as of 2024, it has 396 projects at different stages of R&D&I. Projects in the areas of human health, oncological, infectious, neurodegenerative, autoimmune, and cardiovascular are shining out. In addition to human health, projects related to agriculture and animal husbandry are also ongoing (BioCubaFarma, 2024).

The BioCubaFarma has more than 2400 registered patents in and out of Cuba. Between the years of 2020 and 2022, Cuba's most patenting entities under the WIPO (World Intellectual Property Organization) PCT (Patent Cooperation Treaty) system are in the field of biotechnology. CIBG, which stands out with its interferon production and recombinant protein technology has 17 patents, CIM which carries out studies especially on cancer and autoimmune diseases has 8, IFV, which is a vaccination institute has 4, CIDEM which is a pharmaceutical research and development institution has 4, CNEURO which is famous for its devices and

[39] Notable international joint ventures are with the US-based company Innovative Immunotherapy Alliance S.A., the UK-based company SG Innovations Limited, and the China-based company Changheber. The other partnerships include Japan, Malaysia, and Singapore (Orinoco Tribune, 2020; On Cuba, 2020; Roswellpark, 2021).

[40] On BioCubaFarma's website, in the product portpolio for 2022-2023, there are a total of 218 products from scientific institutions with their own companies. These include 113 products of AICA, which produces laboratory and pharmaceutical products; 32 products of Immunoensayo, which produces diagnostic kits; 16 products of CIBG; 11 products of CIM; 4 products of ONIO, which produces cholesterol medicines and nutritional supplements; 20 products of COMBIOMED, a digital medical technology company; 17 products of CNEURO; and 5 products of IFV (BioCubaFarma, 2024).

computer systems developed for neurological disease has 2 patents (WIPO, 2022). The summary of the data of BioCubaFarma can in Table 13.

Table 13. BioCubaFarma in Numbers

<table>
<tr><td rowspan="2">Companies 47</td><td colspan="2">Domestic 35</td></tr>
<tr><td colspan="2">Abroad 12</td></tr>
<tr><td colspan="3">Entrepreneur units 65</td></tr>
<tr><td colspan="3">Production lines 164</td></tr>
<tr><td colspan="3">Scientific Centres 21</td></tr>
<tr><td rowspan="3">Employees + 16.000</td><td colspan="2">Professionals, technicians, operators + 15.000</td></tr>
<tr><td rowspan="2">R&D&I personnel 6048</td><td>Master’s 1265</td></tr>
<tr><td>Doctorate 265</td></tr>
<tr><td colspan="3">Products + 1600</td></tr>
<tr><td colspan="3">R&D&I projects 390</td></tr>
<tr><td colspan="3">Patents + 2400</td></tr>
</table>

Source: BioCubaFarma website (BioCubaFarma, 2024).

According to the annual Science and Technology statistics by ONEI (2024b), Cuba obtained 55 patents in 2023. Of these, 17 were from domestic applications, while 38 were from non-domestic applications. In contrast, the number of patents obtained in 2019 was 115. BioCubaFarma, having world-renowned and important patents and commercial brand portfolios, has taken approximately 60 patents per year between 2013 and 2016 just from pharmaceutical products. This number was about 30 in between 2006 and 2017 in biotechnology products (Villanueva & Espiñeira, 2023). The blockade is believed to be responsible for the significant decrease in patents in official documents in recent years.

In Cuba, a total of 242 academic scientific journals are published today. 167 of these are in the form of digital, 42 of them are printed, 33 of them are both digital and printed. More than half of these are in the area of biotechnology. Most of these journals are in the field of medicine with the number of 62, followed by pedagogics

with 39, agriculture with 31, technology with 23 and sociology with 18 (ONEI, 2024a).

Cuban biotechnology who started its path with interferon production, with country's investments and qualified human capital, progressed rapidly. Preventative vaccines generated for the national health system's needs in time made the export potential grow. Up until 2001, all said investments in the sector was financed by the government. As seen in Figure 4, the rapidly increasing export revenues of the sector led to a different financing plan in 2001. It has been decided that the sector was going to pay the current expenditure with its own income, however, the investments done on the sector was within the boundaries of central planning (WHO, 2015). For the research purpose of this thesis, contribution of the sector into country's net income couldn't have been found unfortunately. However, it can be seen that, with the sector's product diversity, quality and sheer number of produced goods has allowed the country to make substantial savings, also, with the developed preventative vaccines and treatments made medical expenditure lower in long term. In an assessment covering the years 1995-2010 - prepared according to the data of countries importing from Cuba - it was reported that Cuba's pharmaceutical and biotechnology sector trade balances were always positive except for 1998, 2004, 2005 and 2008 whereas it is always positive for vaccines (O'Farrill, 2014). Additionally, it has been reported that Cuba's total export in 2018 was made up of 48 per cent medical services (6.4 billion USD) and pharmaceutical products (400 million USD) (ECLAC, 2020).

Numerous international institutions reported that among Latin American and Caribbean countries, Cuba's has a high share of GDP expenditure on R&D (GERD). It is emphasised that, after Brazil, Cuba has the second highest GERD in the region. In terms of GERD, World Bank notes can be summarized as:

Between 1996-2021, Cuba's GERD ratios changed between 0.4 and 0.5. The highest GERD ratio was in 2009 with 0.615 and lowest was in 2011 with 0.272. During the pandemic period, these rates were 0.518 per cent in 2020 and 0.323 per cent in 2021. For Brazil, which has the highest GERD rates in the region, this rate generally

ranged between 1 and 1.2 per cent between 1996 and 2021, and it reached its highest rates in 2015 with 1.371 per cent. The average GERD rate of the countries in the region varies between 0.2 and 0.5 per cent. Worldwide, this rate varies between 0.25 and 1 per cent.

In terms of GERD, the highest ratio around the globe is found in Israel, with 5.557, followed by South Korea with 4.93, USA with 3.457 and Belgium with 3.43. As can be seen in Figure 5, GERD ratios of these countries had risen year by year whereas Cuba and Brazil's ratios has not experienced a meaningful change. Lastly, in ONEI (2024b) statistics, Cuba's 2022 and 2023 expenditure in science and technology in research, development and innovation has risen.

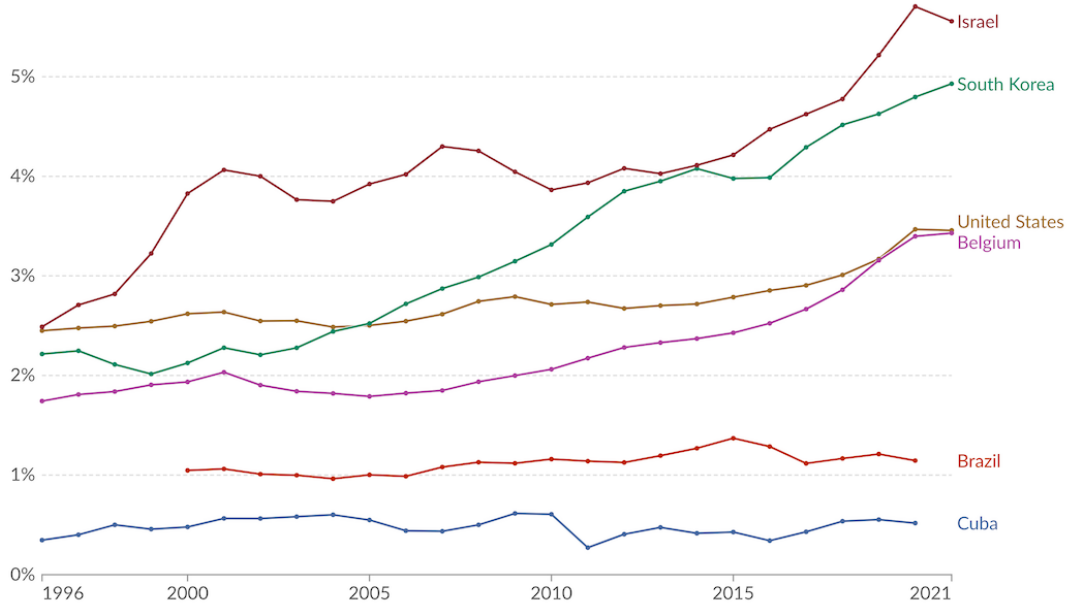

Figure 5. R&D Spending as a Share of GDP (GERD)

Source: Compiled by World Bank

The countries which do not make use of technological advancements or increase the overall educational levels cannot increase the quality of life of their citizens or protect the ongoing well-being of their people. In this sense, it is important for states to support scientific development by allocating a share from their budgets to R&D expenditures. However, as can be seen from the data above, small changes in GERD ratios are far from explaining Cuba's achievements in the field of biotechnology, especially considering the large gaps between the GDP levels of countries. With

GERD ratios generally hovering around 0.4-0.5 per cent, Cuba has achieved success in the field of biotechnology at the level of countries that devote much higher proportions of their GDP to R&D in science and technology. It should be remembered that a similar situation is also observed when the ratio of Cuba's health expenditures to GDP and per capita health expenditure data are analysed.

4.1.4. Quantitative Description of the Blockade's Impact on Public Health and Biotechnology

Cuba has managed to reach Special Period GDP levels prior to Special Period of 1990, again only in 2007 (Medina Borges & Garrido Céspedes, 2022). From 1993 to 2019 the increasing GDP (current USD) and GDP per capita (current USD) values has once again started to decrease in recent years. According to ECLAC (2023), the GDP and GDP per capita were 107,352 billion and 9,449 USD respectively, but in 2022, these values decreased as 16,446 billion and 1,449 USD. Cuba’s real GDP grew by 2 percent in 2022 (it was 1.3 percent in 2021, and -10,9 percent in 2020) (ECLAC, 2023). This economic downturn is driven not only by the pandemic but also by the economic and political crises in some of the countries with which Cuba maintains international trade (Venezuela, Russia, Ukraine). Figure 5 shows the changes in total annual GDP per capita (current USD) of Cuba, Venezuela and Caribbean countries between 1990 and 2022. For comparison, Venezuela, one of Cuba's most important foreign trade partners, and the Caribbean, whose economies were similarly affected by the COVID-19 pandemic due to the tourism sector, were selected. As can be seen, Cuba's GDP per capita values, which were higher than both the Caribbean and Venezuela in 2020, are below both countries by 2022 and even lower than 1990. Cuban economy in the recent years is experiencing a similar shrinking to the times of USSR’s falling crisis. The excessive rise in the prices of some imported products due to the economic, commercial and financial sanctions imposed by the United States - and the worldwide impact of the Ukraine-Russia War - and the reduction in the trade volume with Venezuela have resulted in an increase in the country's import expenditures and a decrease in export revenues. Cuba's increasing financial deficit increases its dependence on foreign currency. One of the most important foreign exchange sources of Cuba is the tourism sector. However,

while tourism in the rest of the Caribbean has revived after the pandemic, Cuba's tourist numbers have still not reached pre-pandemic levels. It has been reported that this is related to Cuba's inclusion in the US list of countries supporting terrorism in 2021, and that the blockade has negatively affected the number of tourists visiting Cuba and tourism revenues (MINREX, 2024).

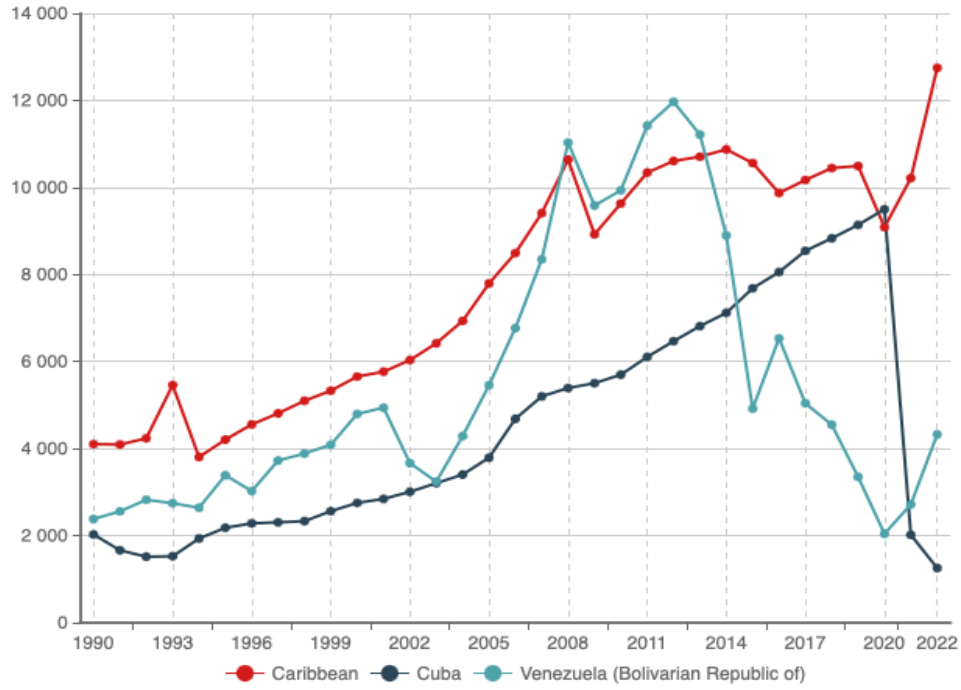

Figure 6. Total Annual GDP Per Capita (Current USD)

Source: ECLAC statistical database (CEPALSTAT, 2024)

Cuba's fiscal deficit to GDP ratio in 2022 is 11.1 percent. Due to the challenges in acquiring raw materials, the yearly inflation ratios for the years 2019, 2020, 2021, and 2022 are as follows: -1.3, 18.5, 77.3, and 39.1 (ECLAC, 2023). The Cuban State and the UN General Assembly point out that these are closely linked to the intensifying US sanctions (UN, 2024). In a general sense, Cuban health sector is also negatively affected by the blockade. In 2021 in order to compensate the need for currency, investments into the tourism sector have risen by 45.6 percent, on the other hand, investments into the health sector has dropped by 0.8 percent (Villanueva & Espiñeira, 2023)[41].

[41] Despite the challenging economic conditions, Cuba aims to increase the share allocated to fundemental services in the 2024 budget. It is planned to allocate 63 percent of the budget for public health, education and social security. This equates to an increase of 37 percent (Global Data, 2024).

Cuban Report, prepared pursuent for UN General Assembly's 78/7 numbered "USA's economic, commercial and financial blockade on Cuba should be ended" named judgment, states that, blockade's economic cost to biotechnology sector from March 2023 to February 2024 is 124.169.500 USD (MINREX, 2024). Same values are found to be 142.886.200 USD for the previous year (MINREX, 2023).

The US Trade Sanctions Reform and Export Enhancement Act of 2000 prevents Cuba from importing goods with more than 10 percent U.S. content. This law alone prevents the biotechnology sector from accessing some materials and equipment required for R&D activities and production. According to MINREX's 2024 report, IFV was unable to carry out a total of 7 operations required for vaccine production last year, including 4 reagents and raw materials, 1 input and 2 equipment, due to the blockade.

The blockade on the sector and health system not only causes problems with supply chains, but also involves a multitude of complex factors. According to MINREX's (2024) report, in the previous years the number of surgical operations that could have been done was around 1 million; today it is just 65 percent of that number. As of the end of February 2024, a waiting list of 86,141 patients (9,000 children, 44,408 eye surgeries, 5,000 general medicine, urology, orthopaedics, and 200 cardiovascular surgeries) is present. Although more than 20 medical devices, such as technologically obsolete incubators, thermal cradles, and neonatal ventilators in neonatal wards, are in need of renewal, they cannot be imported due to the blockade. In addition, the United States launched anti-propaganda against Cuba's international medical cooperations and blocked the country's revenue stream from exported professional medical services. A medical mission in a country was recently cancelled because banks did not want to do transactions. As a result, it was calculated that the cost of the blockade on the health sector in the period from March 2023 to February 2024 was at least 268,515,210 USD (28,700,000 USD more than the previous year).

The biotechnology sector can only meet 51 percent of the Basic Drug List of 651 items, as of June 2024. In addition, the national protocol that guarantees a 120-day

drug stock cannot be followed; the stock period has recently been reduced to 30 days. In short, the national health system, which resisted the US blockade in the 1970s by establishing its own independent pharmaceutical and medicinal supply production system, is facing new challenges due to the Trump Administration and the fiscal, economic, and financial sanctions that have escalated during the pandemic.

4.2. Interpretation of the Qualitative Findings Through the Interviews

In this section, the content of the interviews will be analysed under eight themes on the factors that have influenced the emergence and progress of the Cuban biotechnology sector, the interactions and relationships that exist in the R&D, production and innovation processes, the difficulties encountered, and the understanding of the dynamics of change and development in the sector. These 8 themes were determined according to 3 main categories and sub-categories in order to evaluate the success of the sector in a context. In determining the categories in this thesis, theoretical approaches that draw attention to the impact of the strategic role of the state, institutional organisation and adaptability in the technological development and innovation systems of countries are taken into account. The prominent themes in the interviews were grouped according to these categories. However, due to the fact that Cuba is a socialist country, that the means of production are owned socially, that all sectors, including biotechnology, are state sectors, and that all institutions are state institutions, there is a close intertwining or close relationship between categories and themes.

The first category, the state, was examined under the subcategories of revolution, political and strategic orientation and organisation, all of which are influential in its structure that prioritises social interests in Cuba. Within this category, three themes were assessed: revolutionary leadership, public needs, and central planning. The second category, which focuses on the evaluation of organizational capabilities, analyses the infrastructure of a resource-limited island nation that lays the foundation for the development of biotechnology in the context of supportive policies, institutional structure, and human resources. The themes of human potential, integration, and collaboration are analysed under the second category. The final two

themes, embargo and societal values, were analysed within the adaptability category, specifically in relation to the subcategories of challenges (resource scarcity) and motivation. Table 14 presents a simplified tabulation of the content transcribed from five semi-structured interviews according to the identified themes.

Table 14. Evaluation of the Interviews by Thematic Analysis

Categories	**Themes**	**Sub-Themes**	**A**	**B**	**C**	**D**	**E**
The state (prioritising the interests of society)	Leadership	Revolution	+	+	+		+
		Independence	+				
		Foresightfulness	+		+		+
	Public Needs (social benefits	National health system			+	+	+
		Priorities	+	+	+		
		Economic development		+			
		Social development	+				
		Innovation			+	+	
	Central Planning	Priorities in R&D				+	
		Central budget and investments	+	+			+
		Institutionalisation		+			
		Technological sovereignty	+				+
Capabilities (of an island state with few resources)	Human potential	Learning process			+		
		Education system	+		+	+	
		Development		+	+		
		Values			+		
		Migration	+		+		+
	Integration	National health system	+			+	
		Complementarity			+		
		Efficiency		+			+
		Closed loop system		+		+	+
		Innovation			+	+	
		Interphases		+			+
	Collaboration	Internationalist solidarity	+	+	+		
		Technology transfer		+	+	+	+
		Export capacity		+	+		
Adaptability	Blockade	Supply chains	+	+	+	+	+
		Export barriers	+	+			
		Technology transfer					+
		Scientific development	+		+		+
		Innovation capability			+	+	
		Creative resistance	+		+	+	+
	Social values	Collective responsibility	+			+	
		Trust			+		
		Organisation culture		+			
		Resistance			+		+

4.2.1. Theme 1 Leadership

Sub-themes: Revolution, Independence, Foresightfulness

Four of the interviewees said that the most important thing underlying Cuba's biotechnology achievements was the Cuban Revolution and Fidel Castro. They pointed to the role of the revolution in building the infrastructure of the biotechnology sector through the country's educational moves and the inclusiveness of the education system. They mentioned that the revolutionary leadership has clear and explicit policies for the development of citizens as individuals and also for their professional advancement in the scientific field. One of the striking things in the interviews was that Fidel Castro was believed to have a decisive role in the formation of the country's science policy and especially in the establishment of the biotechnology sector.

> *"All of Cuba's biotechnology achievements are due to the Cuban Revolution and the ideas and works of Commander-in-Chief Fidel Castro. One of the most important steps that made this possible was the democratization of education right after the revolution. Fidel Castro was directly involved in the issue of biotechnology in Cuba. At the beginning, of course, we see a group of scientists who have received education thanks to the revolution (...) One of Fidel's biggest dreams was that Cuban scientists would find medicines to cure cancer."*

Interviewees touched on different aspects of Fidel's relationship with the founders of Cuban biotechnology. It was stated that Fidel directly monitored the education and scholarship support of scientists, the organization of the living conditions of researchers in a way that would facilitate their scientific work, and even the construction of scientific institutions and centres. It has been observed that the reason why these stories are still so vivid is that the scientists who founded the sector continue to work actively and that they continue to communicate with the new generation of researchers.

From the interviews, it is understood that the cadres who carried out the revolution considered the scientific policies that were effective in the establishment of Cuban biotechnology, from the very beginning, in relation to the preservation of

independence and the development of the country. Since the early years of the revolution, Cuba has been subject to the US blockade, which required the country to build its scientific and technological independence in order to maintain its independence.

> *“In the 1980s, Fidel, together with a group of comrades, determined that Cuba’s advanced knowledge in education, science and scientific research could be linked to the country’s development.”*
>
> *"For Cuba to become independent, it had to be a country of scientists. It became clear that the way to Cuba's development was through the establishment of numerous research centres and the training of scientists."*
>
> *“The fact that we were a country under blockade, especially since the early years of the revolution, and that we could not quickly obtain as many medicines as we needed, forced us to embark on a path of scientific independence. Cuba understood that it would have sovereignty in healthcare only if it had sovereignty in pharmaceutical production.”*

It has also been assessed that Cuba, which is in the category of developing countries, has been able to access advanced technology thanks to the revolution.

> *“(...) when we talk about the most advanced technology, including biotechnology, robotics and informatics, we see that third world countries are completely excluded from this development in all of these. Therefore, one of the most important issues for third world countries today is access to biotechnology. We owe this to the social regime in Cuba, to socialism.”*

It is thought that the country's leading cadres are still influential in the biotechnology sector continuing to be supported by the state despite all the economic difficulties experienced in the country. Even though a significant portion of the cadres who made the revolution are no longer alive today, the revolutionary government is still in power. Three interviewees pointed out that current President himself an engineer, continues in different forms what Fidel did in the past. In this sense, it has become clear that the state's science policy is being updated in line with the needs of the country and new moves are being made in line with these updates in some non-biotechnology sectors.

> *“I think this science policy is being updated in a way, because since the creation of the innovation committees, I don't know if you had a chance to*

read President Díaz-Canel's doctoral thesis, where it is about the promotion of science and technology, the application of science and technology in all sectors, the validation and support of those promoted by Fidel in the biotechnology sector."

"Now there is a tradition that has continued since Fidel: Fidel Castro, the leader of the revolution, and later the head of the State Council, has always been in direct contact with the top management of this sector. The Presidents of the State Council have advisors who follow the development of biotechnology in Cuba day by day. This is also an indicator of the personal importance given to the development of biotechnology in Cuba. It is a sector that was directly created by the president of the country and has since been followed and guided."

4.2.2. Theme 2 Public Needs

Sub-themes: National health system, priorities, economic and social development, innovation

All interviewees stated that the most fundamental goal of the Cuban State in the process of establishing and developing the biotechnology sector is to meet the medical supplies and requirements needed for the health of the people. In this sense, it has become clear that the most decisive axis in shaping the Cuban State's science policies in the beginning and today's science, technology and innovation policies are social needs.

"One of the most basic goals was to meet the essential medical needs of the Cuban people, including the most basic health supplies and medicines they would need, with the biotechnology, health sector and biotechnological products that were developed and this was formulated as a state policy."

"A large part of the science that is done in the Cuban biotechnology centres is geared towards pharmaceutical production, and so the relationship with MINSAP is a very close one, with many coordination meetings between the Ministry of Health and BioCubaFarma to understand what the health demand is, what the priorities are, what the priorities are in terms of diagnostics."

"Normally, large transnational companies think business first, and secondarily, they think about health and the effects of the product on health. It is the complete opposite for us. So, our first goal is always to affect the health of people, ours and all the people and children of the world. As a result, of course, we also need it to have an economic impact. Because only in

this way can we complete the cycle, recapitalize and renew it. However, in essence, we always prioritize the health subject first in our mindsets."

One interviewee, unlike the others, mentioned that the country's social needs also included developing the ability to defend itself against biological terror attacks to which it was exposed, and stated that this was also among the reasons why the state invested in the biotechnology sector.

"Cuba has always been subject to serious terrorist attacks by the United States, a biological war has been waged against Cuba, and various bacteria and viruses have been introduced into the country in various ways that will harm agriculture and negatively affect the health of the people. For example, this is how hemorrhagic dengue was introduced into the country, causing more than 100 deaths (...) For this reason, steps had to be taken to rapidly develop the biotechnology field in Cuba. In other words, Cuba invested in biotechnology not only to improve public health but also to cope with these terrorist attacks."

Despite the instability in the country's long-term economic growth, it is understood that the most important reason for the state's stable political and financial support for the biotechnology sector is the priority of protecting and improving the health of the people, while simultaneously aiming for the country's economic and social development. Two of the interviewees pointed out the impact of the country's well-developed biotechnology sector on social development, while the other two pointed out its impact on both social and economic development. It was stated that when the inclusive and universal principles of the national health system are combined with the potential of the biotechnology sector to meet the health needs of the people, this reinforces the people's sense of social justice and equality. In addition, the interviewees stated that the level of development reached by the biotechnology sector has been effective in increasing Cuba's export capacity and the country's income. Thus, they said that having a developed biotechnology sector in the country has positive results both in the construction of social welfare and justice, and in the development of the country.

"Cuban science policy is based primarily on needs; in other words, to put science at the service of people, human development, and social well-being."

"The Cuban biotechnology sector is focused on both things. So, one of its tasks is to guarantee the production of new drugs or biotechnological

products for the Cuban health system, and the other is to generate foreign currency revenue for export (...) And this is vital."

"Therefore, today we are talking about one of the most economically developed sectors in Cuba. Because the various products developed in biotechnology have a number of niche markets even in developed countries. This is a source of income for Cuba. This helps provide the income and financing needed for the auto-financing of Cuban biotechnology. And it contributes to the country's overall GDP."

One of the interviewees noted that the goal of Cuban biotechnology today goes beyond meeting the country's list of essential medicines, medical materials and devices. He pointed out that a sector focused on generic drug production is not a cost-effective way for the state to continue investing, especially considering the conditions in Cuba.

"Cuba's goal is not to produce generic drugs like this, but to enter the market by producing innovative drugs and its own unique drugs. But the market for these innovative drugs is much more controlled by monopolies."

During the interviews, it was understood that Cuban biotechnology has been directing R&D activities in line with the development of public health over time and the new needs that have emerged in the national health system. All interviewees mentioned that the most recent historical example of this in terms of meeting urgent needs was experienced during the COVID-19 pandemic. During the COVID-19 pandemic, the biotechnology sector repositioned its previously developed drugs for the treatment of the disease, developed 5 protective vaccines, and produced mechanical ventilators. One of the interviewees stated that the sector focused on 5 of the many COVID-19 vaccine candidates, and that instead of determining a single vaccine candidate, determining 5 vaccine candidates aimed to increase the chance of success. It is understood that the sector focuses on the most common diseases that affect the country's health system, even outside of crises and extraordinary agendas. One interviewee expressed this as follows:

"So, the new biotechnological products are aimed at the diseases that have the greatest impact and the highest incidence in the country. For example, at the Centre for Molecular Immunology, we are working mainly on immunotherapy, that is, the development of immunotherapeutic medicines for

the treatment of cancer. We have also expanded to other chronic non-communicable diseases, but mainly cancer. So, what are we working on mainly? The types of cancer that have the highest incidence in Cuba."

4.2.3. Theme 3 Central Planning

Sub-themes: Priorities in R&D, central budget and investments, institutionalization, technological sovereignty

The education system and scientific institutionalization have significantly contributed to the learning process in the development of Cuban biotechnology. In addition, it was observed that the interviewees frequently used organisational words such as planning, institutionalisation, and integration in their responses to questions aimed at understanding the establishment and development of the state's biotechnology sector. While three interviewees working in the sector did not mention the state's financial investments in terms of support for the sector—this may be because they have internalised this role of the state, and also because they think of it as a duty—the other two interviewees mentioned the importance of the state's central budget investments, especially during the years of the sector's establishment and its meeting with high technology. It was pointed out that the monitoring of the biotechnology sector at the level of the President and the State Council directly affected the implementation of these investments.

"Within the country's limited resources, allocating revenues from outside this sector to biotechnological investments would only be possible under the supervision of the State Council."

Since 2012, it is known that the biotechnology sector, which has been gathered under the roof of BioCubaFarma, has reached a foreign trade volume that can finance itself, and therefore a re-planning has been made regarding its financing. The institution's revenues cover the organization's current expenditures, while the state's central budget continues to fund R&D activities aligned with the needs of the national health system. In addition to the information from the WHO report (2015), one interviewee asserted that the state continues to allocate a significant portion of the central budget

to the biotechnology sector, while another stated that the national parliament must approve the allocation of the central budget to this currently self-financing sector.

The day-to-day monitoring of the sector from the outset at the level of the President and the State Council is understood to be important in planning research activities according to societal needs. According to one interviewee, the primary advantage of this level of centralization lies in the connection between research activities and the country's economy. The first thing that comes to mind here is the creation of the Biologic Front as early as 1981, a kind of predecessor of BioCubaFarma, which aimed to integrate scientific research directly into production activities and thus transform science into an economic force for the country. Another interviewee mentioned separately, in the context of the foresight of the revolutionary leadership, that Fidel himself led the creation of the Biological Front.

> *"In this establishment process, beyond conducting scientific research, the idea of directly linking the process to the Cuban economy and production was always at the centre. This institutionalisation began to work directly under the State Council. The fact that the institutionalisation was under the State Council had two important advantages: One of these was the assurance that the large amounts of resources required by biotechnology could be allocated to this sector. The second was that it allowed the state's top executives to directly participate in the establishment process of this system and take part in decision-making processes. Thus, the field of biotechnology gradually expanded, and a kind of revolution took place in this field."*

These sentences indicate that Cuban biotechnology has been addressed in relation to the country's development policy since the beginning. Another striking point here is the mutually reinforcing two-way character of the relationship established between the sector and the state. The fact that the sector is owned by the state and that both the sector and the state have a common approach that prioritizes social interests paves the way for this productive, -in a sense- courageous and innovative relationship. It is understood that another advantage of state ownership is that it enables international scientific and commercial collaborations.

> *"I think the most important advantage of central planning is that the large resources needed by this sector can be directed here by the state. In addition, since it is a state-owned company, it increases the potential to negotiate with*

other states, which can bring new business agreements and opportunities to the sector."

One of the interviewees, unlike the others, addressed planning and management by including BioCubaFarma management in addition to the importance of the state. He noted that centralized planning of research according to societal priorities could be interpreted as a restriction of research autonomy, but in fact the centralized structure is functional in establishing an equality between institutions.

"In terms of factors influenced by central management and central planning, I would say that the companies - under BioCubaFarma - do not have autonomy. From a business point of view, it means that this can be considered a challenge. But when you look at it from a centralized point of view (...) if BioCubaFarma did not evenly distribute the income of companies with a positive economy, what would happen to those twenty or thirty companies that did not contribute to the income? That's why we need to understand from which point of view we are analysing the centralized and planned economy. It is true that it affects companies, but only in one way: for their benefit."

From this perspective, it can be seen that the export revenues obtained from the products of CIBG, which has a high number of patents, are directed to agricultural biotechnology production activities in order to solve the country's food crisis, which is also in line with the 2030 National Economic and Social Development Plan (PNDES 2030). One interviewee pointed out that central planning, especially in countries with limited resources, can lead to sectors generally tending to grow more in order to provide their own resources. He said he thinks that this growth could slow down the management of companies and lead to a kind of "unwieldiness". Interviewees working in the sector pointed out that the most important workload of BioCubaFarma management was the process of finding alternative solutions to the problems caused by the blockade.

"I don't know if this can be described as a tendency in socialism in general, but especially in situations of scarcity and deprivation, there is definitely a tendency that emerges: Companies increasingly have problems meeting some of their needs from outside, so they tend to grow in a way that they have to meet those needs from within, and therefore they tend to become somewhat unwieldy. ..we can see companies becoming larger and harder to manage as a kind of side effect of central planning."

In Cuba, science, technology and innovation activities are defined as the driving force of the country's PNDES 2030, not only in the field of biotechnology but in all areas. It is understood that BioCubaFarma, a unique organization that covers all cycles in research, development, production, marketing and sales in biotechnology is guided by this national plan. Another new institution that takes on management responsibility in a type of scientific production in the country is the National Innovation Council, established during the pandemic. This council, which advises the President and consists of scientists, academics, researchers, ministry representatives and sector managers, and CITMA, to which BioCubaFarma is affiliated, also guide the sector's scientific production.

All interviewees frequently mentioned the importance of inter- and intra-institutional integration at different levels and contexts. The multidisciplinary nature of biotechnology in terms of product and production process, as well as the fact that food supply and energy production are among the country's most pressing challenges, requires the sector to develop a close centralized relationship with ministries other than MINSAP. In this sense, the institutional integration established at the central level is not limited to the relationship between BioCubaFarma representatives and the Council of State and the President.

> *"There is a very close relationship between the Ministry of Health and BioCubaFarma, with many coordination meetings. This works very well, but there is also a strong relationship with the Ministry of Agriculture, for example, because there are Cuban biotechnology centres that also work in the agricultural sector, producing vaccines to prevent diseases in livestock, for example. There is also a strong relationship with the Ministry of Energy and other Cuban institutions."*

4.2.4. Theme 4 Human Potential

Sub-themes: Learning process, education system, development, values, migration

In the interviews, the theme of qualified human resources was prominent in the responses to questions posed to understand what made the success of the Cuban biotechnology sector possible and the public policies related to it. The

democratization of education that began immediately after the revolution, the structure of the national education system that includes everyone everywhere (even schools with a single student in rural areas), and the special emphasis on medical sciences, especially at the pre-university and higher education levels, have played an important role in the success of the sector and the formation of today's human potential.

> *"Yes, it is very difficult to produce a biotechnological product, and it is important to understand this. When the revolution was victorious, the commander-in-chief realized that if Cuba wanted to be a medical power or to have an impact on people's health, it had to have three components. Human resources: doctors, nurses, auxiliary health personnel. That is why universities of medical sciences and the training of such personnel were greatly encouraged. Secondly, it had to have infrastructure. That is why a whole health system was created, consisting of primary health care, secondary health care and tertiary health care, which are large hospitals (...) And this is a very Cuban design. But the third element was the need for medicines, and this is where the issue of the economic blockade comes in."*

However, the sector's innovative capacity today stems not only from increasing school enrolment rates, strengthening the scientific content of the curriculum, and encouraging medical sciences, but also from the values system, which plays a crucial role in the quality of human resources. These social values closely relate to the ability and motivation of scientists to generate solutions for blockade conditions and extraordinary and emergency situations such as pandemics and hurricane.

> *"I believe that the state's efforts primarily go through the formation of human resources, human capital. This is the essence of the matter; if you do not have an education that will enable you to raise people in terms of knowledge, education and values, you cannot obtain scientific results."*

> *"(...) the principle of solidarity is a working principle of Cuban doctors. The COVID vaccine is a fundamental example of this. (...) Seeing that the COVID vaccine is a necessity for our country actually led us to quickly make the vaccine. We also made many donations that we did not make public. (...) These kinds of attitudes are essentially what drive the values and principles of Cuban scientists. That is, for all of us, a human life is much more valuable than all the money in the world."*

Just like the decisions made by the country before 1980 to build its technological independence in the pharmaceutical sector, the steps taken to develop human

resources are also in close relation to the national development strategy. The fact that Cuba is an island country with limited resources has, in a sense, obliged it to invest in its most important productive power: human resources.

> *"Cuba is a small island country; it doesn't have many resources. Its most important resource is its human resources. Therefore, teaching the entire population to read and write and making everyone informed was not only a matter of social justice, but also a necessity for the development of the country."*

Questions about the future of the sector sought to obtain information about the tendency of this highly qualified labour force of Cuba to migrate abroad. What drew attention here was the phenomenon of internal migration, which is used in the sense of migration between sectors. It was noted that the economic crisis can lead some qualified personnel to move to sectors with more attractive incomes. On the other hand, it was pointed out that the highly educated labour force who migrate abroad due to socio-economic concerns often are unable to find jobs related to their field of education due to the conditions in the country of destination. One of the interviewees pointed out that the blockade has the political objective of encouraging the emigration of Cuba's intellectual and scientific human resources, while the other two stated that the phenomenon of emigration in Cuba is no different from what is happening in the rest of the world.

> *"What is happening in Cuba regarding immigration is the same as what is happening all over the world (...) When something happens in Cuba, it is exaggerated (...) We are undoubtedly affected by immigration, but it is more due to the economic situation in Cuba. Only a portion of those who go manage to work in research, some do not; some work in sectors that have nothing to do with them, and that is a shame, isn't it?"*

> *"The migration trend is not only abroad, but also leads to a phenomenon we call internal migration. In other words, people are turning to sectors other than our sector, for example, some service sectors, sectors that may be more attractive."*

In summary, human capital investments, which began with the literacy campaign in 1961, have increased the number of qualified human resources, which has greatly facilitated the scientific and technological learning process of the country and the

biotechnology sector in particular. This has also formed the basis of the economic and social development plan of the country, which has limited resources. The conceptualization of "human potential" in the definition of "Human Potential, Science, Technology and Innovation" defined as the strategic axis in PNDES 2030 stems from the fact that the most critical variable for Cuba is human resources.

4.2.5. Theme 5 Integration

Sub-themes: Complementarity, efficiency, national health system, closed loop system, interphases, innovation

During the interviews, it was observed that one of the most important features of the sector is its advanced integration system. This integration is not limited to the integration established with the state, which regulates policy and provides central budget support, and the communication established at the level of the President. The sector has been completely integrated with the national health system since its establishment. Against the challenges faced by the country, in line with the needs of public health, the sector's development and production of products aimed at protecting health contributes to the development of public health, and the evaluation of products by physicians working within the health system contributes to the development of the biotechnology sector.

> *"Cuba is a country under US blockade, which means we have huge restrictions on access to medicines, even modern treatments. So, the idea came up—first—that if we want access to modern treatments and advanced medicines, we need to have our own biopharmaceutical industry. And in this context, the pharmaceutical and biotechnology industry was created. So, in order for the concept of complementarity to work in this case, it had to be concretised and started to work in a holistic way. Cuba's biotechnology industry exhibits strong integration with the health sector. So, there is a great integration based on inter-institutional and inter-sectoral relationships."*

It has been mentioned in previous sections that the sector has a strong coordination with other ministries and sectors in line with the needs of the country, apart from MINSAP. Apart from this, BioCubaFarma has also established a very advanced integration system among the 21 scientific units, 47 companies and many business

units it covers. The most important result of this integration is that all these units complement each other. Institutions never compete with each other. On the contrary, there is a sharing of information, technology, experience and results in line with the research, development and production plan for social needs. During the pandemic, it is this integration that has enabled Cuban biotechnology to develop 5 COVID vaccines, despite the few high-tech COVID vaccines developed worldwide. This integration has enabled one institution to develop the vaccine antigen while another works on the adjuvant. It has been observed that such complementarity also increases efficiency and accelerates the process of completing research.

> *"Cuba's science policy (...) is based on a set of principles such as complementarity, inter-institutional solidarity and centralisation of essential elements in a country with few resources (...) The issue of 'complementarity' (...) is based on the idea that our institutions should not compete with each other. Thus, a science design emerges in which there is complementarity rather than competition between institutions."*

> *"BiocubaFarma promotes different interactions by taking advantage of the established capacities of each of them -scientific units. Some have technological platforms for the production of active pharmaceutical ingredients, others for the final processing of products. Some are dedicated to the production of laboratory animals, others (...) have everything to do with automation and equipment design. In this way, BioCubaFarma establishes, in a holistic way, the interrelationship between each institution and makes the best use of the capabilities of each."*

> *"The country also has a strategy to promote scientific exchange between biotechnology institutions, so we can make the process (...) more efficient. (After talking about the different technological platforms of the different institutions) this integration, for example during the pandemic, has made the process of producing vaccine candidates much more efficient (...) so we have been able to have three vaccines registered by the Cuban Regulatory Authority (...) the integration has brought a great deal of efficiency, which is also greatly encouraged by Cuba's science policy."*

Integration, which allows scientific units to benefit from each other's technological platforms while carrying out R&D projects, also allows different units to combine their products and conduct clinical trials to see if they can develop new products. In short, it has been understood that integration, which can be defined with the concept of complementarity, has a positive effect on the increase in the innovation capacity of the sector.

It is seen that Cuban biotechnology works in coordination and integration from the beginning to the end of the production process. The entire process, from the production of experimental animals required for R&D studies to the quality control, registration and marketing of the developed products, is carried out under the roof of BioCubaFarma. This working strategy, which is a vertical integration, is called a closed-loop system by BioCubaFarma. The closed-loop system, which means that the research, development, production, marketing and distribution processes are carried out under a single structure, also allows institutions to control the different stages of the supply chain themselves.

> *"(...) we know how to make vaccines. But we don't just know how to make vaccines, we also have the capacity to research, develop, produce, market and evaluate vaccines."*

It is understood that the closed loop system prevents scientists and researchers from becoming alienated from the product, ensures that the country's health needs are met, and at the same time, contributes to the sector becoming a global sector by increasing its speed, efficiency and rapid adaptation ability.

> *"Many of these biotechnology centres in Cuba, although they were initially scientific centres, have gradually risen to centres that carry out a full cycle of research, product development, manufacturing and commercialization, and once they have met the country's demand, they can export their products and contribute to the country's economy with the money that comes in. In this way, Cuba is building an arsenal of drugs for its population that can also contribute to the economy."*

It has already been mentioned that BioCubaFarma already coordinates and cooperates with other ministries and sectors in line with the needs of the country, in addition to MINSAP. In addition, the sector has been cooperating with universities for many years. Many researchers working at BioCubaFarma attend universities for their master's and doctoral degrees. Additionally, several faculties collaborate on joint projects with BioCubaFarma. As part of the cooperation, the biotechnology sector provides laboratories and physical structures for universities to conduct their research, and universities in turn provide their scientists, researchers, and students to the sector. As a result, academia and the sector establish a symbiotic relationship.

However, one of the interviewees pointed out that this relationship favors universities. She pointed out that the sector is more supportive and giving in this cooperation compared with the universities, whereas in the rest of the world, this relationship is generally formed in a reverse way. Unlike the rest of the world, Cuban universities face challenges in spearheading research programs due to resource constraints and science policy priorities. At this point, it is understood that the science policies of the state primarily support scientific research that is directly integrated with the economy of the country. The goal of universities to establish their research activities in relation to the country's economy is among the future development plans of the state.

> *"Many universities in the world are dedicated to some types of research and are pioneers in this field, but this is not the case in Cuba. This is due to the lack of resources they have and the way the country's science policy is structured."*

Another interviewee pointed out that one of the fundamental issues of the country's administration today is science and technology, and that the experiences of the biotechnology sector have an impact on this. He conveyed that, as in the biotechnology sector, steps are being taken to relate the science produced in universities to production and economy. It is thought that new interfaces (interphase entities) established for this purpose and having flexible structures (technopark, company or scientific institution, etc., depending on the structure of the university) will enable universities to directly relate to production processes in all sectors, including the biotechnology sector.

> *"These – the interfaces – undertake the mission of directly connecting the work done in various areas of the university with the sector. In other words, they do not expect the relationship to be only between the relevant parties and the State Council, they actively participate in the process and carry out work in a way that will accelerate production."*

4.2.6. Theme 6 International Collaboration

Sub-themes: Internationalist solidarity, technology transfer, export capacity, blockade

Even before the establishment of the biotechnology sector, Cuba had mobilized its greatest asset in the field of international solidarity—its human resources. In one of the interviews, it was pointed out that Cuban medics are currently working in almost all countries in Africa and in many countries in Asia and Latin America, and that there are even some third world countries whose health systems rely entirely on the presence of Cuban medics. Another interviewee working in the sector said that they have carried out many unpublicized vaccine solidarities; for example, during the COVID-19 pandemic, they donated more than 100,000 doses of vaccine for children in detention camps in sub-Saharan Africa.

In addition to international solidarity, Cuba also sends its health professionals abroad for the service exportation. Health professionals travelling abroad on a voluntary basis contribute directly to the country's export revenues, while on the other hand, they act as a kind of health embassy with the medical supplies they take with them.

> *"Therefore, in fact, these health personnel go abroad not only to provide health services in a simple sense but also to provide information and counselling on Cuba's health system, and this means, to some extent, preparing that market for Cuban biotechnology products."*

The fact that the biotechnology sector is a sector based on knowledge, research, development, and innovation that requires wide and systematic cooperation boosts the importance of international cooperation for the sector. BioCubaFarma's scientific units, such as IFV, CIBG, and CIM, organise international scientific events and congresses focusing on the projects they carry out and to which important names in the scientific community are invited. Thus, they are able to transfer the results of their own studies to the world and establish new scientific collaborations in the international arena. In this respect, it is apparent that the Cuban State has been encouraging these cooperations from the very beginning.

> *"Scientific research anywhere in the world cannot be carried out without international cooperation. It is not possible to develop science alone (...) Cuba's biotechnology institutions (...) organise events and congresses that invite opinion leaders from the scientific community (...) many scientific papers are co-authored by Cuban scientists and scientists from other laboratories around the world."*

Scientific collaborations developed in the biotechnology sector, as can be understood from the sentences above, are also functional in overcoming some of the barriers created by the blockade by Cuban scientists. The sector, which faces various obstacles in supplying raw materials and some chemical agents and equipment required for research, transfers technology to foreign laboratories with which it has developed collaborations after completing its basic research and can accelerate research processes thanks to the supply of the materials it needs by these laboratories. In addition, international collaborations help to obtain patents and thus accelerate the production process.

> *"International collaborations also help us move quickly in some of the world's labs. Once we have our evidence, our basic research, we transfer that knowledge to these places and then the supply cycles come into play."*

> *"Despite the situation imposed on us by the US, the way we can progress is through international cooperation. I see that international cooperation (...) has very positive effects on the training of human resources, on the intellectual property patents that may be formed, on everything, in every respect."*

Scientists and researchers working in the biotechnology sector in Cuba have received numerous trainings and participated in research projects abroad. A significant portion of this training has taken place in European countries. Today, the Cuban biotechnology sector has numerous scientific cooperation projects, almost all of which are at the research level, with some research institutions in countries such as Germany, Switzerland, Belgium, England, France and Spain in Europe. Advanced cooperations have been established at the product and production level with China, Vietnam, Iran and Russia. It is understood that all these cooperations are essential for the Cuban biotechnology sector in terms of accessing both the latest technologies and new markets.

The global biotechnology sector has a large international market with a high volume of trade. However, Cuban biotechnology remains outside these large international trade networks. One reason for this is the blockade, while the other is the dominance of large transnational corporations in the sector. At this point, it becomes important for Cuban biotechnology, which is a state sector, to develop new international

relations and manage these relations well in order to find a market for itself. In most of the new markets found, the commercial counterparts are the state and the agreements are made with the public sector. One result of all this is that Cuban biotechnology products are offered for sale at lower prices compared to the international market.

> *"(...) In addition to the domestic market, we also have the capacity to produce and export significant amounts. Being able to use all these opportunities, which are an important source of income for the country, will of course mean that the budgets of many families in Cuba and around the world will be relieved. Because our products are generally offered at lower prices than the national market."*

> *"(...) When an agreement is made with the public sector, it is of course taken into consideration that the prices in question are accessible to the public, and the other party bargains accordingly."*

In addition to research projects and scientific collaborations, and extensive exchange programs of scientists, the Cuban biotechnology sector has established foreign partnerships at the production level. Cuba has joint biotechnology factories with China and Vietnam, located on the territory of these countries. These are of great importance to the sector, again due to the blockade, because thanks to these companies, both technological input can be provided in a stable manner and products can be offered to wider markets. The partnership established with China, especially with its rich raw material resources and large market, makes a significant contribution to the export revenues of the Cuban biotechnology sector. When the foreign exchange crisis that Cuba is experiencing is taken into account, it is understood that the export revenues to be obtained from the biotechnology sector are critical not only for the biotechnology sector but also for the needs of other sectors of the country. Nevertheless, it is seen that it is not possible to completely overcome the difficulties faced by Cuban biotechnology with solutions that focus on international partnerships at the production level. Because the terms of the agreement change, the conditions do not always create significant changes in Cuba's biotechnology revenues.

> *"(...) First of all, such joint ventures may not be established with all countries, and secondly, the agreements there may also vary depending on*

the conditions. Sometimes you can take back a portion of the product you produce to Cuba, sometimes you can't. Sometimes you can only take back a portion of the money you earn, sometimes you can't. Sometimes you have to leave both the product and the income there and use it only in line with the needs of that business."

From the interviews, it was understood that Cuba also has a deep-rooted tradition of solidarity with Venezuela in the field of health and carries out important collaborations with Canada in the field of biotechnology. However, another interesting collaboration, albeit limited, is the scientific collaboration established with the US on cancer research and treatment. It is understood that Cuba has broken the blockade with science in a sense with its therapeutic cancer vaccines and treatments for diabetic ulcers.

"Even Cuba's historical enemy felt the need to use the products of Cuban biotechnology in the treatment of certain diseases and took steps in this direction."

4.2.7. Theme 7 Blockade

Sub-themes: Supply chains, export barriers, technology transfer, scientific development, innovation capability, creative resistance

The most prominent theme in the content of the interviews conducted to obtain more in-depth information on Cuban biotechnology within the scope of this thesis was the blockade. The US blockade, which affected all of the sector's production processes, had to be mentioned from time to time while analysing the previous themes. The interviewees provided information on the effects of the US economic, commercial and financial sanctions, from the emergence of the sector to today's research, development, production and marketing processes, and presented many examples. What is interesting at this point is the adaptability and creative solutions developed by the Cuban biotechnology sector against all these negative effects of the blockade.

The US sanctions, which were voted to be lifted for the 32nd time by the UN General Assembly in 2024, do not only restrict relations between the US and Cuba, but also

cover third countries and companies. These US laws and decrees, which deeply affect biotechnology as well as other sectors in Cuba, include provisions that any product, raw material or input with more than 10 percent US-origin components cannot be sold to Cuba, and that ships that call at Cuban ports cannot call at US ports for 180 days. It is understood that these provisions cause BioCubaFarma to face great difficulties in procuring the reagents and raw materials it needs for research, development and even production. The supply companies refrain from selling the materials it needs to the sector, stating that it is very difficult to find an input that does not contain more than 10 percent US-origin components anywhere in the world. This situation results in the sector turning to countries beyond the ocean, mostly Asian and sometimes European countries, for the supply of raw materials and intermediates, rather than North America or nearby Latin American countries. In case companies are found to supply the necessary raw materials and intermediates, they have to use intermediary companies due to US provisions that penalize commercial cooperation with Cuba. This also causes a significant increase in product costs.

> *"Our industry has very long supply cycles. Because as you can imagine, we (...) bring almost all our raw materials from Asia or some from Europe. And (...) we usually deal through intermediaries and that costs us a lot more. Some of the analysis and research we do shows that every product we buy costs almost 50 percent more than the market price."*

Another difficulty encountered in the supply process is experienced during financial transactions through banks. The US has prohibited Cuba from making any international financial transactions or money transfers using USD. This situation increases the country's need for cash foreign exchange in an objective manner where the international financial system is based on USD. Even if the biotechnology sector has the financial resources to finance the materials it needs, the problems encountered in transferring money through banks lead to breaks in supply chains.

> *"(...)finding a company that will supply us with the materials we need is a problem in itself. And finding a company that will provide the quality and stability products we want is also very difficult. Secondly, there are financial problems; even if we find the company, biotechnology companies still have difficulty making payments. This is again related to the foreign exchange*

crisis in the country, since there is little foreign exchange, it is difficult to finance the things to be purchased."

The biotechnology sector is a sector that requires the supply of materials and products required for any level of the production process not just once, but in a stable manner. Otherwise, entering into an innovative activity carries great risks. Therefore, in order to carry out both a guaranteed and stable commercial activity, it is essential to skilfully manage the disruptions experienced in payment processes. It is understood that BioCubaFarma managers and sometimes state representatives in Cuba have to make great efforts to overcome the financing problems encountered.

"The financing problem can reach high dimensions (...) therefore, in some of the existing contracts, the state needs to intervene, negotiate, mediate, amend the contract to new conditions, etc."

The Cuban biotechnology sector has a large production capacity and a strong infrastructure. The country has the capacity and ability to produce more than 80 percent of the drugs on the list of essential medicines. However, it is understood that the instability in the supply of raw materials and intermediates has caused the sector to be unable to produce more than 100 drugs on the list of essential medicines, despite having the capacity. Another negative effect of the shortage of intermediates and raw materials is related to the sector's innovation potential. Researchers say that research periods can be extended due to material shortages, so they need to anticipate the substances and quantities they will need even before designing research projects, and take early action to supply them.

"(...) since we have an increasingly tightening blockade, the difficulties for Cuba to develop innovative products are enormous. We have to design even scientific research months in advance and anticipate everything we will need to carry out the experiments, because if during the experiments the results require us to do different experiments than planned, we have to buy new reagents, and it takes months, sometimes more than a year, for the reagents to arrive."

The biotechnology sector is a sector that requires high-tech equipment all over the world. This equipment is used not only in research and production activities, but also in the evaluation tests of new products. Cuban biotechnology has its own quality

control and registration systems. However, vaccines, one of the most important export items of the Cuban biotechnology sector, must have WHO quality certification in order to be accepted by the health systems of other countries. Completing these already expensive evaluation and quality tests is becoming more costly in the case of Cuban biotechnology due to the blockade.

It is understood that the increasingly severe US sanctions are directly and indirectly affecting the number of patents in the sector. As in many other topics, it is seen that the patent problem is being partially overcome through international collaborations. Another blockade barrier that affects not only the biotechnology field but also Cuban science as a whole is related to the publication of academic articles in international journals. The number of journals that charge a fee for the publication of articles in international academic publishing is rapidly increasing. It is seen that this situation affects Cuban scientists not only because of the difficulties in financing, but also because of the financial transaction restrictions they experience internationally.

> *"I am so convinced that this – the blockade – has affected the publication of an article that the results cannot be made public. Because now the journals have a policy of charging more than 3,000 USD for articles, and now even if we had the money we could not pay. Because the banks do not allow us to pay for this kind of thing from Cuba."*

In summary, the US blockade has had a negative impact on all aspects of research, development, innovation, production and export of Cuban biotechnology today. All interviewees stated that they thought the biotechnology sector would be more successful if the blockade did not exist, with one additional commenting that the US, knowing that Cuban biotechnology is important for the country's economy and independence, is specifically targeting the sector:

> *"The blockade is almost like an economic war; it is trying to strangle the Cuban economy, and that goes for the biotech industry, the biopharmaceutical industry and the pharmaceutical industry in general."*

> *"This policy - the blockade - is a policy that literally involves a process of surveillance and prosecution. There is a specially created office in the US for this; an office that is occupied with monitoring all economic, commercial and financial relations that Cuba has with the outside world (...) - biotechnology -*

contributes to the development of other sectors of the economy. That is why it is a sector that the US is specifically following and attacking. The main purpose here is to prevent the development of this sector."

4.2.8. Theme 8 Social Values

Sub-themes: Collective responsibility, trust, organisation culture, resistance

In previous sections, international collaborations were mentioned in order to overcome the negative effects of the blockade on the sector or to reduce its effects. To these, the efforts of researchers, scientists and technicians to produce creative solutions to overcome the problems should be added. It is understood that if what the sector cannot supply today is not a raw material, the sector employees are making great efforts to develop creative new alternatives thanks to their knowledge and technological skills. For example, in the recent period when the blockade became more severe, Cuban scientists had to develop the molecules themselves, even for the analytical methods used to measure the quality of the products developed and to evaluate the immune response of the vaccines in the people vaccinated. It is understood that Cubans are trying to overcome the blockade with a creative resistance that characterizes them.

"One of the good things that these evils have left us is that Cuban scientists have managed to find solutions to big problems. They always find a way out but in real, it slows down our research and makes it much more expensive. (...) So this - the blockade - forces us to be very creative, it forces us to be very planned and it also forces us to be very hardworking."

"(...) this situation - the blockade - is not an excuse or an excuse not to move forward. So, moving forward is based on better planning (...) Really, how do we overcome the supply problem now? With a lot of innovation, a lot of imagination, a lot of intelligence, and also the desire to continue working"

The integrated structure of Cuban biotechnology, the fact that institutions act on the principle of complementarity rather than competition with each other, and the social needs, not the market, determine research and production activities, all affect the scientific workers in the sector to have developed cultural and human values. This effect can also be established in reverse. In other words, it can be said that the fact

that human resources have developed human values in addition to in-depth scientific knowledge is effective in the sector's implementation of these working principles. These values, which are not specific to scientists in the field of biotechnology, actually reflect Cuba's national scientific design.

> *"I think the Cuban scientist, although not different, has a special characteristic (...) he/she also has a set of values that make him/her very humane (...) his/her greatest motivation is to ensure that all children, Cuban and all over the world, can continue to smile throughout their lives thanks to our work and that their families can share this happiness (...) such attitudes are essentially what guide the values and principles of Cuban scientists. That is, for all of us, a human life is much more valuable than all the money in the world."*

The scientists who have made Cuban biotechnology what it is today are pursuing their research not only to do more science, but also to direct it in a way that best suits the needs of society and the interests of the country. In this sense, they are conscious of their contribution not only to the advancement of science, but also to the development of the country and the health of the population. The collective work of BioCubaFarma scientists and the country's health professionals, with a sense of social responsibility during the pandemic, has enabled the country to overcome this crisis with its own resources.

> *"While we were working in the laboratory, we had started to bring together our medical teams, vaccine evaluation experts and all the health personnel (...) With the integration and cooperation of all the scientific talents of the country, hundreds of thousands of people worked on this process - vaccination during the pandemic. Afterwards, vaccinating the country was like a celebration."*

The society, which is aware that scientists get their motivation to work despite all the difficulties from their contribution to the health of the society and the development of the country, therefore, unlike other countries in the world, it trusts science and scientific results more. When people in Cuba were invited to be vaccinated, they followed the call with great confidence. Thus, Cuba became the only country that was able to vaccinate more than 90 percent of its population during the pandemic. It is understood that the organizational culture of the society also had an impact on this.

"Our strength is (...) our integrated and centrally managed state system. However, we have a strong organizational culture that focuses not only on the role of the state but also on the role of society as a whole in disaster situations."

4.3. Synthesis of the Quantitative Data and Qualitative Findings

The qualitative and quantitative data analysed in this thesis show that the Cuban biotechnology sector has many unique characteristics. Foremost among these is the significant contribution of Cuban biotechnology to the development of public health. The main goal of the sector, both during its establishment and development, has been to meet the needs of the national health system; in this sense, it has achieved its goal. The vaccines it has developed have eradicated many infectious diseases in the country, and the sector has developed many innovative products to reduce the mortality and morbidity rates of prominent diseases in the society. Therefore, unlike in the rest of the world, it is more meaningful to evaluate the success of the Cuban biotechnology sector in terms of its contributions to public health, rather than market shares or profit rates.

Another uniqueness of the sector is that it provides significant savings for the national economy, both through the domestic production of medicines and through products developed to prevent diseases. The proof of this is that Cuba has health indicators that are equal to or better than those of high-income developed countries, despite having much lower per capita health expenditures. Thanks to the national health system organized with a focus on preventive health and the biotechnology sector that is very well integrated into it, society has been able to be healthier with less health expenditure. As mentioned in the previous sections of this thesis, many international organizations have recommended in their reports and in articles of well-known scientific journals that these achievements of Cuba in the field of health and biotechnology should be examined, especially by developing countries in formulating policies and strategies.

However, the success of Cuban biotechnology is not limited to these positive effects on public health and the country's economy. Cuban biotechnology is also a

successful sector in terms of general criteria such as product development, innovation capacity, patent numbers, export revenues - although not with a steady increase. One of the important things that makes this possible is the number and rate of qualified human resources in the country's health sector. It is an unexpected fact that Cuba, an island country with very limited resources under the US blockade, has a highly educated population, developed health parameters and an innovative biotechnology sector. This sector, established by a socialist country based on social ownership of the means of production, with a long-term strategy focused on needs, has not followed the capitalist path of global market-oriented production and profit-based economic growth. Cuban biotechnology has remarkable differences in terms of the role played by the state from its establishment to its development, its direct relationship with the national health system, its organizational and integration mechanisms, and the innovation and adaptability associated with these.

4.3.1. Discussion from a Growth and Development Perspective

This section discusses the role of the state in the establishment and development of Cuban biotechnology as a strategic sector and, directly related to this, the place of the biotechnology sector in Cuba's national development plan. Many different economic approaches have been produced regarding the need for developing countries to establish their development strategies in different ways than industrialized countries. These approaches differ significantly in terms of the roles assigned to the state. Since the state is the sole investor in Cuban biotechnology, this section is based on state-centred development perspectives for developing countries.

Economic development models have primarily addressed the role of the state in learning processes historically. In this context, it is generally pointed out that the primary function of the state is to cultivate knowledge and human resources, and that the state should also encourage technology transfer and local capacity. In today's world, where education is still largely provided publicly, including in capitalist countries, and science and education policies are determined by states, the role of the state in learning processes is undoubtedly important. However, what is pointed out here is that the state should review its education policy according to the needs of the

sector in which investments are planned in line with a strategy and take action in this direction.

The fact that biotechnology was established in a low-middle income country like Cuba in the early 1980s, just a decade after its emergence as an industrial field in the world, even before Europe, is an 'unexpected' development for many. The establishment of a knowledge-intensive sector in an island country with very limited resources, at a date earlier than the rest of the world, is actually closely related to the significant progress made by the Cuban State in terms of human capital investments and the institutionalization of science in the 1960-1980 period (Medina Borges & Garrido Céspedes, 2022).

Soon after the revolution, in line with the priorities determined by the leadership cadres based on the socio-economic and cultural conditions of the country and the policies they developed accordingly, an inclusive education and health system was rapidly established in the country and medical education was particularly encouraged. It was a great step towards social development for a poor country in the 1960s to have an educational approach that encouraged education for all age groups and easily accessible health services. But these steps were also part of a long-term economic development plan. Thus, Cuba would soon have the qualified human resources it needed to build autonomous technologies in the specified areas. In this sense, in line with the above approach, it is clear that the state has a tremendous role in the learning process in Cuba.

After World War II, theses were produced that well-funded science would direct technology with the knowledge it produced and would be the engine of innovation. It was soon understood that this approach, called the linear innovation model (Bush, 1999), was not generalizable even for developed countries. In an objective situation where capitalism creates frequent crises, stable economic growth periods are becoming increasingly short, and where inequalities between countries are so deep, very few countries have the resources to purchase the technologies in question. Based on this, the academy has produced many economic and political approaches to the development paths of developing countries.

One of these claims that underdeveloped countries can skip the long learning processes that are relevant for developed countries by directly accessing the advanced technologies of industrialized countries. It has been argued that underdeveloped countries, where the state is stronger and the market is less developed, can enter a rapid industrialization process by using these advantages of late development. This theory, which Gerschenkron (1962) calls 'Backwardness Theory', inspired the catch-up theories established in the following years. According to these, underdeveloped countries can imitate or adapt the technologies of advanced countries and gain advantages in terms of time and cost. Or, structural transformations can be implemented under the guidance of the state in sectors suitable for competitive advantage (Lin, 2011). With this plan, it is recommended that states make infrastructure investments in specified sectors, direct public financing, import technology or support the relevant sector with long and low-cost loans, protective regulations, incentives and subsidies. The different leaps of Asian economies such as Japan, Korea and Taiwan are explained by these theories.

The development of Cuban biotechnology cannot be explained by catch-up theories from several perspectives. The first of these is that, as mentioned above, Cuba turned to the biotechnology sector with a long-term plan and at an earlier date than the rest of the world. Another reason is that the Cuban biotechnology sector was not established with the aim of integrating into global value chains, but with the aim of meeting the needs of the national health system with local capacity, without being dependent on foreign trade. Moreover, in those years (as now), the dominant power in the biotechnology sector was the US, and the US has been imposing sanctions on Cuba at various levels since the beginning of the revolution. Cuba mitigates the disadvantages of US sanctions and being an island country with limited resources thanks to the trade it maintains with socialist countries through COMECON (Council for Mutual Economic Assistance).

However, despite the support of the Cuban State and especially Fidel's COMECON, the country has had the goal of establishing its own pharmaceutical industry from the very beginning. Before 1980, Cuba applied to establish its pharmaceutical sector within the scope of a UNIDO project, but it was decided that India would be

supported, not Cuba. Despite this, Cuba did not give up on its goal of establishing its own pharmaceutical industry (Medina Borges & Garrido Céspedes, 2022). In short, the move Cuba has made in the field of biotechnology aims to protect public health, find low-cost solutions in this direction, develop its own research and development capacity in one of the areas where the country is strongest, provide technological autonomy in a strategic sector, and eliminate threats from the US (including biological attacks). In this sense, the global market-determined development focus of catch-up theories is not included in Cuba's sectoral development plan. In addition, Cuban biotechnology has aimed at original knowledge production, not imitation, and foreign capital investment has not been on the agenda as an option due to the country's socialist economy. The only common point between Cuba's biotechnology experience and the catch-up theories is related to the strategic role of the state.

Chang is one of the economists who strongly emphasises the role of the state in the development of developing countries, pointing out that economic development is only possible with the active intervention of the state. Unlike others, the free-market economy has been defined as one of the greatest obstacles to the development of countries in his approach (Chang, 2003). In fact, from a historical perspective, he draws attention to the fact that developed countries such as the USA, England, Germany and South Korea, which later caught up with developed countries, have achieved their high technology and strong industry today thanks to the protectionist policies they implemented in the past, state-supported sectoral investments and R&D activities. Criticizing neoliberal policies, he argues that countries will achieve development success with the active attitude and long-term plans of the state. At first glance, due to the emphasis placed on the aspects of the market economy that restrict development, the active and decisive role of the state and the need to protect and support 'baby industries', Chang's 'kicking the ladder' approach can be considered to be largely consistent with Cuba's move in the biotechnology industry. Until Cuban biotechnology reached a point where it could provide its own self-financing with export revenues, all investments in the sector, R&D expenditures and expenses of the sector were financed directly by the central budget of the state. However, despite the fact that the Cuban economy shrank by up to 35 percent during the collapse of the Socialist Bloc that began in 1989, investments in the biotechnology sector, which

was still an ‘infant industry’, were not abandoned. Another similarity is Chang’s perspective that state policies should aim not only for economic growth but also for increasing social welfare. Cuban biotechnology and the development policies of the Cuban State in general primarily target social development. Despite all these overlapping aspects, Chang’s approach and Cuba’s biotechnology development are clearly separated by a fundamental contradiction. This sectoral move by Cuba has been shaped as part of a socialist state model. In socialist development models, the state is already the sole investor in all sectors in line with central planning. In addition, the role of the socialist state is not limited to being an active support tool in the process of establishing, protecting and strengthening the industry with infrastructure, human resources and R&D investments in the development process. The state is a direct planner of the sector's production and R&D studies, including the subsequent stages, in line with social needs and the interests of the country. In fact, the incomes of the sector in question can be used for other sectors within the scope of a plan. In addition, since the ownership of the means of production belongs to the public (except for very special periods historically), it does not include flexibility regarding cooperation with the private sector. Chang's theory includes the opening of the industry to foreign markets after the development period. The Cuban biotechnology industry also aims to create export potential at the same time as social development from the beginning. However, even in this context, the goal of opening the sector to the outside world is actually determined by the strategy of minimizing these threats, as Cuba, which is being isolated from international trade and its economy is being weakened by the sanctions of the USA. For all these reasons, despite these similarities, it is not possible to explain Cuba's success in the biotechnology industry with Chang's mixed economy model.

It is a general acceptance among economists that state financing, subsidies, credit and tax incentives, and of course protective legal regulations encourage sectoral growth. In the 21st century, the entrepreneurial role has been added to the many roles assigned to the state in development, such as financier, supporter, planner. Mazzucato (2011) notes that the state has the potential to create and direct markets as an entrepreneur. She states that, in addition to providing funds to private capital, the state can establish strong and innovative sectors with long-term and stable

investments. She draws attention to the fact that the greatest innovations take place in sectors where the state is the first entrepreneur. When the innovative character of Cuban biotechnology, which is a 100 percent state sector, is taken into account, Mazzucato's understanding of the state as a catalyst for innovations may come to mind. However, in Mazzucato, the state encourages innovations while the private sector commercializes them. Moreover, social benefit is formulated in the form of the state, which takes the first risk, also sharing in the sector's revenues through public-private partnerships. Mazzucato's theory, like Chang's, cannot explain the developmentalist policies of the Cuban State in the biotechnology industry due to its focus on private capital collaborations and the market economy.

All these theories, which assign proactive roles to the state, emphasise the failures of the market economy, and argue that state intervention in the economy is legitimate, are quite different from neoliberal theses, which assign a mere facilitator role to the state, consider economic growth as development, and argue that state intervention is only necessary in cases of market failure. The increasing number of evolutionary, post-Keynesian, or heterodox theories with the theme of a 'strong' state, which present the state not as a problem but often as a solution to growth and development, may be due to the fact that the idea of the 'ideal' free market has lost its influence. Economies in the world today are becoming increasingly complex, and inequalities between and within countries are deepening. In such a conjuncture, the theoretical and policy approaches that emphasise innovations as drivers of growth and development are growing in number. In the next section, Cuban biotechnology is discussed from this perspective.

4.3.2. Discussion Regarding Innovation Systems and Capacity

The thesis that innovations are not only a result of economic growth but also a trigger for it dates back to classical economic theories. However, the discussions that not every investment in knowledge will encourage innovation and that innovations are not linear but cumulative and uncertain are more recent. The development policies of countries have also been affected by these discussions and have begun to include the concept of innovation in different models and frameworks. Cooke (2013) points out

different innovation models in relation to the economic development models of countries. He states that the three basic innovation models he defines as the entrepreneurial model, the partnership model and the developmental state model are related to liberal market-oriented, regulatory and state-centred economic development approaches, respectively. Therefore, these models are expected to differ in terms of labour resources, their relationship with education systems, economic collaborations and R&D methods.

4.3.2.1. Innovation systems

Innovation systems, which emerged as a concept in the 1980s, define the elements and their interactions required to support innovation activities in a country, region, or sector. In a broad context, innovation systems include approaches that recommend strengthening R&D activities and related infrastructures, establishing university-industry linkages, and investing in technology-based companies (Nelson, 1993). Besides, different approaches have been formulated considering these systems more broadly in terms of the components of innovation and the interactions between them.

The concept of National Innovation System (NIS), which considers the concepts of state, industrial innovation and development within the same key framework, broadly encompasses all actors supporting the production, distribution and utilization of knowledge and the interaction between these actors (Lundvall, 2015). While Freeman and Perez (1988) points to the state's facilitation of technological learning processes within these systems, Lundvall (2015) adds a more dynamic content to the NIS with his emphasis on learning by doing and the concept of learning economy. The Cuban biotechnology sector can be considered to be compatible with this dynamic and interactive structure of NIS in its broader context.

NIS involves a focus and careful planning. This plan, also linked to public policies, encompasses the organizational integration of state-based institutions, rather than those based on companies. In this context, the structure of Cuban biotechnology, which is directly integrated with the national health system, and the planning of its production, including research and development activities, with a central strategy

focused on social needs, suggest that the sector operates within a NIS structure. It may be more explanatory to evaluate this in a narrower historical range, through the process of managing a crisis period. During the COVID-19 pandemic, the rapid establishment of mechanisms that allow the Cuban State administration, experts, and academics in the field of science and technology to directly communicate with each other has enabled the production of many innovative products in the country within a planning and integration framework, the development of creative solutions, and the management of the pandemic more successfully in Cuba compared to the rest of the world. In this sense, the pandemic period is filled with experiences that demonstrate how the Cuban State in general, and the biotechnology sector in particular, operate within an innovation system approach.

The establishment of the Scientific Group for the Fight against COVID-19, the Health Observatory and Innovation Committee, a National Task Force that meets daily under the leadership of the President and the Prime Minister, the Provincial Defence Councils, the active involvement of many experts and academics from very different disciplines, from mathematical modelling to integrated geographical systems with epidemiology, and the updating of economic and social strategies with long-term crisis scenarios show that the state has acted with an effective central plan during the pandemic period and by ensuring the active participation of all relevant elements. In addition, social scientists have been informed by relevant experts and administrators through the daily 'Round Table' television program and press conferences, where all kinds of information and developments regarding the prevention and control of COVID-19 are shared with all their openness, and the country has been enabled to act in a kind of social mobilization (Bermúdez & Jover, 2020). The biotechnology sector has a huge share in Cuba's success in keeping COVID-19 incidence and mortality rates at one-sixth of global rates, reducing reproduction rates to below 1 percent, preventing the health system from being overloaded, and then vaccinating more than 90 percent of the population, all while doing so under a more severe blockade and a kind of commercial isolation. Scientists and researchers in the sector have been very effective components of both the councils and committees listed above and the public information processes. Beyond these, they have developed 5 COVID-19 vaccines, produced ventilators, and rapidly

repositioned existing products that have the potential to be used in COVID-19 treatment. The fact that scientists and vaccine researchers inform the public about their research on informative TV programs every day has enabled the public to absorb information, get to know and trust those who produce the information, and thus more than 90 percent of the population has been vaccinated in a very short time after the COVID vaccines were produced. The pandemic has been a new learning process for all BioCubaFarma employees, where medical, epidemiological and scientific learning has become continuous, as well as “innovating in the innovation process” (Martínez Díaz et al., 2020). Innovation systems emphasize these planned and organized integration processes that are in a constant state of learning.

In the interviews conducted within the scope of this thesis, it was understood that during the pandemic period, BioCubaFarma employees carried out many different stages such as vaccine production, production of evaluation tests, licensing of drugs with new functions in an organized integration, completed each other's deficiencies and needs in every sense, and sought creative solutions to the problems they encountered together. In this context, it is also possible to say that Cuban biotechnology also has a sectoral innovation system operation.

The biotechnology industry is a sector in the category of knowledge economies with a highly qualified workforce. The flow of knowledge between experts from different disciplines within different organizations or between other researchers within the organization contributes significantly to the institutional learning process. In this sense, information flow and interactive and planned collaboration are important for the emergence of innovations in the biotechnology sector, which is a high-risk sector. For BioCubaFarma, these are not processes specific to pandemics or crisis periods. Active complementarity has been encouraged since the sector's inception, which has undoubtedly influenced its ability and pace of innovation.

Cuban biotechnology also interacts with physicians, who are users of their products, recommending biopharmaceuticals to patients and evaluating their effects from a scientific perspective. Family physicians work with a system that centralises some of the clinical and epidemiological information they collect in their field of work. The

community-based information collected with this system, called Infomed, provides data that facilitates and guides the research of the biotechnology sector. This systematic instrumental interaction between the producer and the user of information increases the productivity of both parties by feeding their continuous learning processes. This situation also makes the actors of primary health care as one of the producers of scientific information, unlike the rest of the world.

Another unique feature of BioCubaFarma is that all research, development, production and marketing processes are carried out under the same roof. This model, called the closed-loop approach, describes a process that includes all stages of production, where researchers can also monitor the transformation of research results into a product and their presentation to society. With this cycle, where knowledge is transformed into an economic value, it is aimed for scientists to feel a responsibility over all stages of production and not to be alienated from their production. In this context, it is possible to think of the closed loop itself in the context of the sectoral innovation system mechanism that encourages innovation.

This system, which results in Cuban biotechnology operating efficiently, producing innovative products, having an interesting research pipeline, developing international collaborations, largely meeting the needs of the national health system, contributing to social development and the country's income, is also integrated with non-sectoral research centres and universities. Many researchers from the sector are doing their masters and doctorates at universities, and universities and the sector are carrying out joint projects. Within the framework of the cooperation, BioCubaFarma provides its laboratories and physical infrastructure to some departments of universities, and students studying in fields related to the sector at universities do their internships at BioCubaFarma. In this respect, there is a symbiosis between the sector and universities, and it is possible for students and young researchers in particular to combine science-based learning with experience-based learning thanks to this cooperation.

In light of the discussion above, it is understood that Cuban biotechnology and the Cuban State, especially during the COVID-19 pandemic, have a very high potential

to implement national and sectoral innovation systems approaches. However, the innovation systems developed by Freeman, Lundvall and others, just like the development theories or university-industry-state cooperation models discussed in the previous section, are actually entrepreneur-oriented and defined in terms of market mechanisms (Türkcan, 2009). Although they include social benefit as an element, they put economic growth at the centre. However, the main goal of Cuban biotechnology in the innovation process, the operating logic of their structures and decision-making processes are not market-centred and profit-oriented, but are oriented towards social needs and national strategies. R&D studies are not planned according to market demand or possible niche markets. In innovation processes, collaboration, not competition, is the driving force. These very fundamental differences must be underlined.

4.3.2.2. Innovation capacity

Innovation capacity is actually measured by various indicators that pave the way for the formation of innovation. R&D expenditures and the ratio of these expenditures to GDP, as well as employed R&D personnel, knowledge investments, high-technology product export volume and patent numbers are considered as the basic indicators of innovation capacity (Akçomak et al., 2016). When it comes to developing countries, access to information and technology, the effort to absorb and use this information and technology and develop innovation skills themselves gain priority in the evaluation of innovation capacity[42].

Founded in the early 1980s, Cuban biotechnology has rapidly completed the process of developing the ability to absorb and use information and technology, and has reached the capacity to develop innovation in a short time. However, knowledge-intensive sectors such as biotechnology cannot be satisfied with the acquisition and preservation of information once, because information and technology develop and change very quickly. Therefore, continuous learning is also important for the

[42] In addition to the Oslo and Frascati Guidelines, which are based on the firm as a unit, the Bogota Guidelines, developed for developing countries, are used to measure R&D and innovation, especially in Latin American countries (Akçomak et al., 2016).

biotechnology sector. Since it is a knowledge-intensive industry, the sector requires intensive R&D activities in order to create innovations. The first condition for this is that the sector has a highly qualified workforce; scientists, engineers and technicians. This is followed by the need for a good research infrastructure and up-to-date technology. At this point, it is generally accepted that it is important for the state to encourage R&D activities both at the policy level and financially.

Cuban biotechnology has trained, experienced, and productive human resources. The sector and the national health system, to which it is directly integrated, have a highly educated workforce ratio that is well above the world average. 7 out of 8 high-tech companies in the country are in the biotechnology sector. The sector, which has many patents, interesting pipelines, and good innovation capacity, has a low amount of R&D allocated from the state budget. As quantitative data also indicate, Cuba's GERD rates are well below countries with high innovation capacity, at the same levels as the world average. This situation shows that the innovation performance of the Cuban biotechnology sector is not related to the state's R&D spending.

More than 15,000 of the 16,000 people working at BioCubaFarma are researchers, experts and technicians. In other words, it has a high proportion of R&D personnel. A significant portion of the sector's revenues are used for the domestic and international training of researchers. In a study conducted by Crespi (2004) to determine the determinants of innovation, it was shown that investments in scientific and technological education and its infrastructure were effective in the employment of scientists. In the same study, it was observed that patents obtained for the protection of intellectual property rights generally increased the innovation capacity, but there was no general consensus on which of the different patent policies was more supportive.

In Cuba, patent rights for innovative products are owned by institutions, not individuals. Individuals are defined only as inventors in the system. This seems logical when it is considered that research and development activities are determined by a central plan according to the needs of the national health system. In this way, the results obtained are protected in the interests of the country and the Cuban

people. Patents obtained abroad facilitate the sector's finding new markets, developing new international scientific and commercial partnerships, securing export revenues, and thus providing resources for the sector to develop new technologies.

It is generally accepted that patents are effective in increasing innovation capacity because they are a criterion for receiving government and company research funds and incentives worldwide. However, since patents are actually a measure of output (innovation), not every innovation is patented, regulations vary between countries, and not every patent turns into a product, it is also widely thought that patents are a subjective indicator (Kılıçaslan & Aytun, 2016). In BioCubaFarma, revenues from patent rights are distributed to researchers (inventors) as one of the business incentives (Villanueva & Espiñeira, 2023). However, since there are also different incentives such as housing provision and educational support for all employees of the sector, it does not seem possible to objectively evaluate the impact of patents.

There are various debates about the relationship between innovation and market structure, as well as which type of innovation performs better in different market environments. Also, discussions that focus on whether the needs of global markets or the supply side have a more positive impact on innovation capacity exist. The evolutionary economics approach states that the chaotic structure of capitalism, which includes many crises and uncertainties, triggers technological innovations and that competition is the driving force of innovations. However, this process, defined as *creative destruction*, actually progresses with the deepening of monopolization and social inequalities all over the world. The Cuban biotechnology sector, on the other hand, absolutely excludes competition and strengthens innovation capacity through knowledge sharing and complementarity. This cooperation, carried out within an organized integration, both prevents the loss of good ideas and feeds micro-learning dynamics with new interfaces. In addition, it ensures that the obstacles to innovation are overcome together and the risk is reduced. This phenomenon, which Cubans call *creative resistance*, is a definition they frequently use when describing the COVID-19 pandemic period.

In capitalist economies, innovation gains importance according to the size of the added value it creates, the speed of its spread and imitation, and whether it leads to

other inventions, in other words, to its generativity (Türkcan, 2016). For Cuban biotechnology, the value of innovation lies in preventing diseases, reducing mortality and morbidity, and in short, improving public health. However, another important goal of the sector is to increase export revenues, since the domestic market does not provide a source that will ensure the continuity of innovations. The biotechnology sector worldwide is a very expensive sector (for a goal that consists of meeting the health needs of a country with a population of 11 million). There are very few biotechnology companies that continue their R&D activities with trade revenues, and R&D activities are generally carried out with venture capital. In this sense, Cuban biotechnology has aimed to increase its export capacity from the beginning and to obtain an export revenue at a level that can support different sectors of the country. Dávila (2019), one of the founding scientists of the sector, states that the products of the sector start to generate income in a period of 4-5 years, which is shorter than the world average. The dominance of transnational companies in the global market and strong competition require the continuity of innovation capacity. In order to ensure this continuity, what is as essential as updated knowledge and the latest technological devices is the stable supply of raw materials, intermediates, chemical reagents and some equipment required for R&D and production activities. However, Cuban biotechnology is facing a major supply problem due to the worsening blockade conditions. The sector's export revenues, which were increasing until 2014, have decreased in the last decade. Nevertheless, it is among the top ten sectors contributing the most to the country's export revenues.

Oslo Manual (2018) reported that economic factors such as high costs and lack of demand, firm-specific factors such as lack of qualified personnel and knowledge, as well as government regulatory and taxation systems can have negative effects on innovation capacity. According to Mazzucato (2011), another obstacle to innovation is financialization. She says that companies allocate fewer resources to high-risk, long-term innovation investments due to short-term profit maximization strategies. It is stated that corporate systems based on shareholder value are an obstacle to innovation. BioCubaFarma, on the other hand, does not have any value traded on the stock exchange. It is a state holding and its ownership belongs to the public.

4.3.3. Discussion by the Impacts of the US Blockade

According to evolutionary economics, the adaptability of a sector is the capacity to adapt to changing environmental, technological, economic and institutional conditions. This ability determines the survival, competitiveness and innovation ability of the sector. Adaptation is one of the concepts that is affected by both internal (technological innovation, diversity) and external elements (market conditions, international politics) and shapes the sustainability and therefore the success of the sector. Concepts such as natural selection (creative destruction), diversity and innovation are used in the discussion (Schumpeter, 1942).

Since the early years of the revolution, Cuba has faced serious obstacles in accessing goods, raw materials, intermediate materials, technological devices and equipment due to economic, commercial and financial sanctions imposed by the USA. The Cuban State has been able to carry out its import and export, which were greatly restricted due to the blockade, for many years without experiencing a significant supply crisis thanks to the commercial agreements it made with the Soviet Union and other socialist countries. The USSR sold cheap oil, industrial machinery and technology to Cuba in exchange for the sugar it purchased from Cuba at a high price. Again, socialist countries made important contributions to the modernization of the sugar and nickel industries, and many scientists, engineers and technicians were educated in socialist countries. With its membership in COMECON in 1972, Cuba's commercial relations with the Socialist Bloc were established in a more planned and stable framework.

The US blockade has been the biggest obstacle to Cuba, which has very limited resources except for sugar and tobacco production and the nickel industry, importing all other products and raw materials that are not available in the country from neighbouring Latin American countries or North America. Even though it was able to supply its basic needs to a large extent during the COMECON period, Cuba accelerated its search for technological independence and sovereignty under various threats from the US. One of these sectors and the priority is the pharmaceutical industry. It is aimed to develop domestic technological capacity in order to reduce

the country's dependence on imports for critical products such as drugs on the essential medicines list and vaccines in the national vaccination program. However, efforts were made to develop early diagnosis kits and vaccines and treatment methods for major epidemics with an understanding that focused on preventing diseases rather than treating them, and thus the sector soon gained the ability to innovate. By the 2000s, Cuba was now able to produce 85 percent of the drugs on the essential medicines list and most of the vaccines in the national vaccination program (O'Farrill, 2014). Thanks to the domestic biopharmaceutical industry, Cuba managed to produce medical products at low cost, making the health system sustainable and reducing its dependence on imports. The vaccines produced by the sector, interferon, insulin, and chemotherapeutics, which are quite expensive on the global market and quite critical for public health, have become economic and strategic resistance tools against the blockade. From this point of view, it is possible to say that Cuba's investment in biotechnology is a direct response to the US blockade, and that this innovative sector has increased the resistance of the country, which is in the middle of an economic war, against the blockade (Kirkham, 2024).

Taking advantage of the collapse of the USSR, the USA increased its pressure on Cuba with laws such as the Torricelli Law in 1992 and the Helms-Burton Law in 1996. The blockade laws were aimed at preventing Cuba, which had lost a significant portion of its foreign trade market, from developing new trade relations and from supplying vital products such as food, medicine and fuel (Kuntz, 1994). In return, Cuba tried to bypass the US blockade with the country's scientific potential and innovative biotechnology sector. Even during the Special Period, the sector was supported by large investments from the central budget and it was ensured that it had high technology for research, development and industrial production activities. It is understood that the important aim here was to increase the country's export revenues by utilizing the biotechnology sector, which has a high innovation potential.

The number of scientific and commercial collaborations developed internationally by Cuban biotechnology, whose successes began to attract attention in the scientific community, also began to increase in the 2000s. These are very important for the Cuban State and the biotechnology sector in reducing the negative effects of the

blockade. The most important collaboration that attracted attention in the field of health in the early 2000s was the collaboration agreements made with Venezuela during the Chavez era. Cuba's strong infrastructure in the field of health and Venezuela's oil wealth were used for the mutual benefit of both countries. According to this collaboration, many Cuban physicians and health experts provided free health services in poor neighbourhoods of Venezuela - with the Barrio Adentro Program -, Venezuelan students received medical education at the Latin American Medical School (ELAM) in Havana, and Cuban biotechnology products were sent to Venezuela. In return, Venezuela provided discounted oil and energy products to Cuba[43].

Apart from the health brigades that go to all corners of the world for international solidarity in times of epidemics, disasters and emergencies, the Cuban State exports professional health services. In addition to Venezuela, countries to which professional health services are exported include Brazil, Bolivia, Ecuador, Angola, South Africa, Qatar, Pakistan, Saudi Arabia and Portugal (Cuba Archive, 2020). The importance of this service export for the biotechnology sector is that Cuban health professionals also promote domestic biotechnology products in the countries they go to. In this way, the country can find new markets, even if they are small, for biotechnology products. In this sense, it is understood that the biotechnology sector, which is a direct component of the national health system in the country, also works in a complementary integration with the health system abroad.

The US blockade, which was a kind of catalyst in the establishment process of the sector, has turned into a full-fledged inhibitor in the following years. As a result, it is understood that Cuban biotechnology has become a sector that the US is following and targeting more closely, as it contributes more to the economic and social development of the country and its reputation in international scientific circles increases. The blockade hinders the activities of the biotechnology sector at all levels, with laws preventing the supply of raw materials, intermediates, and reactive agents from third countries and companies, provisions prohibiting trade in USD,

[43] Health cooperation between Cuba and Venezuela continues, but its intensity has decreased significantly in recent years following the economic and political crises in Venezuela.

precautionary measures preventing the actual use of the international banking system, and commercial agreements that are broken at the signing stage. Concrete examples and evidence are included in the documents containing the sectoral effects of the blockade that MINREX (2024) presents to the UN General Assembly every year: According to the report, in 2023, the South Korean company Macrogen and the US company Addgene refused to send immunological tests and materials to Cuba. Again, US National Cancer Institute researchers were prevented from sending reagents they wanted to send to Cuba. Another obstacle in 2023 is the denial of access to analytical data required for Cuba's own vaccine production project against human papillomavirus (HPV)[44]. It is seen that the sector has developed various methods to overcome these difficulties; in this sense, cooperation established in the scientific and commercial fields is critical. Not only state officials and BioCubaFarma managers, but also scientists and researchers make great efforts to establish international cooperation and partnership agreements. New international scientific research project agreements are made with the organized international scientific congresses, and thus, in some cases, R&D studies are carried out directly abroad in order to overcome the supply and banking obstacles of the blockade. As it is understood from the study, cooperation agreements are not only research-based. BioCubaFarma has production facilities in Vietnam and China that it is a partner in. These production-based partnerships are also functional in overcoming another difficulty for the sector in finding new markets.

The diplomacy and collaborations carried out in the field of health are seen to be beneficial in terms of the sector being able to generate export revenues, maintain its innovative potential and continue local production. It can be said that the sector uses these cooperation agreements made in the scientific and commercial fields to survive and stay innovative. However, it is clear that these are not enough to solve all the blockade-related problems. The 243 restrictive measures taken by the Trump Government (2017-2021) against Cuba and the re-inclusion of Cuba on the list of countries that support terrorism have made it even more difficult for the sector to

[44] HPV is the most important cause of cervical cancer in women. Cervical cancer is the second most common cancer type in Cuba among women aged 15-44. It is also the fifth leading cause of cancer-related death in women. For this reason, the Cuban National Center for Scientific Research has been working on a project to produce a local HPV vaccine for some time (MINREX, 2024).

provide import substitution for raw materials and other production inputs. One result of these decisions, which have a direct impact on the increase in production costs and the decrease in export revenues, is the instability in the production line. BioCubaFarma, which was able to produce 85 percent of the drugs on the national essential medicine list in the early 2000s, was able to produce only 51 percent of this list in 2024 and was able to provide the health system with a stock guarantee of 30 days instead of 120 days (MINREX, 2024).

The blockade has made it imperative for the country to use local resources at maximum efficiency in order to make production processes sustainable. In this respect, the biotechnology sector has developed innovations and low-cost solutions that inspire the whole of society. It has made great efforts to produce devices that cannot be supplied, vaccine evaluation tests, and the molecules required for these with existing resources, and although difficult, it has achieved successful results. Thus, the resilience of the sector is ensured. The sector's strong adaptability encompasses an approach that not only strives for continuous production, but also for sustainable development and social progress, despite the country's general blockade and limited opportunities, as explained by the concept of creative resistance.

Cuban scientists, aware that the US blockade would be a major obstacle to access to vaccines and medicines produced during the COVID-19 pandemic, immediately began vaccine studies. As a result, the names of the five COVID-19 vaccines developed are Soberana 01, Soberana 02, Soberana Plus, Abdala and Mambisa. This naming of the vaccines symbolizes Cuba's resistance against the blockade and its cultural, historical and ideological character along with its claim to independence. Soberana, meaning sovereign, indicates that Cuban biotechnology can protect the health of the people with vaccines developed without the support of large biopharmaceutical monopolies. It symbolizes Cuba's autonomous achievement in the scientific field and the pride of its scientists. Abdala is the name of a young warrior character who heroically defends his country in a poem by José Martí, Cuba's most famous national hero, revolutionary and poet. It points to the country's resistance against the US blockade, the revolutionary spirit of the youth and its self-confidence in health innovations. Mambisa is the name given to the African guerrillas who

fought against Spanish colonialism for Cuba's independence. It expresses the Cuban people's struggle for equality in health and their defiance of oppression (Yaffe, 2021).

Cuba, despite managing the pandemic without overloading its health system, took action to increase the number of mechanical ventilators it had in its possession as part of its worst-case scenario preparations, but US sanctions prevented it from importing these devices. In response, BioCubaFarma and engineers and intensive care specialists from universities began working to improve the country's ability to produce mechanical ventilators, which are essential for treating severe COVID-19 patients. Today, the BioCubaFarma CNEURO Science Centre can produce the device called Pcuvente, which is used for emergency mechanical ventilation in adult patients. This innovation, which has an important place in the country's strategy to achieve technological sovereignty, received the National Technological Innovation Award in 2022 (Prensa Latina, 2022).

This strong adaptability of the sector is actually related to the sense of responsibility of Cuban scientists to use their knowledge to meet the human needs of society. In this respect, it can be said that the most advanced aspect of the country's science and technology policy is the social values that guide it. Scientists offer their knowledge to the service of society not only to produce science, obtain patents, or publish articles, but also to meet the needs of the society they are a part of and the country's development demands. What makes Cuban biotechnology innovative and resilient is actually that scientists act with values such as collective responsibility, complementarity, and solidarity.

The pandemic has been experienced as a crisis period that has far exceeded the health sector all over the world. National economies have been negatively affected by the pandemic and the economic parameters of the countries have deteriorated significantly. However, recovery has begun in economic indicators worldwide in 2022. Cuba's economy, with its other accumulated problems[45], has not yet recovered

[45] The decrease in the income of the country's economy, the problem of fuel supply and energy production, causes a decrease in total production.

after the pandemic, and permanent and significant improvements have not been achieved in economic indicators such as GDP growth rates, inflation rates, and export-import balance. On the contrary, the country's current account deficit and foreign exchange needs are increasing. The blockade continues to be the biggest external obstacle to economic development (Rodríguez, 2024). Export and tourism revenues are of great importance in meeting the country's foreign exchange deficit. However, the number of tourists and tourism revenues are still far from reaching their pre-pandemic levels. Although the number of tourists in other Caribbean countries has reached their pre-pandemic numbers after the pandemic, the fact that Cuba has still not reached this level suggests that the country's inclusion on the US list of countries supporting terrorism in 2021 may have an impact on this. COVID-19 vaccines, which are indicators of the innovation and adaptation capacity of Cuban biotechnology, have actually created a huge opportunity in terms of increasing the country's export revenues and alleviating its economic crisis. Pfizer/BioNTech has earned 21.5 billion USD and Moderna 19.6 billion USD from COVID-19 vaccines as of March 2021 alone. Cuban vaccines have only been exported to Vietnam and Venezuela due to US economic, commercial and financial sanctions (The Guardian, 2021). Thus, once again, the opportunity to strengthen the biotechnology sector and thus alleviate the effects of the country's economic crisis has been hindered by the US blockade.

4.4. Concluding Remarks

Cuba stands out with its remarkable health indicators compared to countries within its income group. These indicators, comparable to those of developed nations with much higher per capita health expenditures, validate the success of Cuba's preventive health-focused community-based medical model. The biotechnology sector, through R&D and production activities aligned with public health needs, has contributed significantly to the eradication of infectious diseases, the rapid improvement of maternal and child health indicators, and the reduction of mortality and morbidity rates related to major health issues in the country.

Cuba allocates only 0.4-0.5% of its GDP to R&D, a level consistent with global averages but insufficient to fully explain the innovative capacity of its biotechnology

sector. With a broad portfolio of innovative products and an extensive product pipeline, the biotechnology sector has made significant contributions to the national economy since the 2000s, generating foreign currency through the export of innovative products.

However, the sector faces significant challenges due to the economic, trade, and financial sanctions imposed by the United States. Difficulties in procuring raw materials and intermediates necessary for the production of pharmaceuticals and biotechnological products disrupt industrial production stability and deplete the country's drug stockpiles. The annual cost of the embargo on the biotechnology sector alone is estimated to exceed $100 million.

The sector can only secure suppliers from distant regions such as Asia and Europe. Moreover, supplier companies often rely on intermediaries to avoid the impact of U.S. sanctions, further inflating costs. To mitigate the effects of the embargo, Cuba leverages technology transfer, partnerships in production processes, and international collaborative scientific projects. These collaborations are not limited to South-South partnerships but also include South-North collaborations.

Cuba exports vaccines to many countries for their national immunisation programs, and the deployment of professional healthcare workers abroad promotes the country's biotechnological capabilities, paving the way for new international collaborations.

Centralised planning and revolutionary leadership have played a significant role in the asymmetric development of biotechnology in Cuba. Under Fidel Castro's leadership, investments in human resources, aligned with national independence and social development goals, have bolstered the sector. Guided by a strategic plan, Cuban biotechnology set out to build local capacity tailored to the needs of the national health system, achieving technological independence in a critical sector.

The biotechnology sector operates in full integration with the national health system and other state institutions, adopting a model based on complementarity rather than

competition. This approach has enhanced efficiency and innovation capacity, accelerating scientific progress.

Limited official statistics on Cuban biotechnology and the rapidly evolving scope and complexity of the global biotechnology sector make comparative analyses across countries challenging. This limitation hampers a detailed assessment of issues encountered during the sector's development or potential shortcomings in planning. Nevertheless, Cuban biotechnology remains the only sector in which the country has successfully built technological independence. While revolutionary leadership has acknowledged shortcomings in preparing for the collapse of the Socialist Bloc, the literature does not report any significant failures or adverse experiences in the biotechnology sector.

CHAPTER 5

CONCLUSIONS AND POLICY RECOMMENDATIONS

"Independence is not a flag, or an anthem, or a coat of arms; independence is not a question of a symbol, independence depends on development, independence depends on technology, it depends on science in today's world." Fidel Castro, 1990

5.1. Policy Recommendations for Developing Countries

Cuba is an island country with very limited resources, isolated after the collapse of the Socialist Bloc and subjected to a policy of economic strangulation since the beginning of the revolution. Despite this, Cuba has stood out as an exception in the international arena with its remarkable achievements, especially in the biotechnology sector and public health indicators. Policies centred on social needs in the field of health, strategic investments in science and technology, and long-term efforts to develop human potential have been the cornerstones of these achievements. Various challenges from different historical periods have shaped this process, which has not progressed linearly and contains important experiences that developing countries can benefit from.

Cuba's path in this sector has been further complicated by limitations on access to the global supply chain, restrictions on international commercial and financial transactions, the prolonged political and economic crisis in Venezuela, one of the country's most important international trading partners, and the costs raised by the Ukraine-Russia War, among other factors. Furthermore, the country's position within the hurricane belt and the challenges associated with energy and electricity infrastructure, which necessitate significant investments, heighten the number of obstacles the sector must surmount. Cuba's biotechnology offers several lessons in

terms of strategies for achieving success as well as overcoming or mitigating challenges through various adaptation and resilience mechanisms. What lies at the root of the sector's success and adaptability has policy relevance, especially for developing countries.

5.1.1. Prioritising State-Led Social Development

Developing countries are generally countries with limited resources or less capacity to utilise their existing resources for various reasons. Their production systems are dependent on external resources, and their economies are more fragile in this sense. Social inequalities are more obvious and often deeper. In this context, state-led development models offer a way to utilise limited resources rationally and efficiently and to make development more balanced and sustainable.

The success of a country with a low-middle (then became an upper-middle) income level, Cuba, in biotechnology primarily proves that there is an alternative path other than the capitalist relations of production or purely market-related exchanges that prevail all over the world. State investment in sectors with high-risk capital is a common practice in capitalist countries, but the aim here is usually for the state to take on the potential market failure as a first entrepreneur. In these models centred on economic development, social interests are overshadowed by a focus on profit maximisation. The primary goal of Cuban biotechnology is not-profit maximization but rather the promotion of public health and securing the country's health independence. Another difference of Cuban biotechnology from the capitalist path is that it puts human capital, not risk capital (of state or firm), at the centre.

Cuban biotechnology has demonstrated that a sector requiring intensive capital investment due to its high technology and knowledge-intensive structure can also be established with a focus on social needs rather than market-oriented approach, and could make a significant difference in the health of the society. This basic objective of the sector is, of course, related to Cuba's state-led development model, which is based on public ownership of the means of production and centralised planning.

Cuba has a small and open economy. It is not a continental country like the USSR, but a blockaded island with minimal natural resources. Therefore, it must rely on more than its own resources. In the absence of other socialist countries, market mechanisms inevitably determine the country's international trade. The country's current economic model is described therefore as market-driven central planning (Díaz-Canel Bermúdez & Fernández, 2021). The Cuban biotechnology experience teaches developing countries that prioritising social development over sole economic development significantly improves citizens' quality of life and their access to basic human rights. Development strategies based on economic growth, on the other hand, even if they are successful, provide a virtual improvement in the economic indicators of the country, not in the social life of the citizens. Since capitalism does not ensure fairness in distribution, increased incomes or market shares do not necessarily mean improved living standards for citizens. The most important proof of this is the deepening social inequalities in today's centrally capitalist countries.

A social development-oriented approach necessitates the development of appropriate policies in all areas, such as education, health, science, culture, and sports. Policies built within this integrity enable the emergence of professionals with values that will enable them to address social problems in the country in the future (Jover, 2019). Thus, the social development goals of the country, which have, of course, economic repercussions, can be updated, and the ground for progress can be created with continuity and dynamism.

5.1.2. Central Planning and Priority Setting

Countries differ in terms of their underground and aboveground natural resources, human resources, cultural structures, infrastructures, technology levels, and international dynamics. In response, people's needs and priorities change. For this reason, each country needs to assess its existing resources, potential, and challenges in a holistic manner and establish a development strategy accordingly. In this sense, rather than applying exactly a successful development strategy to another country, a methodological adaptation should be considered. The method that developing countries can adopt from Cuban biotechnology should be centralised planning.

Central planning primarily seeks answers to three questions: (1) Where are we now? (2) What will we need in the future? (3) How do we move coherently from today to the future? (Politsturm, 2020). Only such a holistic assessment can make it possible to achieve long-term goals in strategic and high-risk sectors such as biotechnology. Firstly, the objective situation of the country should be assessed, and the prioritised needs of society should be identified. The next stage is to make a kind of inventory of the existing resources of the country in line with the prioritised needs and targets and to identify what is needed.

Right after the revolution, we know that Cuba's answer to the question ‘where are we now?’ is not very encouraging and that the people do not have the most basic human rights such as education, health, housing, and nutrition. Making an inventory of the productive forces reveals a similar situation, with the uneducated labour force being the single most important productive force in Cuba. However, the revolutionary government evaluated human resources not based on their existing characteristics but rather on their potential. They then developed policies that aligned with the answer to the second question and swiftly implemented them. From the beginning, the main goal of central planning was to eliminate social inequalities, guarantee the independence of the country, and make Cuba a country of scientists. However, constructing a strategic plan based on priorities and determining a path of development accordingly is necessary to achieve this goal. The first milestone of this strategic plan for the establishment of Cuba's biotechnology sector is the establishment of an inclusive and transformative education system and the institutionalisation of science. These steps, which are vital for the establishment of the biotechnology sector are, in fact, shaped by the answers to the aforementioned third question and reflect the perspective of a long-term plan.

Centralised planning does not end with the identification of the strategic sector and the strengthening of scientific research and education infrastructure through short-, medium-, and long-term policies. Once developing countries have a skilled labour force and technological learning potential, the process of establishing industrial infrastructure and making supply plans in line with set targets begins. The next stage is the planning of production and distribution in line with national needs and

international commercial agreements. Thus, the integration of the process from raw material to the consumer occurs. This model is also a cost-effective method for developing countries, as it offers an integrity that ensures efficient use of resources.

The Cuban biotechnology sector has progressed towards its long and short-term goals in line with a centralised planning, sometimes step by step and sometimes by leaps and bounds. In this context, it is impossible to describe a rigid process that creates a plan once and implements it until the end without conducting any interim evaluation. A strategic plan involves the assessment of new developments and opportunities, the collective overcoming of difficulties, the management of crises, and, if necessary, a revision according to changing priorities. This method, which minimises risks, increases the chances of success, and makes it possible to achieve objectives, should be considered by developing countries.

Centralised planning has paved the way for Cuba to achieve success in the biotechnology sector, and Cuban biotechnology has enabled the improvement of public health, the country's technological autonomy in a strategic sector, and the reduction of expenditures for the national health system. Thus, both the sector and the country have become resilient to crises, and social progress has been achieved through a sustainable development model. Developing countries can sustain their development processes with less crisis and more success in the priority sectors that they have determined in accordance with their national conditions through a central planning strategy.

5.1.3. Nationalisation of Strategic Sectors

Vaccine production is one of biotechnology's most successful areas in Cuba. The number of vaccines developed and produced by the sector is gradually increasing, and the vaccine technology used is also improving. BioCubaFarma has minimised the country's dependence on imports in meeting the vaccine needs of the national health system (9 of the 12 vaccines in the national immunisation program). However, today it supplies vaccines for immunisation programs to dozens of countries. Vaccines account for a significant share of the sector's total exports. Like all other

sectors in the country, the public sector owns Cuba's biotechnology and directs its research and production to meet social needs. During the pandemic—as a necessity due to the blockade—Cuban biotechnology sector quickly took action to develop local vaccines and played an important role in overcoming a major crisis in the country.

Immunisation is one of the most effective ways to improve the health of a society. Every year, national vaccination programs implemented worldwide prevent millions of deaths and disabilities, while also controlling the spread of infectious diseases. In this respect, immunisation is of great importance in protecting public health and reducing the burden on national health systems. However, fewer developing countries have a local vaccine industry. Yet, the disease burdens of developed and developing countries differ from each other for various reasons (access to clean water, healthy housing, coverage of the health system, etc.), and the biotechnology industry, which is concentrated in developed countries, largely does not carry out R&D studies and production practices in line with the needs of developing countries. Therefore, it is highly advantageous for both public health and the national economy of developing countries to aim for national vaccine production as a policy.

The COVID-19 pandemic has clearly demonstrated how strategic it is for developing countries to have a local vaccine sector and how essential public ownership of this sector is. Private sector ownership of the production rights and technology of vaccines that were developed with the collective knowledge of humanity and largely public resources deepens social inequalities through the field of health. Local vaccine production is also closely related to national defence strategy. This is already evidenced by the fact that the priority of access to vaccines during a global pandemic belongs to developed countries and that biological attacks are becoming more and more of a threat in the world. Due to all these strategic features, the public (state) ownership of the local vaccine sector as a critical part of the health system, economic and social development plan and national security policy gains additional importance.

Having local vaccine production technology does not guarantee that this sector will carry out R&D and production activities that align with the needs of the country and

society. Today, the inequality defined as the 90:10 gap is proof of this. Accordingly, 90 percent of investments in global health research focus on diseases affecting only 10 percent of the world population (WHO, 2002). This situation is the result of the monopolies in the sector focusing on profit-making products and markets, while research on diseases affecting low- and middle-income countries and the production of basic protective vaccines are neglected. Leaving vaccine production to the profit-oriented mechanisms of the private sector always carries the risk of neglecting the health needs of the population and deepening health inequalities. In this context, it is recommended that developing countries establish their vaccine sector as a pure public sector or nationalise the existing local vaccine sector.

The vaccine sector is, of course, not the only strategic sector. In line with the development goals of the developing countries, the strengthening of public ownership of science- and technology-intensive sectors and the nationalisation of strategic sectors should be recalled and put on the agenda as a policy.

5.1.4. Government Management Based on Science, Technology and İnnovation[46]

Despite all the challenges faced by Cuban biotechnology, the achievements of Cuban biotechnology during the pandemic, such as the production of COVID-19 vaccines, the repositioning of existing products for the treatment of the disease, the development of respiratory devices, etc., have shown that the country has built its technological autonomy with an innovative capacity in a strategic sector. Inspired by the success of the biotechnology sector, the Cuban State is developing a management system approach that puts scientific knowledge and technological innovation at the centre, in order to overcome the challenges faced, mitigate the effects of the economic crisis and the blockade, and further advancing the social development model. The main motivation for this system is based on the fact that despite the human potential and scientific and technological capacity created by the revolution, these resources are not being used effectively, widely, and efficiently enough for the

[46] Díaz-Canel Bermúdez, who became President of Cuba in 2018, completed his doctoral dissertation in 2021 with this title. Since 2018, Cuba has been revising its state policies and national development plan through an approach formulated as a science, technology and innovation-based government management system (SGGCI).

social and economic development of the country (Díaz-Canel Bermúdez, 2021). However, during and before the pandemic, the biotechnology sector has repeatedly proved that it is possible to develop knowledge-based creative solutions to social problems and challenges and that the country has this potential and capacity. In this respect, the strengths and weaknesses of the country were analysed and good experiences were used to improve the weaknesses.

Science, technology, and innovation-based government management (SGGCI), developed by the Cuban State based on the experiences of the biotechnology sector, includes a policy design method that can also be utilized by the developing countries. Accordingly, scientific knowledge should be at the core of government decision-making processes. It aims to generate scientific and innovative solutions to the challenges faced by the country through the strategic use of knowledge and to support national development. Despite the blockade constraints during the pandemic period, this method enabled the biotechnology sector to produce innovative solutions through strong collaborations and synergies, thereby successfully managing the pandemic process.

The SGGCI defines science and technological innovations as the engine of the state in order for the country to grow economically, develop socially, and sustain development by maintaining its independence. However, the innovations defined as the motor of the state here are not innovations created with a profit-oriented goal in a competitive market environment, but innovations that are social benefit-oriented and the outcome of a collective effort. Innovations aim to solve social problems, fulfil social needs, or contribute to social development.

The integration of scientific knowledge into government decision-making requires the establishment of mechanisms where scientists and experts can directly advise and guide the decision-making of central government boards. For Cuba, one of these mechanisms is the National Innovation Council, that has been established after the pandemic. In addition, it is aimed for the state to use scientific data as the main tool in the process of developing and implementing policies.

One of the main applications of SGGCI is that the state directs scientific research focused on problem solving through well-defined missions, for example, controlling an epidemic, reducing energy dependence, and increasing productivity in agriculture. This approach can be considered as a version of the mission-oriented approach. The issue here is not only the generation of knowledge but also its application in a result-oriented manner. One of the strategic uses of knowledge in state administration is future planning through predictive analyses or data management. Accordingly, for example, it is possible to ensure effective management of resources through economic projections or to strengthen the health infrastructure through epidemiological modelling. Such applications support the country's readiness for crises, the strengthening of technological independence, and the realisation of the country's development plans.

SGGCI, which is in a way the name of Cuba's own national innovation system, does not aim at capital accumulation, capital expansion, or increasing market shares. In the medium and long term, the goal is to fix the structural imbalances in the national economy, keep the country growing while protecting values like equality, sovereignty, and independence, strengthen the strategic sectors, and ensure development at the local level (Díaz-Canel Bermúdez & Fernández, 2021). In this context, the SGGCI offers a holistic policy approach for developing countries. In addition to these key determinants, it has many components. It includes a planning process from the identification of priorities to the allocation of resources, the creation of institutional and regulatory frameworks, the strengthening of human potential, the socialisation of knowledge, the motivation of all actors involved, the promotion of interaction at all levels, the establishment of flexible interfaces, the realisation of all this also at the local level, and, of course, the provision of financing (Batista & Jover, 2021). In this way, it is like reformulating the lessons learnt from the Cuban biotechnology experience and adapting them to the general and local context. The economic value generated by an innovation product, service, or process designed for societal interests, through the reduction of costs or the increase of revenues, is used to meet societal needs, overcome societal challenges, strengthen public services, and reduce inequalities, just as in the Cuban biotechnology sector.

The unique aspects of the SGGCI system that distinguish it from other national innovation systems are that it is society-oriented, there is state-led planning, coordination and guidance, it is built with a collective social effort and it is supervised by the public. In this sense, science, technology and innovation are not only the work of scientists and governments but also the product of the collective efforts of society as a whole. The SGGCI system, which puts science, technology and innovation at the centre of national development and public policies, includes an approach that will increase the potential of developing countries to implement their own innovation systems.

5.1.5. Strategic Integration and Complementarity

One of the most important factors influencing developing countries' ability to advance and succeed in a strategic sector that aligns with development goals is the integration capability of these countries. Today, it is not possible to achieve technological progress and economic growth in a state-based development model without good integration. Good integration requires relevant actors, institutions or systems to define resources, identify needs, define challenges, and establish effective coordination and cooperation with this common knowledge at the outset. It provides a basis for developing effective cooperation towards a common goal in an increasingly complex division of labour, especially in knowledge-intensive sectors. It ensures effective and efficient utilisation of the limited resources of developing countries.

However, Cuban biotechnology shows us that a much more advanced and higher level of integration is possible. This advanced organisational and functional integration has been an important determinant in the achievements of the sector (O'Farrill, 2014). The Cuban biotechnology sector is first and foremost integrated with the national health system. It plans its R&D activities with the aim of improving public health within this integration. This has a tremendous value in terms of its impact on the development of public health, as well as the bonds that scientists establish with society. Scientists who directly monitor the practical results of their studies, including data, strengthen their ties with society and thus tend to produce solutions to social problems in line with their values.

The socially benefit-oriented production activities of the sector ensure that knowledge is shared at all levels and that a complementary integration towards the goals is a natural part of the functioning. The collective working culture, in which there is no competition and even patents are obtained on behalf of the institution, has a positive impact on the continuity of technological learning and the increase in innovation capacity. These complementary integration mechanisms, where organisations can benefit from each other's established capacities and capabilities, ensure that even a sector with raw material and intermediate supply problems can maintain its efficiency.

Another integration mechanism of the sector is closed-loop production based on vertical integration. This form of integration, which means that all stages of production from the research process to the distribution process are carried out under a single structure, increases the speed, efficiency and adaptability of the sector. At the same time, this structure, which ensures the integration of science into the economy, ensures that scientists are aware of their contribution to the social development of the country.

Cuban biotechnology is also integrated at different levels with the Council of State, numerous ministries, research institutes and universities in different disciplines. All this allows the sector's know-how and innovation capabilities to be utilised according to the needs of social development. The industry, which focused on the fight against COVID-19 during the pandemic, is now also working on solving the country's food and energy crisis through these integration mechanisms. For all these reasons, it is recommended that developing countries use integration not only as an economic tool but also as a strategic development policy. Integration based on the principle of complementarity will contribute to sustainable development not only for the biotechnology sector but also for every targeted sector.

5.1.6. Strengthening the Social Values Context of Education to Maximise Human Potential

One of the key reasons for the Cuban biotechnology sector's advanced capacity for innovation and adaptability, as well as its significant contribution to public health, is

the strong bond that sector employees and scientists have established with society. This study reveals that the quantitative and qualitative characteristics of the skilled labour force in the sector are crucial for the development strategy identified for this field. The success of the Cuban biotechnology sector has been shaped not only by the high proportion of qualified labour and the number of researchers but also by scientists' sense of social responsibility and their culture of collective work. In this regard, what makes the sector innovative is not creativity driven by competition but the complementarity of organisational and functional integration. This was once again tested during the pandemic period.

The best aspect of Cuba's science and technology policy is the social values that guide it, particularly its dedication to placing knowledge at the service of development demands and the fundamental human needs of the entire population (Díaz-Canel Bermúdez, 2020). The issue is not to produce more or better science but to conduct science with the aim of addressing economic, social, environmental, and even cultural problems and to use knowledge in this direction for societal progress. The commitment of Cuban biotechnology sector employees to improving public health, as well as their creativity and resilience in overcoming challenges, is rooted in these social and human values.

The sense of responsibility that scientists feel toward society plays a crucial role in motivating efforts to overcome the challenges faced by the sector and the country. The internalisation of concepts such as patriotism, independence, and internationalism further strengthen the orientation toward using knowledge for societal benefit and organising research around social priorities and needs. In this regard, it is recommended that the long-term development strategies of developing countries integrate an enriched educational curriculum tailored to these goals.

Enhancing the inclusivity of education systems and increasing enrolment rates, along with introducing reforms that strengthen the scientific content of education and support experiential learning, are critical for maximising human potential in the long-term development plans of developing nations. However, these measures alone, if approached with a narrow focus on scientific content and technical knowledge

transfer, are insufficient for fostering a nation’s scientific and technological advancement. While such an approach may enhance individuals’ vocational skills, addressing complex problems and managing extraordinary situations requires more.

Drawing insights from the Cuban biotechnology experience, it is proposed that developing countries not only strengthen their education systems in terms of scientific content but also emphasise values-based education. Cultivating individuals with a culture of collective action from an early age, fostering traditions of collaboration and solidarity in addressing social and individual challenges, and embedding these principles into the education system are essential.

Scientific production carried out with an understanding that puts people and society at the centre and in line with social benefit enables scientists to establish a strong bond with society beyond the boundaries of laboratories, not to be alienated from what they produce, and thus to be more creative. The strengthening of the interaction between scientists and society fosters societies' trust in science and scientists. Thus, scientific and technological progress in society and sustainable development in the country become possible.

5.2. Concluding Remarks

The main objective of the Cuban biotechnology sector is to meet the needs of the national health system in order to improve public health. The main success of the sector should be sought not in the sector's profit rates or high international market shares but in its enormous contribution to the protection and development of public health.

The sector, which has the potential to produce a large proportion of the drugs and vaccines included in the country's essential drug list and national vaccination schedule, reduces Cuba's dependence on imports in a strategic sector and contributes to the increase of the country's export revenues. In this sense, it is understood that scientific research is highly integrated with the national economy, and the biotechnology sector is highly integrated with the national health system. This

integration includes directing the R&D activities of the sector in accordance with centralized planning. Additionally, institutions and researchers collaborate with each other based on the principle of complementarity, which positively influences the sector's potential for innovation.

With numerous product pipelines, the primary challenge for Cuban biotechnology lies in the supply issues resulting from the blockade. The difficulty in the supply of raw materials and intermediates is one of the most important obstacles to stable scientific research and biopharmaceutical production in an island country with scarce resources. At this point, the sector is trying to overcome the barriers through scientific and commercial international collaborations and cooperation. The adaptability of the sector in the face of challenges is strong. Cuban biotechnology tested this once again during the pandemic, developing three licensed COVID-19 vaccines, repositioning its existing products for COVID-19, and producing domestic mechanical ventilators.

Table 15 provides a summary of the objectives and tools with which the Cuban biotechnology sector is addressing the challenges it faces. It outlines how the sector has followed a path to meet the needs of the national healthcare system, minimize the impact of the US blockade on the sector and public health, and contribute directly or indirectly to overcoming the country's major economic problems.

It would be beneficial for developing countries to examine the public policies that have underpinned the success of Cuba’s biotechnology sector as they formulate their own development goals and strategies. This sector was established in a country where the means of production are publicly owned, as part of a carefully designed development plan guided by strategic planning. Influenced by long-term policies in education, healthcare, science, and technology, the sector developed significant innovation capacity within a relatively short period after its inception. The state has played a pivotal role in directing the sector's growth, with societal needs and priorities serving as the primary drivers of research, development, and production activities.

Table 15. Summary of Objectives and Tools of the Cuban Biotechnology Sector

Issue	Objective	Tools
The needs of the national health system (High international costs of medicines, vaccines, medical devices, equipments, and etc.)	Domestic production of the medicines in the Basic Drug List	Providing technological independence with a high innovation capacity
	Development and production of the vaccines for the National Immunisation Programme	Generation of local analytical tests The establishment of quality certifications
	Being prepared for extraordinary situations, epidemics, and pandemics	A strong primary health care system Organisational integration Social organisation
	Having early diagnosis systems and providing screening programs	Providing technological independence Enhancing innovation capacity
	Building a permanent and strong integration mechanism for actual requirements	High-level communication and interaction mechanisms between the State Council, ministries, scientific organisations, universities, etc. Establishing the National Innovation Council
	Strengthening preventive health services	Providing healthy housing, healthy nutrition, etc. Improving social participation
	Increasing the number of health professionals	Promoting education in medical sciences Empowering social values content of education
	Minimising the import dependency in public health	Formulation of science, technology, and innovation policies
The effect of the US blockade on Cuban biotechnology and public health	The building of independent technologies	Centralised planning and strategy Fostering human potential National innovation system (SGGCI)
	Supply of raw materials, intermediate materials	Searching for intermediary firms
	Reducing the impact of trade sanctions	Founding of factories abroad through joint ventures
	Overcoming financial sanctions	Trading with cash foreign currency Trade through interstate agreements
	Increasing patents and international recognition	Founding of factories abroad through joint ventures
	Increasing health diplomacy and scientific collaborations	Health diplomacy activities Increasing the number of international health missions
	Strengthening internationalist solidarity	Reports and presentations submitted to international organisations, congresses, and meetings

Table 15. (continued)

The economic problems of the country	Reducing the local production costs Reduction of import costs	Promoting creative solutions Improving efficiency through integration
	Increasing export revenues	Increasing innovation capacity Strategic international agreements Strengthening health diplomacy
	The integration of science with the economy	STI Policy Interphases
	Supporting regional technological development	Regional innovation system (SGGCI) Promoting education at all levels and strengthening its scientific and social content
	Increasing foreign exchange revenues	International collaborations to increase the export revenues of the biotechnology sector and healthcare services Internationalist solidarity against the blockade to support tourism
	Reducing the food and energy problem	Promotion of agricultural and animal biotechnology, biofuel research
	Strengthening social solidarity	TV programs promoting interaction between health professionals and the public

Globally, the biotechnology sector is characterized by intense competition and tendencies toward monopolization due to its high profit potential. However, R&D investments in this field are predominantly directed toward addressing the health needs of high-income populations in developed countries, while the disease burden of low- and middle-income countries is often neglected. This dynamic exacerbates global health inequities. In this context, the local production of medicines and vaccines has become critical for developing countries—not only to strengthen their healthcare systems but also to secure their economic and strategic independence.

Cuba stands out as a rare example of a country that has largely achieved technological independence in biotechnology and developed the capacity to transfer technology, despite being in the lower-middle income bracket. This success is rooted in the country's long-term and holistic implementation of centralised planning and

state-led development policies focused on societal advancement. For developing countries, studying the public policies that enabled the success of Cuba's biotechnology sector could provide valuable insights as they establish their own development frameworks.

The success of Cuba's biotechnology sector can only be fully understood when evaluated within its historical and dialectical context. This achievement, which positions Cuba as an exception among developing countries in biotechnology, has been made possible by the Cuban Revolution and its socialist character. In this sense, it is imperative for developing countries to question the assumption that market-driven models are the only viable path for development. In this context, it is essential for developing countries to question the illusion that market-oriented models are the only option for societies when formulating their development strategies. Cuba's experience shows that an alternative path that prioritises the common good and community-based development is possible.

5.3. Limitations of the Study

One of the difficulties encountered in this study on Cuban biotechnology is the lack of access to quantitative data. The lack of detailed and regular publication of Cuba's sectoral statistical data is a contributing factor. Another reason is that access to some official Cuban websites is limited, probably due to the blockade. Within the scope of this thesis, there were problems in accessing the website of the Cuban Institute of Statistics and the files of the Infomed Cuban health information network. The ONEI reports used could be accessed through the Telegram channel of the institute. Another qualitative data constraint is that the available data are not easily comparable with other countries. This has partially limited the comparative analyses within the scope of this thesis.

The number of people interviewed within the scope of this thesis could not be increased due to geographical distance, time difference, and problems in Cuba's electricity and internet infrastructure for various reasons. This situation may have limited access to more detailed and wider information.

Due to the dynamic nature of the biotechnology sector and the economic structure of the world, the data available during this thesis were outdated from time to time with newly published data, therefore frequent updates were needed.

This study analysed in depth the factors that have contributed to the success of Cuba's biotechnology sector. The focus of the study was on the literature and data review process on the unique aspects of the sector that made it successful. What kind of results the Cuban State has achieved in other sectors with a similar development model, failure stories, if any, and the reasons for this can be the subject for further researches. Moreover, the difference of Cuba's development model from other socialist countries, Cuba’s health diplomacy and technology transfer to other countries all deserve to be researched separately.

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APPENDICES

A. APPROVAL OF THE METU HUMAN SUBJECTS ETHICS COMMITTEE

B. THE OPEN-ENDED QUESTIONS USED IN THE SEMI-STRUCTURED INTERVIEWS

Question 1. Cuba's biotechnology achievements, despite limited material resources and years of blockade, have garnered widespread recognition. In addition to essential medicines and medical equipment, Cuba has developed five vaccine candidates with proven national and international effectiveness during the COVID-19 pandemic. Does Cuba have a science policy that makes these achievements possible? If so, is the policy being updated, and how?

Question 2. Can we say Cuba has a holistic national strategic approach to biotechnology and innovations? If so, can you give information about it?

Question 3. What is the planning process for biotechnology production in Cuba? Did Cuba establish inter-institutional or inter-sectoral relations in this sphere?

Question 4. Does Cuba establish or consider the development of international cooperation on research and development in biotechnology important? What international collaborations in biotechnology has Cuba established so far, if any?

Question 5. Cuba is known for its internationalism in the field of health. Several countries dispatch international medical brigades during extraordinary circumstances, disasters, or emergencies. Does Cuba retain this kind of internationalist orientation both in the development of biotechnological innovations and in the process of manufacturing such products?

Question 6. What are the challenges your country encounters in the field of innovation and the manufacturing of biotechnological products? How do you overcome the problem of sourcing raw materials in a country with minimal surface and underground resources?

Question 7. What are the government's endeavours in the Cuban State in terms of specialising and developing skills in the biotechnology sector? Which institutions other than universities is Cuba working with, and with what kind of cooperation and planning?

Question 8. During the COVID-19 pandemic, even large pharmaceutical monopolies had some difficulties developing an effective vaccine. However, Cuba developed five different vaccines, three of which received licenses and went into use quickly. How do you think Cuba achieved this in such an extraordinary period and under such difficult circumstances?

Question 9. The Cuban government is grappling with significant economic challenges that have intensified in recent times. Do you only produce vaccines, medicines, and equipment to meet national needs? Isn't it possible to alleviate economic distress by exporting domestic products in the field of biotechnology, especially vaccines?

Question 10. Cuba submits various reports to the international public, highlighting the severe economic and social consequences of the blockade against the island. Under such circumstances, the highly educated population may be particularly likely to emigrate. How are the working lives and living standards of scientists, workers, and managers working in the field of biotechnology affected by this situation? What motivates and demotivates you to continue innovation and scientific productivity?

C. TURKISH SUMMARY/ TÜRKÇE ÖZET

Çalışmanın motivasyonu

COVID-19 pandemisi, tüm dünyada ülkelerin sağlık sistemlerinin güçlü ve zayıf yönlerini gözler önüne serdi. Ülkeler, sağlık altyapılarının olağanüstü durumlara hazırlıkları ve kriz yönetebilme becerileri açısından önemli bir sınav verdi. Büyük ekonomileri ve demokrasileri ile tanınan çok sayıda gelişmiş ülke bu sınavda başarısız oldu. Uzun bir ekonomik ve sosyal belirsizliğin yaşandığı bu dönemde, aynı zamanda insanlık için yaygın bir karamsarlık da söz konusuydu. Bir çıkış yolu olarak COVID-19'a yönelik tedavi ve aşılarla ilişkili haberler tüm dünyada günbegün takip edildi ve biyoteknoloji sektörü bu defa yalnızca iş çevrelerinin değil, hükümetlerin ve toplumların da ilgi odağı haline geldi.

Küba Cumhuriyeti ise pandemi döneminde bir kez daha ulusal sağlık sistemi ve biyoteknoloji sektörü ile dikkatleri çekti. Sadece bir ülkenin salgınla nasıl mücadele edebileceğine dair bir örnek teşkil etmekle kalmadı, aynı zamanda tüm bu belirsizlik ve karamsarlık içinde ulusal sağlık sistemleri ve kriz yönetimine dair insanlığa olumlu bir anlatı sundu. Yıllardır maruz kaldığı ekonomik, ticari ve finansal yaptırımlara ve içinde bulunduğu zorluklara rağmen Küba'nın kapsayıcılığından asla taviz vermediği sağlık sistemi ve yenilikçi biyoteknoloji çözümleri pandemi döneminde insanlık için bir umut kaynağı oldu. Bu tez çalışması, geleceksizlik kaygısının hala önemli ölçüde hissedildiği dünyamızda, olumlu örneklerin bağlamları ile birlikte daha derinlikli incelenmesi ve daha çok paylaşılması sorumluluğu ve motivasyonu ile yürütüldü.

Çalışmanın özgünlüğü ve önemi

Biyoteknoloji, köken aldığı moleküler biyoloji, genetik ve mühendislik bilimlerinin ötesinde, toplumsal faydaları, yüksek inovasyon potansiyeli, yarattığı ekonomik

değerler ve taşıdığı yüksek yatırım riskleri nedeniyle ekonomi ve siyaset biliminin de önemli bir inceleme alanı haline gelmiştir. Son kırk yıla damgasını vuran bu çok yönlü endüstri, sadece birden fazla sektörü etkilemekle kalmamış, aynı zamanda yeni sektörlerin ortaya çıkmasına olanak tanıyarak teknolojik sistemlerde önemli değişiklikler yaratmıştır. Bugün bile büyük bir hızla gelişimini sürdürmekte olan biyoteknoloji sektörü, toplumun farklı kesimleri tarafından kimi zaman umut ve hayranlıkla, kimi zaman ise endişe ve korkuyla takip edilmektedir. COVID-19 pandemisi sürecinde aşı karşıtlığı ve tereddütünün artış göstermesi, bu endişe ve korkuların önemli bir yansıması olarak görülmektedir. Aşı tereddütünün temelinde, biyoteknoloji bilgisinin özel mülkiyet odaklı olması ve sektörün kar maksimizasyonuna dayalı yapısının bulunduğu söylenebilir.

Küba biyoteknolojisi örneğinde ise, bilimin toplumsal fayda için üretilmesi ve bilginin hem üretim hem de paylaşım süreçlerinin kamu tarafından organize edilmesi temel bir yaklaşım olmuştur. Bu yaklaşım sayesinde Küba, pandemi döneminde kendi biyoteknoloji sektörü tarafından geliştirilen yerli COVID-19 aşıları ile 2 yaş üzerindeki nüfusunun %90'ını aşılayabilen dünya çapında tek ülke olmuştur. Bu başarı, biyoteknolojik yeniliklerin sağlığı koruma ve geliştirme üzerine odaklanması halinde, korku ve güvensizliğin yerini umut ve heyecana bırakabileceğini göstermektedir.

Küba biyoteknolojisinin öne çıkan en önemli özelliği, toplumsal karakterini koruyarak bilimi ekonomiye entegre etmiş olmasıdır. Küba, ulusal aşı programında yer alan 12 aşının 9'unu kendi üretmekte ve temel ilaç listesindeki ilaçların yüzde 50'den fazlasını yerli üretimle karşılamaktadır; bu oranın yüzde 80'i aştığı dönemler de olmuştur. Yerli aşı ve biyoteknolojik ürünlerin üretimi ile sadece tasarruf sağlanmakla kalınmamış, aynı zamanda bu ürünlerin ihracatı yoluyla ülke ekonomisine önemli katkılar sunulmuştur. Küba biyoteknolojisi, stratejik bir sektörde ithalata bağımlılığı azaltmış ve dikkat çekici birçok yenilikçi ürün geliştirmiştir. Özellikle ABD tarafından altmış yıldan uzun süredir uygulanan sert ekonomik, ticari ve finansal yaptırımlara rağmen bu başarıları elde etmiş olması, Küba deneyiminin bir vaka çalışması olarak incelenmesi gerekliliğini ortaya koymuştur.

Bu çalışma, “Gelişmekte olan bir ülke olan Küba, biyoteknoloji alanındaki özgün başarısını nasıl elde etti?” sorusuna yanıt aramış ve bu sektörün deneyimlerinden yola çıkarak gelişmekte olan ülkelerin kalkınmasına yönelik politika önerileri sunmuştur.

Çalışmanın Akışı ve Metodu

Toplam beş bölümden oluşan çalışma giriş bölümünden sonra literatür taraması ile devam etmektedir. Çalışmanın konusuna ilişkin genel bir altyapının oluşturulması amacıyla yapılan literatür taramasında dünyada ve Küba’da biyoteknoloji sektörünün temel dinamiklerine odaklanılmıştır. Biyoteknoloji sektörünün ortaya çıkışına ve sektörün ekonomi politiğine dair incelenen literatür tarihsel bir diyalektik içinde genel hatları ile sunulmuştur. Ardından özel olarak Küba’da biyoteknoloji sektörüne ilişkin literatür benzer bir tarihsel yöntemle sunulmuştur. Sektörün kuruluşuna giden süreçte belirleyici olan şeyler, bugün neler üretildiği, sektörün sağlık sistemi ile olan ilişkisi, pandemi döneminde oynadığı rol ve ABD ablukasının sektör üzerindeki etkisine dair incelenen literatür yapılan araştırmaya ışık tutacak bir şekilde paylaşılmıştır. Çalışma, daha sonra niceliksel ve niteliksel verilerin birlikte değerlendirildiği karma yöntemin sunulduğu bir analiz ile devam etmektedir. Niceliksel verilere, uluslararası kuruluşların rapor ve veri tabanlarından, Küba Devletine ait resmi istatistikler ve raporlardan ve literatürden ulaşılmıştır. Niteliksel veriler ise araştırma sorusuna derinlemesine bir yanıt verebilmek için yapılan açık uçlu yarı yapılandırılmış sorulardan elde edilmiştir. Küba biyoteknoloji sektöründe çalışan ve sektörle ilgili bilgiye sahip olan 5 Kübalı bilim insanı, akademisyen ve diplomat ile yapılan görüşmeler tematik analiz yöntemi ile değerlendirilmiştir. Elde edilen bulgularla, büyüme ve kalkınma perspektifi ile, inovasyon sistemleri ve kapasitesi ve ABD ablukasının sektöre etkileri üzerinden literatür eşliğinde bir tartışma yürütülmüştür. Çalışma Küba biyoteknolojisi deneyimi üzerinden gelişmekte olan ülkelere yapılan politika önerileri ile sonlandırılmıştır.

Literatür Eşliğinde Çalışmanın Arka Planı

Biyoteknoloji tarihin bir anında aniden ortaya çıkan bir keşfi değil bir birikimi temsil etmektedir. Kökeni neolitik çağlara kadar dayanır. İnsan topluluklarının bira, ekmek,

yoğurt, peynir gibi dayanıklı gıdalar üretirken deneysel olarak kullandığı bir yöntem olan fermantasyon, hayvanların melezlenmesi, kanalizasyon arıtma sistemlerinin kurulması gibi uygulamalar biyoteknolojinin temelini oluşturmaktadır. Bugünkü modern biyoteknoloji ise moleküler biyoloji ve genetik bilimine dayanır. Tıp, tarım, çevre ve enerji gibi birbirinden farklı alanlarda kullanmakta ve giderek daha karmaşık ürünlere ve ürün proseslerine sahip olmaktadır.

Biyoteknoloji sektörü hem bilgi yoğun hem de sermaye yoğun bir sektördür. Yüksek inovasyon potansiyeli ve kar oranları ile dikkat çekmektedir. Ürünlerin piyasada üretim ve satış fiyatları yüksektirancak Ar-Ge çalışmalarının çok azı nihai bir ürüne dönüşür. Laboratuvarda sentezlenen her 10.000 maddeden yalnızca 1-2 tanesi pazarlanabilir bir ürün haline gelebilmektedir. Bunlara rağmen, biyofarmasötik sektörün küresel düzeyde büyümeye devam etmekte olduğu, ancak ülkelerin büyümedeki paylarının oldukça eşitsiz olduğu görülmektedir. Örneğin, 2023'te 1,6 trilyon dolara ulaşan küresel ilaç pazarının yarısından fazlasını ABD elinde tutmaktadır. Modern biyoteknolojinin bir sektör olarak ortaya çıktığı 1980'li yıllardan beri sektörün gelir ve pazar payları açısından lider ülkeleri ABD ve İngiltere'dir. Son yıllarda Kanada, Brezilya ve Hindistan ve özellikle Çin gibi ülkelerin de sektördeki varlıklarının arttığı görülmektedir.

Biyoteknoloji sektörü, yüksek maliyetli Ar-Ge süreçleri ve uzun ürün geliştirme aşamaları olan risk sermayesi büyük bir sektördür. Biyoteknolojik ürün çeşitliliği giderek artmakta, onkoloji, immünoloji ve endokrinoloji gibi alanlara yapılan yatırımlar ön plana çıkmaktadır. Sektör, ağırlıklı olarak gelişmiş ülkelerin ve yüksek gelirli kişilerin sağlık sorunlarına odaklı bir yatırım stratejisi uygulamaktadır. Öyle ki, biyoteknoloji alanında küresel çaptaki Ar-Ge harcamalarının yüzde 90'ı dünya nüfusunun yüzde 10'unun hastalıklarına yönelik yapılmaktadır. Düşük gelirli ülkelerde önemli bir toplum sağlığı sorunu olan enfeksiyon hastalıkları alanındaki çalışmalarda yalnızca pandemi dönemlerine özgü geçici artışlar söz konusu olmuştur.

Biyoteknoloji gibi sermaye yoğun ve yüksek risk barındıran sektörlerde ilk yatırımcı genellikle devlettir. Ancak devlet daha çok sektörün kuruluş aşamasında riski üstlenen bir görev üstlenir. Sektör gelişmeye başladıktan sonra genellikle özel

sektöre devri ya da kamu özel ortaklıklarının kurulması söz konusudur. Teknolojik öğrenme ve oryantasyonda daha etkili sonuçlar alınmasını sağlayan devlet müdahalesinin, yatırımların uzun vadeli sürdürülebilirliği açısından mümkün olmadığına dair görüşler vardır. Yine de biyoteknoloji sektörünün risk sermayesini absorbe etme potansiyeli nedeniyle Hindistan, Çin ve Güney Kore gibi ülkeler kalkınmacı devlet modelleri doğrultusunda biyoteknoloji sektörüne öncelik vermişlerdir. Biyoteknoloji sektöründe inovasyon kritik önemdedir ve gelişkin bir araştırma altyapısı gerektirir. Literatür bu altyapı desteğinin çeşitli üniversite, sanayi ve devlet işbirlikleri ile sağlanabileceği ve sektörün başarısının bu modellerle artırılabileceğine dair çok sayıda teorik yaklaşım barındırmaktadır.

COVID-19 pandemisi, sağlık inovasyon sistemlerinin önemini yeniden gündeme taşımıştır. Sağlık inovasyonları biyoteknoloji, bilgi teknolojileri ve tıp bilimlerinin kesişiminde yer alır ve teknolojik gelişmelerin yanı sıra düzenleyici çerçevelerin dönüşümünü gerektirir. Kimi örneklerde toplum sağlığını iyileştirme potansiyeli taşırken bazı uygulamalar eşitsizlikleri daha da derinleştirebilir.

Küba'nın ulusal sağlık sisteminin doğrudan bir bileşeni olan biyoteknoloji sektörünün başarısı tüm dünyada bilim camiası ve hatta Küba'nın siyasi rejimine eleştirel yaklaşan çevreler tarafından dahi kabul görmektedir. Ocak 1959'da gerçekleşen devrimden hemen sonra devrimci hükümetin ilk icraatları arasında yer alan devletleştirme hamlesi, toprak reformu, okuma-yazma seferberliği ve sağlık hizmetinin tam kapsayıcılık ile yeniden organizasyonu biyoteknoloji alanındaki gelişmeler için zemin oluşturmuştur.

Devrimden önce sunumu oldukça zayıf ve büyük şehirlerle kısıtlı olan kamusal sağlık hizmeti, devrimden sonra tamamen ücretsiz ve tüm nüfusu kapsayan bir biçime kavuşmuştur. Ülkede yer alan çok sayıdaki özel klinik ve az sayıdaki farmasötik endüstri kuruluşu devletleştirilmiş, sağlık hizmeti koruyucu ve önleyici tıp yaklaşımı ile yeniden organize edilmiştir. Bugün Küba'ya özgü olarak hastalıkların tedavisine değil, önlenmesine yönelik bir amaçla merkezi olarak planlanan ulusal sağlık sistemi desantralize olarak yönetilmektedir. Yerelde sağlık hizmeti sunumuna toplumsal katılımı teşvik ederken merkezde sağlık dışı sektörlerin

(beslenme, barınma, eğitim vb.) de sorumluluk almasını sağlayan sağlık sistemi yüksek düzeyde organizasyonel entegrasyona sahip bir yapıya sahiptir. Sistemin gereksinim duyduğu çok sayıdaki hekim ve sağlık personelinin yetiştirilmesi için 1960'lı yıllardan itibaren oluşturulan eğitim politikası ile tıp ve sağlık eğitimi teşvik edilmiştir. Bugün nüfusa düşen hekim sayısı, gelişmiş ülkelerin çok üstünde olan Küba'nın sağlık göstergeleri de kişi başı sağlık harcamaları oldukça yüksek olan ABD, İngiltere, Kanada gibi ülkelerle yarışabilecek durumdadır.

Küba biyoteknolojisi, yukarıda yapısı kısaca özetlenen sağlık sisteminin ihtiyaçlarına yanıt vermek amacıyla oluşturulan altyapı ve stratejik bir plan ile şekillenmiştir. 1965'te kurulan Ulusal Bilimsel Araştırma Merkezi (Centro Nacional de Investigaciones Científicas - CNIC), sektör için önemli tarihsel köşe taşlarından biridir. CNIC, 1980'li yıllardan sonra kurulan ve bugün BioCubaFarma çatısı altında toplanan çok sayıda biyoteknoloji enstitüsünün kurucusu bilim insanı ve araştırmacısını yetiştiren adeta bir kuluçka merkez olmuştur. Bu bilim merkezlerinin arasında bugün çok sayıda inovasyona ve patente imza atan Genetik Mühendisliği ve Biyoteknoloji Merkezi (CIGB), kanser araştırmaları yürüten Moleküler Araştırma Merkezi (CIM), tanısal testler ve cihazlar üzerine çalışan İmmünoesey Merkezi (CIE), Finlay Aşı Enstitüsü (IFV) ve Sinirbilim Merkezi (CNEURO) yer almaktadır.

Küba biyoteknolojisini farklı kılan özelliklerinden biri "kapalı döngü" yaklaşımıdır. Aynı kurumsal çatı altında araştırma, geliştirme, üretim ve pazarlama faaliyetlerinin içerilmesine dayanan kapalı döngü yaklaşımı 1981'de Havana'da oluşturulan Biyolojik Cephe ile deneyim edilmiş ve 1992'de kurulan Bilimsel Kutup ile daha da geliştirilmiştir. Bugün BioCubaFarma çatısı altında toplanan biyoteknoloji sektörünün tüm bilimsel kuruluşları, üretim tesisleri ve iş üniteleri, Bilim, Teknoloji ve Çevre Bakanlığına (CITMA) bağlı biyoteknoloji kuruluşları ile Küba Halk Sağlığı Bakanlığına (MINSAP) bağlı jenerik ilaç üretimi kuruluşu QUIFEMA'nın 2012 yılında birleşmesi ile oluşturulmuştur.

1991'de Sovyetler Birliği'nin çözülmesi ve sosyalist bloğun yıkılması sonrası yüzde 35 oranında küçülen ülke ekonomisine rağmen Küba Devleti ve Devlet Başkanı tarafından özellikle desteklenmeye devam Küba biyoteknoloji sektörü ülkenin sınırlı

kaynaklarına rağmen yenilikçi süreçler geliştirebilme potansiyeli kazanmıştır. Ülkenin ihracat gelirlerine önemli bir katkısı olan BioCubaFarma bugün aşı, kanser tedavisi, kardiyovasküler hastalıklar gibi alanlarda dünyaca ilgi gören yenilikçi ürünler geliştirmiştir. Bu karakteri ile ülkenin COVID-19 pandemisi krizini yönetilmesine büyük katkısı olmuştur.

Sektörün geliştirdiği beş COVID-19 aşısından üçü (Abdala, Soberana 02 ve plus) lisanslanmış ve Küba geliştirilen bu aşılar ile 2 yaş üstü nüfusunun yüzde 90'ından fazlası aşılanabilen tek ülke olmuştur. Devrimden hemen sonra başlayan ABD yaptırımları ve ablukası pandemi döneminde bile esnetilmemiştir. Ülkenin kötü senaryolara hazırlık çerçevesinde sayısı arttırılmak istenen mekanik ventilatörleri ve geliştirdiği COVID-19 aşılarının endüstriyel üretimi için gerekli maddeleri satın alması ABD'nin finansal ve ticari yaptırımları nedeniyle engellenmiştir.

Ülkenin temel ilaç listesinin tamamını üretebilme potansiyeline sahip olan sektör bugün ABD ablukası nedeniyle hammadde ve ara madde tedarikinde yaşanan problemlerden dolayı ancak temel ilaçların yüzde 51'ini üretebilmektedir. Uluslararası alanda yürütülen sağlık diplomasisi, bilimsel araştırma projelerinde kurulan işbirlikleri ve ticari ortaklıklar yoluyla ablukanın bu olumsuz etkilerini azaltmaya çalışmaktadır. Yurtdışında yaklaşık 2.500 patent kaydına sahip olan BioCubaFarma 2024 yılı içerisinde 74 ülkeye 300'den fazla ürün ihraç etmiştir.

Küba toplum sağlığının gelişmesine ve ülkenin sağlık alanında ithalata bağımlılığının azalmasına önemli katkısı olan biyoteknoloji sektörü, gelecekte ülkenin bugün yaşamakta olduğu gıda ve enerji krizlerine çözüm üretme potansiyeli de barındırmaktadır.

Niceliksel Verilerin ve Niteliksel Bulguların Analizi

Karayiplerin en büyük ada ülkesi olan Küba gelişkin sağlık göstergeleri ve biyoteknolojisi ile dikkat çekmektedir. Bölge ülkelerine ve kendi gelir düzeyindeki dünya ülkelere göre yüksek insani gelişme düzeyine ve bilimsel kapasiteye sahip olan ülkenin kişi başına düşen hekim ve sağlık personeli oranları dünya ortalamasının üzerindedir.

Gelişmiş ülkelere kıyasla daha düşük GSYİH'ya ve kişi başı sağlık harcamalarına sahip olan Küba'nın onlar kadar iyi sağlık göstergelerine sahip olması, sağlık sisteminin önleyici sağlık odaklı toplumcu tıp yaklaşımının başarılı olduğunu kanıtlamaktadır. Küba biyoteknolojisi, sağlık sisteminin bu yapısı için stratejik bir araçtır. Sektörün ürettiği koruyucu aşılar sayesinde çok sayıda bulaşıcı hastalık ekarte edilmiş, erken tanı ve tarama testleri ile bazı hastalıkların mortalite ve morbidite oranları düşürülmüştür. Bugün BioCubaFarma çatısı altında 47 şirket, 21 araştırma merkezi ve 164 üretim hattı faaliyet göstermekte, 16.000'den fazla kişi çalışmaktadır. Sektör geniş bir yenilikçi ürün portföyüne ve ilgi çekici bir ürün boru hattına sahiptir.

Küba, GSYİH'dan Ar-Ge çalışmaları için yüzde 0.4 - 0.5 oranında bir pay ayırmaktadır, bu oran bölge ülkeleri ve dünya genelindeki oranlarla benzer bir aralıktadır. Yani Küba biyoteknolojisinin yüksek yenilik kapasitesini bu oranla bir ilişkisi içinde açıklamak mümkün değildir. Sektörün yenilikçi ürünleri ve aşılarının ihracatı ülke ekonomisine 2000'li yılların başından beri önemli katkı sağlamaktadır. Ne var ki ABD yaptırımları, sektörün Ar-Ge faaliyetlerini ve üretim süreçlerini zorlaştırmakta, uluslararası alandaki işbirliklerini olumsuz yönde etkilemektedir. 2023-2024 döneminde ablukanın sektöre maliyetinin 124 milyon USD olduğu tahmin edilmektedir. Abluka sağlık sistemini ayrıca etkilemektedir. Eskimiş tıbbi ekipmanların yenilenememesine ve ilaç stoklarının azalmasına neden olmaktadır. Tedarik edilemeyen bazı tıbbi malzeme ve ekipmanlar nedeniyle uzun ameliyat bekleme listelerinin oluşmuş ve ameliyat sayılarının önceki yılların yüzde 65'ine kadar düşmüştür.

İstatistiksel verilere ek olarak, Küba biyoteknoloji sektörünün yeteneklerini ve potansiyelini derinlemesine anlayabilmek için bu çalışma kapsamında yapılan yarı yapılandırılmış görüşmelerin içerikleri üç ana kategori altında sekiz tema ile analiz edilmiştir. Bu kategoriler; devlet, organizasyonel yetenekler ve adaptasyon yeteneğidir. İlk kategori olan devlet, Küba'daki devrim, politik yönelim ve merkezi planlamayı ele alırken, biyoteknoloji sektörünün kuruluş ve gelişme dinamikleri devrimci liderlik, toplumsal ihtiyaçlar ve merkezi planlama temaları ile değerlendirilmiştir. İkinci kategori, ülkenin sınırlı kaynaklarıyla biyoteknolojiye

yönelik altyapı inşa etme çabalarını ve işbirliği temasını, üçüncü kategori ise adaptasyon yeteneğini, abluka ve toplumsal değerlerin sektörün gelişimi ile olan ilişkisini ele almıştır.

Buna göre sektörün kurulması ve gelişmesinde devrimci liderliğin ve özellikle Fidel Castro'nun ileri görüşlülüğü oldukça etkilidir. Ülkenin bağımsızlığının korunması ve toplumsal gelişmenin hızlanması için devrimci liderlik ülkenin elindeki en önemli üretim gücü olan insan potansiyeline güvenmiş ve ona yatırım yapmıştır. Eğitim ve bilim politikası ve özellikle tıp eğitiminin teşviki sayesinde yetişmiş insan kaynaklarının sayısı hızla artmıştır. Ülkede sektörün hızlı gelişmesinde etkili olan tüm bu politikalar ve yatırımlar merkezi bir planlama doğrultusunda organize edilmiştir. Bununla birlikte ülkenin ablukaya karşı direncinde stratejik bir önemi olan biyoteknoloji alanında teknolojik bağımsızlığın kurulması için kuruluşundan bugüne Küba biyoteknolojisi Devlet Başkanı ve Konsey düzeyinde izlenmiş ve sektörün Ar-Ge çalışmaları ve üretimi ulusal ihtiyaçlarla uyumlu hale getirilmiştir.

Yapılan görüşmelerde sektörün rekabet içinde değil, tamamlayıcılık ilkesi ile bir işbirliği içinde çalıştığı görülmüştür. Ulusal düzeyde sağlık sistemi ve ilgili diğer tüm sektörler ve merkezi devlet kurumları ile tam bir entegrasyon içinde çalıştığı anlaşılmıştır. Kurulan bu yüksek düzeydeki örgütsel ve işlevsel entegrasyon ve işbirliğinin verimliliği ve inovasyon potansiyelini arttırdığı ve simbiyotik bir ilişki ile bilimsel ilerlemeyi hızlandırdığı saptanmıştır.

Küba, ulusal aşılama programları için çok sayıda ülkeye aşı ihracatı yapmaktadır. Biyoteknoloji sektörünün ürettiği aşı ve diğer ürünler uluslararası pazara düşük ücretlerle sunulmaktadır. Yurtdışına profesyonel sağlık hizmeti için gönderilen sağlık personeli, Küba'nın biyoteknolojik kapasitesini tanıtmakta ve yeni uluslararası işbirliklerine zemin hazırlamaktadır. Bu işbirliği anlaşmaları güney-güney işbirliği anlaşmalarından ibaret değildir. Bazı Avrupa ülkeleri, Kanada, Japonya ve hatta -bir istisna yapılarak- terapatik kanser aşısı CIMAvax-EGF özelinde ABD ile kurulan bilimsel işbirlikleri de bulunmaktadır. ABD ablukası hala ülkenin ve sektörün uluslararası ticaret anlaşmalarının önündeki en önemli engeldir. Bu engeller üretim aşamasında Vietnam ve Çin ile bu ülkelerde kurulan ortak fabrikalar ile teknoloji

transferi yapılarak aşılmaya çalışılmıştır. Ancak bu yöntemin ablukanın neden olduğu sorunların çözümü için yeterli olmadığı anlaşılmaktadır.

Tedarik zincirlerini, ihracatı ve ürün inovasyonlarını doğrudan etkiliyen ablukaya karşı Küba malzeme ve ekipman tedarikini yakın bölge ülkelerinden değil de Asya ve Avrupa gibi uzak bölgelerden sağlamak zorunda kalmaktadır. Tedarikçi firma bulabildiği durumda bile aracı firmalara gereksinim duymaktadır. Bu durum maliyetlerin iyice artmasına neden olmaktadır. Küba'nın 2021 yılında ABD tarafından terörü destekleyen ülkeler listesine dahil edilmesi ülkenin uluslararası finans sektörünü kullanmasını iyice engellemiştir. Tüm bu kısıtlar sektörün araştırmacı ve bilim insanlarının yaratıcı çözümleri ile aşılmaya çalışılmaktadır. Ülkenin bilim, teknoloji ve inovasyon politikaları, biyoteknoloji sektörünün çözüm odaklı bu yaklaşımından alınan ilhamla pandemi sonrası revize edilmeye başlanmıştır.

Bu tez kapsamında yürütülen araştırmada Küba biyoteknoloji sektörüne ilişkin istatistiklerin (Ar-Ge harcamaları, ihracat gelirleri, yatırım harcamaları vb.) sınırlı olduğu, bununla birlikte dünya genelinde biyoteknoloji sektörünün gelişen ve karmaşıklaşan kapsamı nedeniyle ülkeler ve yıllar arasında karşılaştırmalı analizler yapmanın zorlukları olduğu görülmüştür**.** Bu nedenle araştırma sorusuna daha derin ve bağlamsal yanıtlar verebilmek için niteliksel bir araştırma yürütülmesi ve niceliksel veriler ve niteliksel bulguların birlikte yorumlanması çalışmanın gücünü arttırmıştır.

Sonuçlar ve Politika Önerileri

Çalışma son olarak, bulguları özetlemekte ve gelişmekte olan ülkeler için Küba'nın biyoteknoloji alanındaki başarılarından elde edilen derslere dayanan politika önerileri sunmaktadır. Sektör üretim araçlarının kamusal mülkiyetinin söz konusu olduğu bir ülkede, stratejik bir planlama doğrultusunda, dikkatlice tasarlanmış bir kalkınma planının parçası olarak kurulmuştur. Uzun vadeli eğitim, sağlık, bilim ve teknoloji politikalarının da etkisiyle kurulmasından kısa bir süre sonra inovasyon yeteneği geliştirmiştir. Sektörün kurulması ve gelişmesinde devlet öncü ve yönlendirici iken,

üretim prosesinin planlanmasında toplumsal gereksinimler ve öncelikler belirleyicidir. Sürecin tamamı toplumsal ihtiyaçları piyasa odaklı mekanizmaların önüne koyan devlet tabanlı kalkınma modellerinin etkinliğini ortaya koymaktadır.

Kaynakları sınırlı olan gelişmekte olan ülkelerin ekonomileri de genellikle daha kırılgandır. Bu bağlamda devlet temelli kalkınma modelleri ve merkezi planlama, kaynakların etkin kullanımı ve kalkınmanın sürdürülebilir kılınması için önemli bir araçtır. Merkezi planlama Ar-Ge ve üretim faaliyetlerinin toplumun öncelikleri ve hedefleri ile uyumlu hale getirilmesinde kritiktir. Gelişmekte olan ülkeler, devlet temelli kalkınma ve merkezi planlama modeli ile ülkenin kendi nesnelliğine göre belirledikleri öncelikli sektörlerde, kalkınma süreçlerini daha az krizle ve daha çok başarıyla sürdürebilir. Bunun için önemli bir diğer yaklaşım bilim ve teknoloji alanındaki kamusal mülkiyetlerinin güçlendirilmesidir. Bir ülkenin biyoteknoloji ve aşı gibi stratejik sektörlere sahip olması ve bu sektörlerin kamusal mülkiyeti ülkenin krizlere ve dış tehditlere karşı dayanıklılığının arttırdığı pandemi döneminde daha açık bir görülmüştür.

Küba biyoteknolojisi özelinde bilim ve teknolojinin ulusal kalkınma planına entegre edilmesi hem toplum sağlığının güncel gereksinimlerine yanıt veren yenilikler geliştirilmesine hem de sektörün dayanıklılığının güçlenmesine hizmet etmiştir. Bununla birlikte bilim merkezlerinin kendi içinde ve biyoteknoloji sektörünün sağlık sistemi, diğer devlet kurumları ve sektörler ile yüksek düzeyde entegrasyonu sektörün inovasyon kapasitesinin ve adaptasyon yeteneklerinin artmasını mümkün kılmıştır. Böylece sektörün sürdürülebilirliği ve dengeli kalkınma sonuçlarının elde edilmesini sağlanmıştır. Gelişmekte olan ülkeler için toplumsal kalkınma planları çerçevesinde yüksek örgütsel ve işlevsel entegrasyon ile hareket etmek sadece kaynak verimliliğini maksimize etmek için değil yenilikçi ve dayanıklı bir sektörel kalkınmayı sağlamak önemlidir. Pandemi dönemi bunu bir kez daha ispatlamıştır.

Küba'nın bilim ve teknoloji politikalarının temelinde, bilginin toplumsal çıkarlar için ve ekonomik, sosyal, çevresel ve hatta kültürel sorunların çözümüne yönelik kullanılması ilkesi yer almaktadır. Bilimsel çalışmalar, toplumsal fayda ve insani ihtiyaçlar doğrultusunda yönlendirilmektedir. Bilim insanlarının yurtseverlik,

bağımsızlık ve enternasyonalizm gibi kavramları içselleşmiş olması bu motivasyonunu artırmaktadır. Gelişmekte olan ülkelerin uzun vadeli kalkınma stratejileri doğrultusunda eğitim politikaları oluştururken eğitimin bilimsel içeriğinin ve teknik bilgi akışının güçlendirilmesinden ibaret bir yaklaşımla yetinmemeleri önerilir. Toplumsal ve ilerici değerler açısından içeriği zenginleştirilmiş, kolektif çalışma kültürünü teşvik eden, dayanışmayı ve toplumsal sorumluluk bilincini aşılayan bir eğitim sistemi bir yandan bilim insanlarının topluma yabancılaşmasını önleyerek yaratıcılığı artırır ilen öte yandan toplumun bilime duyduğu güveni pekiştirir. Bu da bilimsel ilerleme ve sürdürülebilir kalkınmayı mümkün kılar.

Özetle, bir olgu olarak Küba biyoteknolojisi tarihsel ve diyalektik bir bağlam içinde değerlendirildiğinde başarısının Küba Devrimi ve onun sosyalist karakteri ile ilişkili olduğu anlaşılmaktadır. Bu bağlamda piyasa belirlenimli ulusal ve sektörel kalkınma modellerin ülkelerin ve toplumların tek seçeneği olduğu bir yanılsamadır. Küba'nın deneyimi, kamu yararını önceliklendiren ve toplum temelli kalkınmayı önceleyen alternatif bir yolun mümkün olduğunu göstermektedir.

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