Beyond Potential

The Realities and Future of Iran's Biotechnology Industry

The First Edition
2024

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Beyond Potential: The Realities and Future of Iran's Biotechnology Industry

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  Iran Expo 2024 Exhibition (www.iranexpofair.com)
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- **Date:** March, 2024
- **Edition:** The First
- **Executive Summary:** Iran's burgeoning Biotechnology industry holds immense potential, fueled by robust research capabilities, advanced infrastructure, and a relentless drive for innovation. This report unveils these strengths and explores high-growth areas within the sector. We further examine Iran's strong foundation in the global health industry, providing an overview. To empower potential partners seeking collaboration and capitalize on exciting opportunities, the report also highlights prominent Iranian Biotechnology companies.

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Introduction

Iran, a nation steeped in history and cultural richness, boasts a burgeoning health industry poised for significant growth. This dynamic sector, embedded within a rapidly evolving economy, presents a compelling picture of potential and capability.

Standing at the crossroads of East and West, Iran leverages its unique position to combine a rich heritage of medical knowledge with cutting-edge advancements. This strategic location fosters a diverse talent pool and facilitates collaboration with both Eastern and Western partners. Furthermore, Iran's vast reserves of natural resources provide the foundation for a robust pharmaceutical industry, while its well-established scientific community fuels research and development efforts.

This report delves into the heart of Iran's healthcare potential, exploring the strengths and resources that position the country as a major player in the global market. We will meticulously analyze the factors that contribute to Iran's competitive edge, including its highly skilled medical professionals, advanced medical infrastructure, and commitment to innovation.

Specific areas within the healthcare sector with high growth potential will be identified, highlighting opportunities for domestic and international collaboration.

This in-depth analysis will serve as a valuable resource for businesses, policymakers, and investors seeking to explore the untapped potential of the Iranian healthcare market.

As we delve deeper, you will gain a comprehensive understanding of the factors shaping the future of healthcare trade and collaboration within this dynamic nation.

This report was prepared with the support of the promotion organization of Iran (TPO). The TPO stands as a pivotal force in fostering trade between Iran and other nations. Established in 1966, it carries the crucial mission of promoting and developing Iran's non-oil trade through a comprehensive set of initiatives. The TPO role extends far beyond simply being a mediator. It actively engages in various endeavors to cultivate a thriving trade environment.

Iran Expo Exhibition is one of the TPO plan to facilitate trading with Iran. Iran Expo is a global platform dedicated to showcasing the achievements and exceptional products of Iran, held in Tehran, serves as a bridge, connecting the world with the rich heritage and dynamic industries of this captivating nation.

Structure of the Report

Report Specifications

Mission of the Report

Empowering Iran's Medicine and Healthcare industry for Global Excellence is the main mission of this report. This mission is driven by a commitment to:

- Access to critical market insights
- Direct Access to Potential Partners
- Establish Valuable and Strategic Connections
- Minimize trade Risks

Purpose of the Report

The primary purpose of this report is to serve as a comprehensive resource for foreign businesses and investors interested in exploring export opportunities in Iran's Medicine and Healthcare industry. It aims to provide a holistic understanding of the sector current status, strengths, opportunities, challenges, and future prospects.

Scope of the Report

The report encompasses a broad scope, covering various aspects of the Iranian Medicine and Healthcare industry export potential. It delves into the following key areas:

- Key Export Products
- The most Attractive Target Markets
- Trade Promotion and Investment Opportunities
- Industry Challenges

Research Methodology

This report analyzes the export potential of Iran's Medicine and Healthcare industry for international traders. It employs a three-step approach:

- **Macroeconomic Analysis:** Data on Iran's GDP, trade volume, and major trading partners was gathered from reputable sources such as the World Bank, International Monetary Fund, and International Trade Center (ITC). This data was analyzed to draw a big picture of the overall economic landscape, highlighting market size, growth potential, and relevant consumer trends.
- **Industry-Specific Research:** Information on Iran's Medicine and Healthcare industry exports, key product categories, and major competitors was collected from specialized databases like Trade Map, FAOSTAT, and COMTRADE. Based on this data, specific Medicine and Healthcare industry segments with high export potential were identified for further study.
- **Primary Data Collection & Company Profiling:** Semi-structured interviews were conducted with representatives of prominent Iranian Medicine and Healthcare industry export companies within the chosen segments. Company Profiles were created for key players, highlighting their strengths, target markets, and export capabilities.

Limitations

It is important to acknowledge that this study has limitations. Access to certain primary data, particularly within specific industry segments, might be restricted due to market competitiveness or data availability. Additionally, the dynamic nature of the global economy and trade regulations necessitates continuous updates to maintain the report accuracy.

Target Audience

The report is primarily tailored to foreign businessmen and investors seeking opportunities to collaborate or invest in Iran's Medicine and Healthcare industry. It aims to cater to a diverse range of stakeholders, including:

- Medicine and Healthcare industry producers and processors
- Medicine and Healthcare industry technology companies
- Investment firms and financial institutions
- Consulting firms and advisors

An Overview of Iran

Iran at a Glance

- Area: 1,648,195 square kilometers
- Population: 88,860,005 people
- Capital: Tehran
- Official religion: Islam
- Official language: Farsi (Persian)
- Currency: Rial
- Number of provinces: 31
- Number of industrial parks: 824
- Number of science & technology parks: 54
- Number of technology incubators: 264
- Number of high-tech companies: 9620
- Number of industrial companies: 30400
- Number of universities: 2183
- Number of ports: 12
- 2023 GDP: 368 billion USD
- The export volume in 2023: 81 billion USD
- The import volume in 2023: 59 billion USD

Iran boasts a rich history and a strategic location, fostering a dynamic and diverse economy. This report delves into the nation's flourishing industries, showcasing its vast potential for international collaboration and growth. With a skilled workforce and a strong entrepreneurial spirit, Iran is poised to play a significant role in the global marketplace. Iran's economy is underpinned by a robust mix of industries. This report explores the strengths of each sector. Iran possesses a strategic location and well-developed infrastructure, making it a key player in international trade. This report examines the country's trade landscape, showcasing the opportunities for foreign businesses to partner with Iranian companies and reach new markets.

GDP

Exhibit 1 shows the GDP (current USD) of Iran from 2010 to 2028, with projections for 2023 to 2028. The GDP is a measure of the total value of goods and services produced within a country in a given period. The graph shows that the GDP of Iran has been growing steadily in recent years, with an average annual growth rate of around 2%.

In 2022, the GDP of Iran was estimated to be around 414 billion USD. Exhibit 1 shows the forecast for Iran's GDP growth between 2023 and 2028 is for modest growth, in the range of 2% to 3% per year. This means that the Iranian economy is expected to grow slowly but steadily over the next few years.

Exhibit 1: GDP (USD) of Iran from 2010 to 2028
(Source: World Bank)

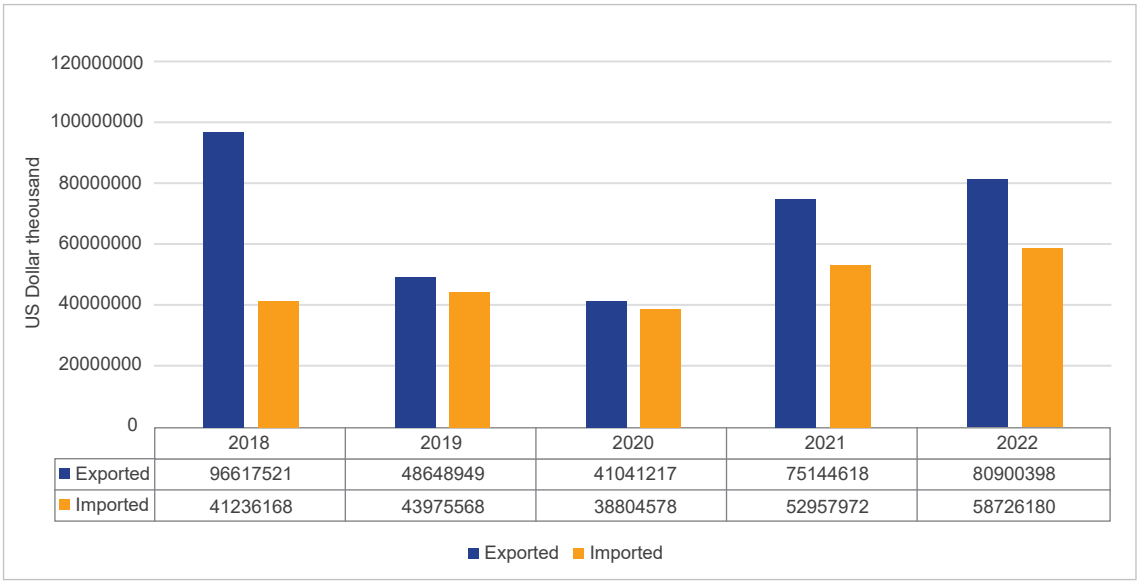
Exchange Rate
The Iranian Rial has weakened against the US dollar in recent years. This weaker exchange rate, meaning more rials are needed per dollar, can make Iranian exports cheaper on the global market.

This could potentially lead to increased demand and production due to lower labor costs (in dollar terms) and a decrease in the unit cost of goods.

Trade Statistics
Iran's overall import statistics have experienced an approximate growth of 40% during the last four years.

Iran's largest imports in 2022 are from the United Arab Emirates (UAE) accounting for 30.7%, followed by China at 26.5%, Turkey at 10.4%, and India at 4.6%.

Exhibit 2: Value of Iran's Export and Import from 2018 to 2022 (Source: TRADE MAP)



	2018	2019	2020	2021	2022
Exported	96617521	48648949	41041217	75144618	80900398
Imported	41236168	43975568	38804578	52957972	58726180

Iran's overall export statistics are also going through an upward trend, especially in the last two years. Exports from 2020 to 2022 have grown by 100 percent. Iran's largest export in 2022 is to China with 27.7%.

The reason for the drop in exports in 2019 is the withdrawal of the United States from the JCPOA signed by Donald Trump, the former president of this country, and the return of sanctions in 2018, which resulted in a significant drop in Iran's oil exports.

This trend reached its lowest level in 2020 regarding the impact of the Corona pandemic. After that and under the same conditions, Iran was able to increase its exports.

Iran's Health Sector

The healthcare industry, as one of the important and vital areas in any society, plays a very important role in improving the quality of people's lives and economic development. Medical knowledge in Iran has a long history and has trained many skilled scientists and physicians throughout history who have had a profound impact on the advancement of human knowledge. In ancient times, great figures such as «Abu Ali Sina» and «Zakariya Razi» were born in this land.

In modern times, prominent figures such as «Professor Samii» (the world's best brain surgeon) and «Professor Mussivand» (the Iranian Inventor of Artificial Cardiac Pump) have also been raised here.

Key Factors of Iran's Health Sector

Iran's health sector is positioned for growth and international collaboration, fueled by a robust foundation of strengths.

This report explores these key advantages, highlighting the skilled workforce, commitment to self-sufficiency, and strategic government support that drive innovation and position Iran as a competitive player in the global health market. Among the strengths of Iran, the following can be mentioned:

- **Human Capital:** Iran boasts a large pool of highly trained medical professionals, including doctors, pharmacists, researchers, and scientists. This strong human capital base fuels innovation and research and development (R&D) in the health sector.
- **Focus on Self-Sufficiency:** Iran has prioritized self-sufficiency in healthcare, leading to the development of a robust domestic pharmaceutical industry capable of producing a wide range of essential and generic medications.
- **Government Support:** The Iranian government recognizes the importance of the health sector and invests in R&D initiatives, infrastructure development, and promoting domestic production of medical products.
- **Competitive Advantage:** Iranian medical products are often competitively priced due to lower production costs compared to some international counterparts.
- **Growing Domestic Market:** Iran's large and growing population creates a strong domestic market for pharmaceuticals and medical devices, fostering continuous development within the industry.

- **Advancements in R&D:** Iranian researchers and companies are actively engaged in R&D, developing innovative medical technologies and generic drugs.
- **Focus on Specialties:** Iran has established expertise in specific areas like biopharmaceuticals, herbal medicines, and Nano medicine.
- **Patent Activity:** The increasing number of patents registered by Iranian entities in the medical field demonstrates the country's growing technological capabilities.

The concluding part of this text emphasizes the bright future of Iran's health sector due to the strong foundation it possesses. However, simply stating the potential isn't enough. To truly showcase Iran's capabilities, we need to delve deeper.

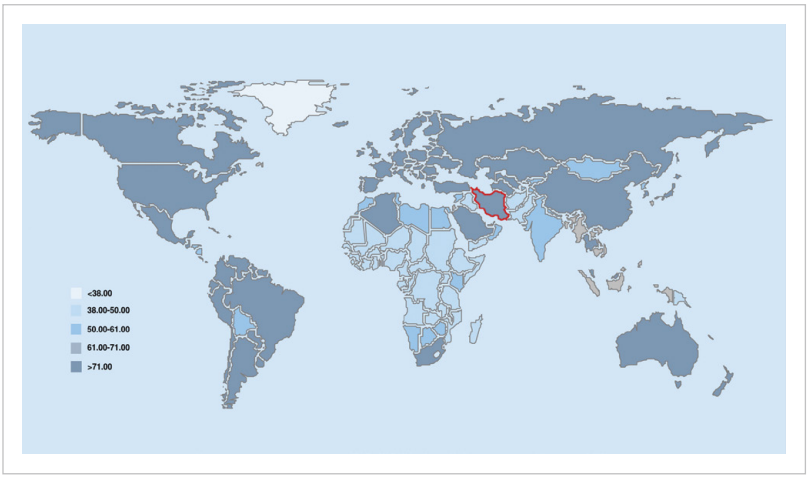
In the continuation of the report will examine specific examples within the health sector, providing concrete evidence to support the claims made about Iran's strengths and technological advancements. This will give a more comprehensive picture of what Iran has to offer in the global healthcare landscape.

Iran's Health Status

Exhibit 3 displays the Universal Health Coverage (UHC) effective coverage index for various countries worldwide. Iran presently offers over 70% of the essential and impactful health and treatment services.

This index aims to represent how well health services cover a population's needs and the impact these services have on improving overall health. It considers factors like Accessibility, Quality, and Affordability.

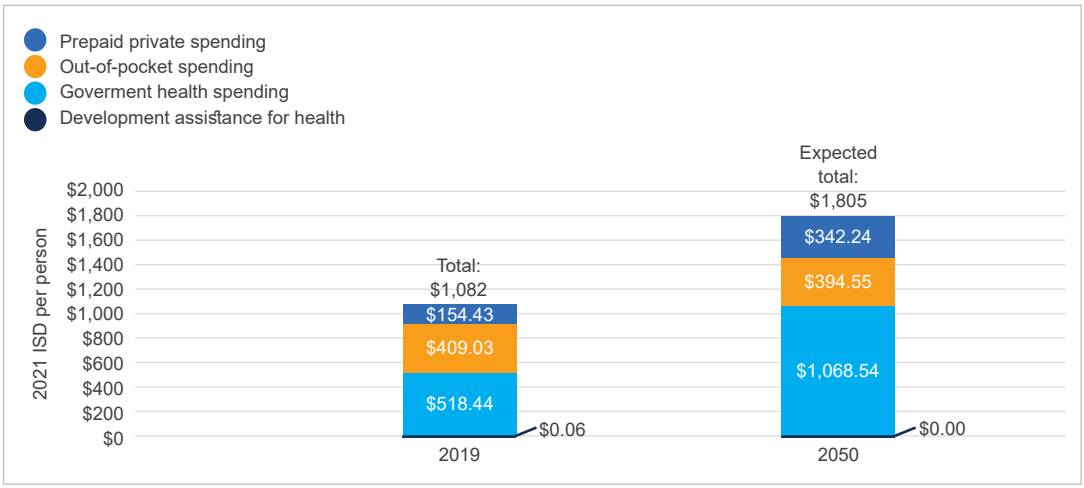
Exhibit 3: Universal Health Coverage Illustration in 2021 (Source: IHME)



A report by the Institute for Health Metrics and Evaluation (IHME) predicts a dramatic shift in Iran's healthcare landscape by 2050.

Government health coverage is expected to more than double, exceeding 100% growth compared to 2019. This translates to a significant decrease in out-of-pocket expenses for citizens, with a projected 4% reduction.

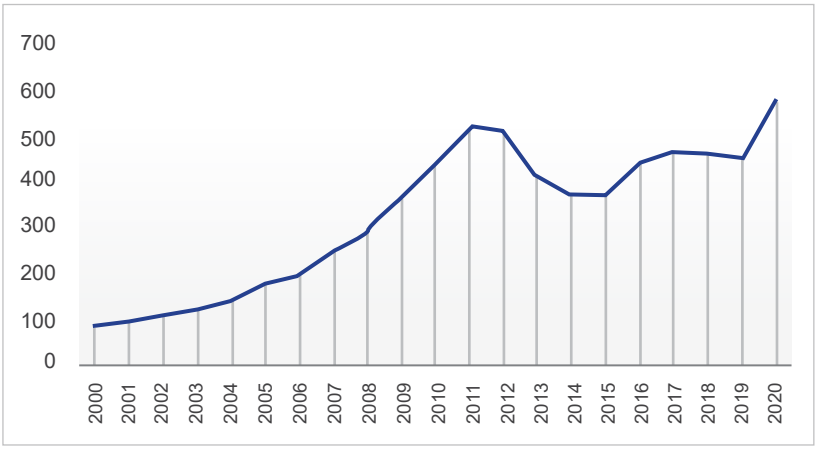
Exhibit 4: Health Coverage in Iran (Source:IHME)



In 2020, according to the World bank report, Iran's health expenditure per capita reached 573 US dollars, reflecting a significant increase from 94 US dollars in 2001.

This translates to an average annual growth rate of 10.76%. This data highlights Iran's growing investment in healthcare, prioritizing the well-being of its citizens.

Exhibit 5: Health Expenditure per Capita (current USD) in Iran (Source: World Bank)



Iran's Health Sector Workforce

- **311,121 Paramedical personnel**
  52,050 Physicians
  - 17,433 General practitioners
  - 4,683 Dentists
  - 304 PhDs in laboratory sciences
  - 2,623 Pharmacists
  - 17,967 Medical specialists
  - 2,553 Subspecialists
  - 6,497 PhDs in specialized fields

(Source: Statistical Center of Iran)

Iran's Health Sector Infrastructure

- Total number of hospitals: 1,020
  - Public hospitals: 705
  - Non-public hospitals: 315
- Number of active comprehensive health service centers: 5,881
- Number of active health bases: 5,535
- Number of active health houses: 17,821
- Number of medical diagnostic laboratories: 4,680
- Number of genetic diagnostic laboratories: 128
- Total number of active pharmacies: 13,052
- Number of veterinary pharmacies: 2,330
- Number of private veterinary clinics: 2,058

(Source: Statistical Center of Iran)

Due ot Statista, in 2024:

- Estimated number of hospital beds per 1,000 inhabitants: 1.54
- Estimated number of beds per hospital: 131.10 (assuming even distribution across hospitals)
- Number of physicians: 52,050 (as per your previous translation)
- Number of nurses per 1,000 inhabitants: 2.03
- Number of dentists per 1,000 inhabitants: 0.54
- Number of physiotherapists per 100,000 inhabitants: 14.86

It's important to consider that these are estimates and may not reflect the exact situation in every region of Iran. The number of beds per hospital is an estimate based on the total number of beds and hospitals and may not be representative of every hospital.

Scientific and Technological Potential and Opportunities in Iran

Iran boasts a strong position in medical science according to reputable international organizations. The country ranks 17th globally and 1st in the Middle East and North Africa (MENA) region for its overall medical knowledge. This accomplishment is further supported by Iran's 16th place in the world for publishing medical research. However, Iran's performance is even more impressive in specific medical fields. For instance, Iran ranks a remarkable 4th globally in infertility treatment, solidifying its leading position within the MENA region.

Healthcare Research: Over the past three years, 12 Iranian researchers in the field of health have had an h-index of over 40. This indicates a high level of research productivity in the Iranian healthcare sector.

Scientific Publications: There are currently 53 scientific and research journals in the fields of health and hygiene, 180 journals in the fields of medical sciences, 20 journals in the fields of pharmacy, and 14 journals in the fields of paramedical sciences that are approved by the Ministry of Science and Health. This shows a strong commitment to scientific publishing in the Iranian healthcare sector.

Education and Training: In the field of health sciences, there are numerous universities in Iran that offer admission, education, and training for students in various fields, including medicine, dentistry, pharmacy, paramedical sciences, nursing and midwifery, veterinary medicine, biology, rehabilitation and social health, and health and safety. A total of 67 universities and medical schools are active in Iran. This indicates a well-developed healthcare education system in the country.

Knowledge-Based Companies: The number of knowledge-based companies in Iran has reached 9620 by 2023, showing a 17% growth compared to the previous year. Of these, more than 1600 companies operate in the healthcare sector. 30% of knowledge-based companies in the healthcare sector are active in the field of pharmaceutical raw materials, and 24% are involved in the production of medical equipment. This demonstrates the growing importance of the healthcare sector in Iran's knowledge-based economy.

Science and Technology Parks: There are 13 science and technology parks and 95 technology incubator centers in the field of health. This shows a strong infrastructure for innovation and technology transfer in the Iranian healthcare sector.

Licensed Products and Patented Inventions: Iranian scientists and companies are making significant strides in healthcare innovation, as evidenced by the impressive number of patents they've secured – nearly 180 – with the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO).

This surge in intellectual property protection reflects a broad range of advancements across various healthcare fields including Pharmaceuticals (81 patents), Medical Equipment (162 Patents), Biotechnology (27 Patents), Herbal Plants and Medicine (9 patents).

This surge in innovation signifies several positive developments:

- **Scientific Prowess:** The high number of patents demonstrates the strength of Iranian scientific research and development in the healthcare sector.
- **Global Recognition:** Securing patents in prestigious international offices like USPTO and EPO highlights the global significance of Iranian healthcare advancements.
- **Economic Potential:** These patents have the potential to attract foreign investment, foster the growth of Iranian healthcare companies, and create new jobs within the sector.
- **Improved Healthcare:** Ultimately, these innovations offer the potential to improve the quality of healthcare available not only in Iran but potentially worldwide

Spotlight on Iran's Health Sector

Cell Therapy: Iran has been utilizing cell therapy for nearly two decades, placing it among the top 10 countries to implement this technology. While many nations are still in the research phase, Iran has successfully applied stem cells in various transplants, including cornea, heart, and skin.

Infertility Treatment: Iran stands out as a leading and highly capable nation in assisted reproductive technologies. Royan Infertility Clinic holds the distinction of being Iran's most reputable and well-equipped center for infertility treatment.

Royan not only provides services through specialized centers for infertility, cell therapy, and diabetes, but also actively engages in research through dedicated institutes focused on reproductive sciences, cell and stem cell biology, and biotechnology.

Biotechnology: Iran is now one of the top three producers of biotechnological products in the world. The country produces vaccines for hepatitis B, erythropoietin, interferon, streptokinase, GCSF, and interferon beta.

Largest Anti-Cancer Drug Production Plant in the Middle East: The Actoverco pharmaceutical group has launched nine production lines for anti-cancer drugs with an investment of over 100 million euros. This is the first German-American bioreactor in the Middle East with OFAC and BAFA licenses.

All products from these production lines are evaluated and controlled Actoverco's advanced quality control laboratories. These laboratories are equipped with the latest and most accurate analytical equipment, including 16 HPLC devices, seven UV and IR spectrophotometers, four TOC devices, and three GC devices.

Iran's Pharmaceutical Production: Iran ranks first in pharmaceutical production in the region. 97% of the country's needed medicines are produced domestically. Iran is now the fourth producer of recombinant drugs in Asia. So far, 14 such drugs have been produced in the country. Recombinant drugs are mainly used in the treatment of incurable diseases such as cancers, some viral diseases, multiple sclerosis, and hemophilia.

Medical Equipment: Iran has made significant strides in the development and production of medical equipment in recent years. This progress is driven by a combination of factors, including government investment, a growing knowledge-based economy, and the dedication of researchers and entrepreneurs. Iran has successfully produced image processing equipment for CT scan devices, a vital component for accurate medical imaging.

Medical Plants: Leaning on its rich history of herbal medicine, Iran is experiencing a resurgence in this field. The establishment of refineries for processing medicinal plants alongside the development of innovative extraction methods, like the tripling of rose essence yield, showcases this commitment. Furthermore, AI-powered machines are being built to improve the efficiency and quality of harvesting valuable saffron. This surge in research and development, coupled with the vast array of native medicinal plants in Iran, positions the country as a potential leader in the revitalization of traditional medicine.

Health Tourism: Leveraging its long history of medical excellence and world-class facilities, Iran's health tourism sector is booming. With 247 licensed medical centers catering to over 1.2 million medical tourists from 164 countries in 2023 alone, Iran has secured its place as a leading destination (ranking 46th globally). The recent establishment of two herbal refineries in Razavi Khorasan Province further strengthens this position by providing innovative treatment options, attracting even more international patients seeking high-quality healthcare.

Additional Areas of Focus: Iran is actively researching and developing cutting-edge solutions in areas like nanomedicine, advanced medical imaging, telemedicine, gene therapy, and tissue engineering. These advancements have the potential to revolutionize healthcare delivery, disease detection, and treatment options in Iran and beyond.

Iranian Government's Support for the Health Sector

The Iranian government has implemented a multi-faceted approach to support the growth and innovation of the domestic health industry.

A significant 52% increase in healthcare funding for the Ministry of Health and affiliated organizations was allocated in the 2023 budget. The government prioritizes strengthening infrastructure for the production of high-quality pharmaceuticals, vaccines, medical supplies, and equipment that meet international standards.

This focus aims to reduce reliance on imported medical products and potentially make healthcare more affordable. A specific support package has been developed to incentivize domestic production of medicines and health products. This initiative aims to reduce dependence on foreign imports and potentially lower healthcare costs for the population.

Recognizing the potential of the Iranian health industry, the government provides direct financial support to manufacturing companies to participate in and visit international health exhibitions. This initiative enhances visibility for Iranian healthcare products in the global market and potentially opens doors for export opportunities.

Biotechnology Industry in Iran

Biotechnology harnesses the power of living organisms and cellular processes to develop innovative products and technologies that improve our lives and the health of our planet. This technology builds upon a long history of human interaction with biology. For over 6,000 years, we've utilized the natural processes of microorganisms to create essential food products like bread and cheese, and preserve dairy goods.
Modern biotechnology offers groundbreaking solutions to some of humanity's most pressing challenges. It allows us to:

- **Combat diseases:**

Biotechnology is revolutionizing healthcare by developing new tools to fight debilitating and rare illnesses.

- **Reduce environmental impact:**

Biotechnological advancements are helping us minimize our environmental footprint through sustainable farming practices and cleaner industrial processes.

- **Improve food security:**

Bioengineered crops are contributing to a more secure food supply by increasing yields, reducing reliance on harmful chemicals, and enhancing nutritional content.

Biotechnology plays a crucial role in promoting global health by leveraging the body's natural processes and genetic makeup. This translates into several key benefits:

- Reduced rates of infectious diseases
- Improved childhood survival rates
- Increased hope for managing serious illnesses
- Personalized treatments with fewer side effects
- More precise tools for disease detection
- Effective solutions for global health challenges

Biotechnology is transforming agriculture by enhancing crops with desirable traits:

- Increased insect and herbicide resistance
- Environmentally friendly farming practices
- Higher yields with fewer resources
- Reduced reliance on pesticides and tilling
- Crops with improved nutritional profiles
- Development of allergen-free and toxin-free foods
- Enhanced food and crop oil content for better health

An Overview of Iran's Biotechnology Industry

Iran has a surprisingly long history with modern biotechnology. The foundation was laid in the early 20th century, following a devastating influenza pandemic. This prompted the establishment of research centers dedicated to microbiology and immunology. Notably, vaccine production in the Pasteur and Razi Institutes, established in 1920 and 1925 respectively, marked the beginning of Iran's journey in modern biotechnology. Today, the local production of biopharmaceutical products like interferon, growth hormone, and erythropoietin represents a significant investment in Iran's pharmaceutical sector.

Biotechnology is recognized as a critical driver of national security, impacting economic well-being, food security, and public health. Among Eastern Mediterranean countries, Iran stands out as a leading contributor to this vital field. After overcoming past concerns, there's now a surge of interest in both research and everyday applications of biotechnology within Iranian society. Notably, public acceptance is particularly strong for medical biotechnology, encompassing areas like genetic research, pharmaceutical development, and environmental bioremediation.

This growing enthusiasm positions Iran as a fast-evolving innovator in Asia's biotechnology landscape. Numerous research centers are actively engaged in this field. Key players include the National Institute for Genetic Engineering and Biotechnology, Pasteur Institute, Razi Institute, Persian Gulf Biotechnology Research Center, and prominent universities like Sharif, Tarbiat Modares, Tehran, Shiraz, Mashhad, Isfahan, and Tabriz. Additionally, the Agriculture Biotechnology Research Center plays a significant role.

This section highlights the significant progress Iran has made in biotechnology, drawing on information from the Biotechnology Development Council of Iran in 2021.

Economic I mpact:

- Biotechnology has resulted in approximately 1.8 billion USD in savings within the medical field. This is attributed to a robust innovation ecosystem that fosters domestic production, reducing reliance on foreign exchange for medicine and treatments.

- Nearly 800 knowledge-based companies are currently active in the biotechnology sector, contributing significantly to the Iranian economy.

Domestic Production:

- Iran boasts the production of around 30 types of biotech medicines, alongside essential medical supplies like kits, vaccines, and blood products. Notably, 80% of these pharmaceutical items are domestically produced.

- The Biotechnology Development Council has launched 129 production projects specifically aimed at saving up to 1.44 billion USD in foreign currency.

Global Standing:

- Iran has secured an impressive 12th place ranking worldwide and the top position in West Asia within the biotechnology sector. This is further emphasized by the fact that 9.5% of the income and over 60% of the exports from knowledge-based companies are related to biotechnology.

Project Implementation:

To achieve a 3% market share and leverage biotechnology for economic development, Iran has implemented projects encompassing:

- 27 biotechnology medicines
- 12 vaccine projects
- 90 pharmaceutical raw materials
- 55 projects in agriculture and food security

This data demonstrates Iran's commitment to advancing its biotechnology sector, fostering economic growth, and achieving self-sufficiency in crucial medical supplies.

- **Scientific Ranking:** Iran ranks 12th globally in biotechnology publications (SJR 2022) and 1st in the Middle East, with over 12,800 published articles.
- **Technological Hub:** The Pardis Technology Park, Iran's premier S&T park, fosters innovation and houses over 470 high-tech companies, with 23% specializing in biotechnology and medical equipment.
- **Market Dynamics:** The Iranian Biotechnology Reagents market shows increasing competition (HHI declining from 2017 to 2023), indicating an influx of new players.
- **Stem Cell Leadership:** Iran ranks 1st in the region and 13th globally in stem cell research, with over 20 active cell therapy centers and 1,300 annual hematopoietic stem cell transplants.
- **Advanced Therapies:** Iran is the 3rd country offering gene therapy for cancer treatment.
- **Agricultural Impact:** The Agricultural Biotechnology Research Institute has delivered significant economic benefits, with its achievements implemented on over 200,000 hectares of farmland.

Key Findings

- Strong domestic production capabilities in various biotech products.
- Leading position in scientific research and publications in the Middle East.
- Supportive infrastructure for technology development and commercialization.
- Growing competitiveness within the biotech market.
- Advancement in stem cell research and application.
- Pioneering use of gene therapy for cancer treatment.
- Positive economic impact of agricultural biotechnology innovations.

Iran's Innovative Achievements in Biotechnology

Iran's biotechnology sector is witnessing a surge in groundbreaking advancements, solidifying its position as a key player in the global arena. Here's a closer look at some of the recent milestones:

1. Global Recognition for Biotechnology:
Iranian scientists and companies have secured a remarkable 27 patents in the European and US patent offices for their work in biotechnology. This achievement not only highlights the exceptional quality of Iranian research but also showcases the country's growing competitiveness in the international market. This recognition is likely to attract further investment and boost the domestic medical device sector, leading to job creation.

2. Pioneering Parkinson's Treatment:
Iran stands as the sixth country globally to initiate clinical trials for a revolutionary Parkinson's treatment using stem cells. This achievement positions Iran at the forefront of medical research, joining a select group of nations (USA, Sweden, China, Japan, and Australia) actively exploring this promising therapeutic approach.

3. Life-Saving Innovation:
A significant breakthrough came with obtaining the first-ever license in Iran for producing a «transplant tissue preservation solution» (kidney, liver, etc.) This collaborative effort by Shahid Beheshti University of Medical Sciences, Royan Research Institute, and Lotus funding has the potential to save countless lives by improving organ transplant success rates.

4. Fertility Treatments Take Flight:
A collaborative project between Shahid Beheshti University of Medical Sciences and Royan Research Institute has yielded the «Iron-Xylanonan nanocomposite,» a bio-nanotechnology product with significant benefits for in vitro maturation (IVM) and fertilization (IVF) procedures. This innovation holds immense promise for improving assisted reproductive technologies in clinical settings.

5. Leading the Fight Against Cancer:
Iranian researchers at Tehran University of Medical Sciences, in collaboration with a research-based startup, have made significant strides in developing CAR-T Cell therapy, a cutting-edge approach to cancer treatment. This positions Iran as one of only three entities globally offering this advanced therapy, demonstrating its commitment to providing patients with the latest advancements.

6. Advanced Cancer Treatment:
In 2021, Iran established the first-ever advanced ion therapy center in West Asia. This innovative technology provides highly targeted radiation therapy, minimizing risk to healthy tissues while effectively treating various cancers.

7. Gene Therapy Triumph:
Scientists have achieved success in developing the "Advanced CART-Cell Therapy Gene Therapy Technique" for treating acute lymphoblastic leukemia (ALL). This advancement signifies a significant leap forward in the fight against this form of blood cancer.

8. Hope for the Future:
The first Iranian mRNA vaccine, "CoronaPsin," has successfully completed phase 1 clinical trials. This vaccine, developed by a knowledge-based company, has demonstrated safety and immune response in healthy volunteers, paving the way for phase 2 and 3 human testing. This achievement signifies Iran's commitment to developing effective solutions for global health challenges.

These remarkable achievements paint a vibrant picture of Iran's thriving biotechnology sector. The country is actively contributing to global progress in various fields, from tackling chronic diseases to improving human fertility and offering cutting-edge cancer treatments.

As research and development continue to flourish, Iran is poised to solidify its position as a leader in the ever-evolving world of biotechnology.

Market Segmentation by Application

Biotechnology's reach extends far beyond the realm of human healthcare. According to a Grandview Research report (2023), this transformative technology finds application in a multitude of fields, including:

Health: This remains the dominant application segment, driven by factors like the rising burden of chronic diseases, increasing availability of agricultural biotechnology products and bioservices, and continuous advancements in bio-industrial processes.

Bioinformatics: The integration of artificial intelligence (AI), machine learning, and big data analysis with bioinformatics is revolutionizing sectors like food and beverage production. These advancements are facilitating the development of more efficient and sustainable food systems.

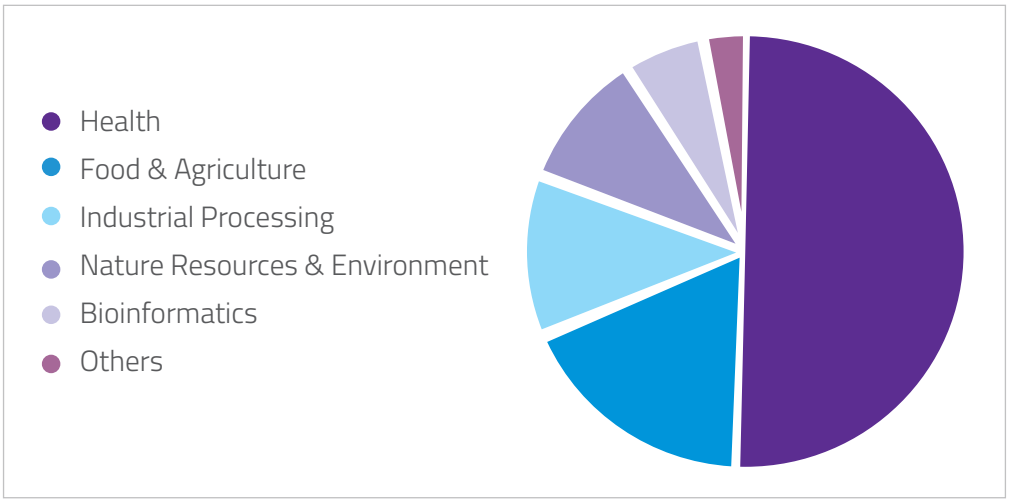
Food and Agriculture: Agri-biotech solutions are playing a crucial role in addressing global food security challenges. From genetically modified crops with enhanced yields and pest resistance to advanced biofertilizers, this segment is poised for significant growth.

Industrial Processes: Biotechnology is transforming industrial processes across various sectors. Bio-based fuels, bioplastics, and bioremediation techniques offer eco-friendly alternatives to traditional methods, promoting environmental sustainability.

Natural Resources and Environment: Biotechnology plays a vital role in environmental protection and conservation efforts. Bioremediation techniques utilize microorganisms to clean up polluted sites, while advancements in biofuels offer alternatives to fossil fuels, mitigating climate change impacts.

The synergy between these diverse applications is a key driver of the overall biotechnology market growth. Advancements in one segment, such as AI-powered bioinformatics, can unlock potential and accelerate innovation in other areas like food production. This interconnectedness highlights the vast potential of biotechnology to address some of humanity's most pressing challenges.

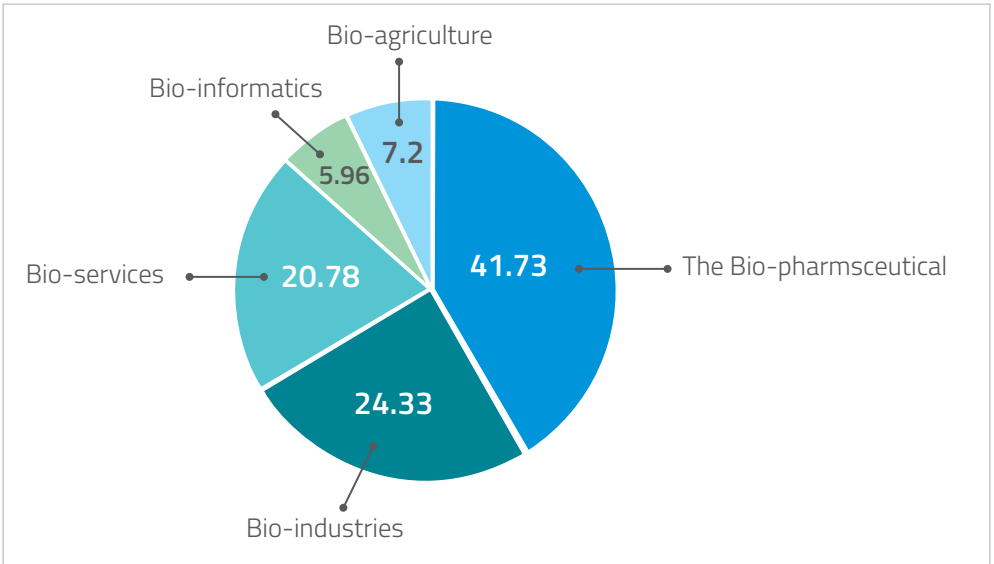
Exhibit 6: Global Biotechnology Market Share, by Application, 2023 (%) (Source: Grandview Research)



Precedence Research (2023) identifies several key sub-sectors within the broader biotechnology market, each with its own unique growth drivers:

- **Bio-pharmacy:** This segment reigns supreme, fueled by the unfortunate reality of rising disease prevalence globally. As chronic and complex illnesses become more widespread, the demand for innovative medicines and drugs soars. Bio-pharmaceutical companies are at the forefront of developing these life-saving treatments, propelling segment growth.
- **Bio-industries:** Beyond healthcare, biotechnology is transforming numerous industries. Bio-based solutions are making waves in sectors like manufacturing, chemicals, and energy. The development of bioplastics, biofuels, and bioremediation techniques exemplifies this trend, offering sustainable alternatives to traditional methods.
- **Bio-services:** This segment encompasses a wide range of services that leverage biological processes for various applications. Contract research organizations (CROs) offering drug discovery and development services are a prime example. Bio-services play a critical role in supporting the innovation pipeline across the entire biotechnology industry.
- **Bio-agriculture:** As the global population continues to grow, ensuring food security becomes paramount. Bio-agriculture offers a powerful toolbox for addressing this challenge. This segment encompasses technologies like genetically modified crops with improved yields and pest resistance, along with the development of biofertilizers and advanced farming practices.
- **Bioinformatics:** This rapidly evolving field sits at the intersection of biology and computer science. By harnessing the power of artificial intelligence, machine learning, and big data analysis, bioinformatics unlocks a treasure trove of insights from biological data. This segment is revolutionizing fields like drug discovery, personalized medicine, and food production, with its impact expected to grow exponentially in the coming years.

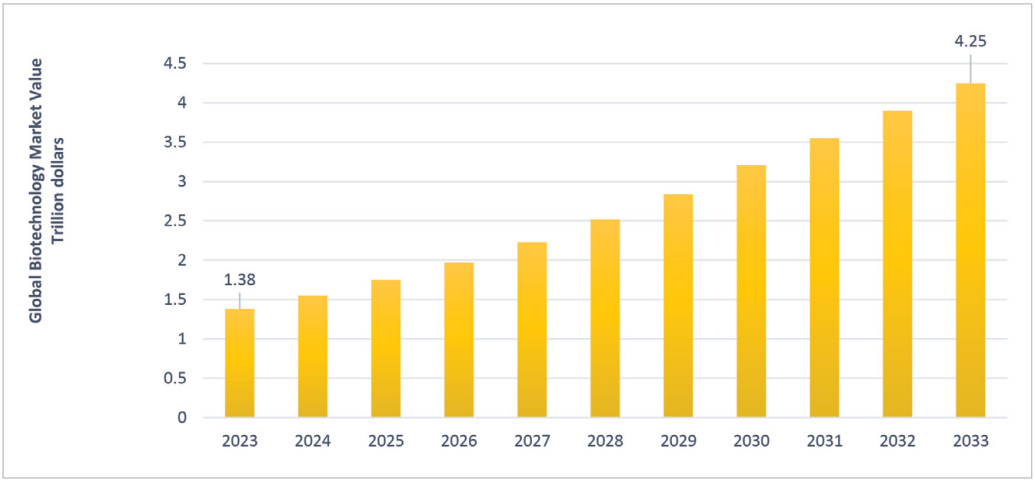
Exhibit 7: Biotechnology Market Share, by Application in 2023 (Source: Precedence Research)



The dominance of bio-pharmacy reflects the pressing need for solutions to combat the global disease burden. However, the other segments within biotechnology are poised for significant growth, driven by innovation and the increasing demand for sustainable solutions across various industries.

This diversification of applications underscores the vast potential of biotechnology to shape a healthier and more sustainable future.

Exhibit 8: Global Biotechnology Market Volume Forecast to 2033 -Unit: Trillion USD
(Source: Precedence Research)



Global Market of Biotechnology

The global biotechnology industry is experiencing a surge, driven by several key factors. According to a recent market report published by Precedence Research in 2023, the global biotechnology market was valued at a st aggering 1.38 trillion USD in 2023.

This momentum is expected to continue, with projections indicating the market will reach a monumental 4.25 trillion USD by 2033. This translates to a noteworthy Compound Annual Growth Rate (CAGR) of 11.8% from 2024 to 2033.

This impressive growth signifies the increasing importance and vast potential of biotechnology across various sectors.

Market Concentration & Characteristics

The global biotechnology market is currently experiencing a period of high growth. According to Grandview Research (2023), the market is in an acceleration phase, indicating a rapid rise in its value. This dynamic environment is fueled by a relentless pursuit of innovation.

Advancements in various fields, including genomics, molecular biology, cellular & tissue engineering, bio imaging, and novel drug discovery methodologies, are constantly pushing the boundaries of what's possible. These breakthroughs are expected to significantly enhance diagnostic capabilities by providing more precise tools for disease detection.

Additionally, they hold immense promise for broadening treatment alternatives, leading to the development of new and more effective therapies.

Another defining characteristic of the biotechnology market is the high level of merger and acquisition (M&A) activity. Leading players are actively seeking to consolidate their positions by acquiring smaller companies with promising technologies or expertise in specific areas. This trend is driven by the desire to gain a competitive edge and accelerate internal R&D efforts. The combined forces of innovation and consolidation are expected to shape the future landscape of the biotechnology industry.

Exhibit 9: Market Concentration and Characteristics in Biotechnology (Source: Grandview Research)

High-Growth Opportunities in Biotechnology

The future of healthcare hinges on groundbreaking advancements in biotechnology. Fueled by technological breakthroughs, evolving healthcare needs, and a dynamic global market, several key areas are poised for explosive growth. Here, we explore three particularly exciting frontiers:

1. Gene Editing and CRISPR Technology: A Revolution in Drug Development

Gene editing, spearheaded by CRISPR technology, empowers biotechnology companies to revolutionize drug development. This transformative technology allows for precise manipulation of the human genome, enabling the correction of genetic defects at their source. Imagine tackling diseases like cystic fibrosis or sickle cell anemia by directly fixing the underlying genetic mutations – CRISPR holds immense potential for such targeted interventions.

Beyond direct correction, CRISPR accelerates drug development by creating highly accurate disease models in cells and animals.

These models expedite the testing phase, potentially bringing life-saving therapies to market faster. As CRISPR research expands, its applications broaden, paving the way for potential treatments of complex ailments like heart disease, Alzheimer's, and autoimmune disorders.

Here are some specific ways gene editing and CRISPR technology are empowering drug development:

- Tumor Mutation Targeting: Precisely targeting mutations that fuel cancer growth.
- CAR-T Cell Engineering: Engineering immune cells (CAR-T cells) to recognize and attack cancerous cells.
- Gene Therapy Vector Development: Creating safe and effective delivery systems for gene therapies.
- Unlocking New Targets: Identifying previously unknown targets for therapeutic intervention in neurodegenerative and cardiovascular diseases.

2. Stem Cell Technology: Redefining Drug Discovery

Stem cell technology offers a multitude of advantages for biotechnology companies, fundamentally reshaping drug discovery. These versatile cells allow researchers to create disease models that closely mimic human tissues.

This streamlines the testing of potential drugs, significantly accelerating the discovery process. Furthermore, stem cells pave the way for personalized medicine. By utilizing patient-derived stem cells, companies can tailor treatments to individual genetic variations, optimizing therapeutic outcomes and minimizing side effects.

The potential for stem cell-based cell therapies is vast. Researchers are exploring their application in regenerative medicine, aiming to heal tissues damaged by conditions like heart disease, Parkinson's, and spinal cord injuries. Additionally, stem cells play a crucial role in drug safety testing.

By assessing the impact of potential drugs on human cells and tissues beforehand, companies can identify potential safety concerns early in development, allowing for crucial refinements before human trials.

3. Tissue Engineering and Bioprinting: Personalized Therapies Take Center Stage

Tissue engineering and bioprinting are revolutionizing drug development by providing biotechnology companies with powerful tools for innovation. These technologies enable the creation of highly accurate 3D tissue models that mirror human organs.

This paves the way for far more effective drug testing processes. Bioprinting patient-specific cells further personalizes drug screening. By testing drugs on miniature, lab-grown versions of individual organs, researchers gain invaluable insights into a patient's unique drug response, allowing for optimized treatment plans.

Tissue engineering empowers companies to delve deeper into disease mechanisms. Sophisticated models of tumors or inflamed blood vessels can unveil previously unseen drug targets. Bioprinting also facilitates the rapid generation of multiple tissue models, significantly accelerating preclinical testing and ultimately streamlining drug development timelines.

Furthermore, bioprinting opens doors for the design of customized drug delivery systems, such as implantable scaffolds or targeted nanoparticles, maximizing drug efficacy while minimizing side effects.

These are just a few examples of the exciting frontiers pushing the boundaries of biotechnology. As research and development continue to accelerate, we can expect even more groundbreaking advancements that will reshape healthcare for generations to come.

SWOT Analysis

Strengths

- **Robust Research Capabilities:** Iran boasts a growing pool of skilled scientists and researchers dedicated to advancing biotechnology. This expertise fuels innovation and development of novel biotech solutions.
- **Advanced Infrastructure:** Investments in modern facilities and resources provide the foundation for cutting-edge research, efficient production, and quality control within the Iranian biotechnology industry.
- **Focus on Innovation:** A culture of innovation fosters the development of groundbreaking products and technologies across various biotech applications. This focus allows Iran to compete in the rapidly evolving global biotechnology landscape.
- **Government Support:** The Iranian government recognizes the strategic and economic importance of biotechnology and provides support through funding initiatives, research grants, and infrastructure development projects. This backing creates an environment conducive to industry growth.
- **Strong Human Capital:** A growing pool of skilled professionals in various fields like bioinformatics, genetic engineering, and bioprocessing supports the industry's needs. This skilled workforce is crucial for translating research and development into commercially viable products.
- **Cost-Competitive Potential:** Production costs for some biotech products in Iran may be lower compared to certain competitors. This advantage can help Iranian companies offer competitive pricing and penetrate the global market.

Weaknesses

- **Limited Commercialization Experience:** While research capabilities are growing, Iran may have less experience compared to established players in translating research into commercially successful products. This can hinder industry growth and profitability.
- **Intellectual Property Challenges:** A robust intellectual property protection system is crucial for attracting investment and encouraging innovation. Weaknesses in this area can discourage research and development efforts.
- **Access to Advanced Technologies:** Iran may face limitations in accessing the latest and most advanced biotechnologies due to sanctions or resource constraints. This can hinder research capabilities and slow down innovation cycles.
- **Skilled Labor Shortages:** The rapid growth of the industry may outpace the development of a skilled workforce in specialized areas like biomanufacturing and regulatory compliance. Addressing this gap is crucial for long-term sustainability.
- **Bureaucracy and Regulatory Hurdles:** Complex regulations and bureaucratic processes can hinder the speed and efficiency of research, development, and commercialization activities within the industry. Streamlining procedures can be beneficial.

Opportunities

- **Growing Global Market:** The global biotechnology market is experiencing significant growth, driven by advancements in areas like gene editing, personalized medicine, and biopharmaceuticals. This presents Iranian companies with vast opportunities for exports and market share.
- **Focus on Biosimilars:** The biosimilars market offers significant growth potential for Iran. By developing high-quality and affordable biosimilars, Iranian companies can cater to the increasing demand for cost-effective alternatives to biologic drugs.
- **Integration with Other Sectors:** Biotechnology can be integrated with other sectors like agriculture, pharmaceuticals, and environmental remediation. This convergence can create new opportunities for innovation and product development.
- **Public-Private Partnerships:** Collaboration between public research institutions and private companies can accelerate innovation and commercialization of biotech products. This partnership approach can leverage strengths from both sectors.
- **Focus on Niche Markets:** Identifying and targeting specific niche markets within the broader biotechnology sector can be a strategic approach. This allows Iranian companies to tailor their research and development efforts to cater to the needs of distinct segments.

Threats

- **Competition from Established Players:** The global biotechnology industry is dominated by established players with significant resources, brand recognition, and extensive distribution networks. Iranian companies need to develop effective strategies to compete effectively.
- **Stringent Regulatory Requirements:** Meeting strict regulatory requirements in major markets like the US and EU can be challenging and expensive for Iranian companies. This can hinder their ability to access these lucrative markets.
- **Fluctuations in Oil Prices:** Since oil is a major source of revenue for Iran, fluctuations in oil prices can impact government funding for research and development in biotechnology. Economic instability creates uncertainty for the industry.
- **Biosecurity Concerns:** Strict biosecurity measures are essential to prevent the accidental or intentional release of harmful biological agents. Addressing these concerns is crucial for maintaining public trust and fostering international collaboration.

International Regulatory Frameworks

Biotechnology plays a significant role in healthcare. Due to its direct impact on human health, maintaining high-quality standards is paramount. Here's an overview of key standards applicable to this sector:

1. Good Manufacturing Practices (GMP):

- Focuses on quality assurance for consistent production and quality control of medicinal products.
- Ensures products meet intended use and product specification requirements.
- Defines quality measures for production, quality control, personnel, premises, and materials used.
- Covers legal aspects of distribution, contract manufacturing, testing, and product defect response.
- Offers specific requirements for various product classes (e.g., sterile pharmaceuticals, biological medicines).

2. Medical Device Quality Management System (ISO 13485):

- Defines requirements for a quality management system for organizations producing medical devices.
- Ensures devices consistently meet customer and regulatory requirements throughout the lifecycle (design, development, production, distribution, etc.).
- Applies to organizations involved in any stage of the medical device lifecycle.
- Adaptable for organizations of all sizes and types.

3. Quality Management System (ISO 9001):

- A globally recognized standard for quality management across all industries and organization sizes.
- Helps organizations improve performance, meet customer expectations, and demonstrate a commitment to quality.
- Defines a framework for establishing, implementing, maintaining, and continually improving a quality management system (QMS).
- Implementing ISO 9001 signifies effective processes and trained staff for consistent product or service delivery.

4. Environmental Management System (ISO 14001):

- The international standard for environmental management systems (EMS).
- Provides a framework for organizations to design, implement, and continually improve their environmental performance.
- Promotes proactive measures to minimize environmental impact, comply with regulations, and achieve environmental goals.
- Covers aspects like resource usage, waste management, environmental performance monitoring, and stakeholder engagement.

5. Safety and Health Management System (ISO 45001):

- An international standard outlining requirements for an occupational health and safety (OH&S) management system.
- Provides a framework for managing risks and improving OH&S performance.
- Establishes criteria for policy, objectives, planning, implementation, operation, auditing, and review of OH&S practices.
- Key elements include leadership commitment, worker participation, risk identification, legal compliance, emergency planning, incident investigation, and continual improvement.
- Utilizes the Plan-Do-Check-Act methodology for systematic OH&S risk management.
- Applicable to organizations of all sizes and can be integrated with other ISO management systems.

6. Health System & Safety OHSAS 18001:

While no longer actively developed, OHSAS 18001 provides an alternative framework for occupational health and safety management systems.

7. Laboratory Management (ISO 17025):

- An international standard for testing and calibration laboratories.
- Focuses on offering quality and improving processes within laboratories.
- Comprises two key areas:
  - » Management Requirements - ensure the performance and efficiency of the laboratory's Quality Management System.
  - » Technical Requirements - emphasize employee competencies, testing methodologies, equipment, and test/calibration results.

8. Competence Management System (ISO 10015):

- Provides guidelines for establishing, implementing, maintaining, and improving competence management and people development systems.
- Aims to positively influence outcomes related to product and service conformity, and stakeholder needs/expectations.
- Applicable to organizations of all types and sizes.
- Does not modify requirements of the ISO 9000 family or other standards.

Some Iranian Prominent Companies in Biotechnology Industry

Farabi Pharmaceutical Company

Brief Overview

Farabi Pharmaceutical Company which was inaugurated in January 1993 for the mass production of antibiotics is the leading pharmaceutical company in the region. The Complex enjoys a wealthy ten-acre workspace site built in a forty-hectare stretch of land, itself advantageously placed on the higher grounds adjacent to the southern mountains of Isfahan.

Products/Services

The company products are divided into 4 main groups including:

- Antibiotic and Anti-virus
- Food and drug supplements
- Gastrointestinal drugs
- Anti-migraine drugs
- Cardiovascular drugs
- Common cold and Allergy
- Anti-obesity and cholesterol drugs
- Sexual enhancement drugs
- Neuroleptics
- Diabetic drugs
- Anti-Nephrotic and Anti-Prostatic drug
- Anti-inflammatory and pain release drug

Industrial achievements and awards and Export

- The Complex produces various oral antibiotic-related and non-antibiotic products and dietary supplements which sets the prestigious annual production record of 1,200,000,000 capsules 45,000,000 suspensions and 460,000,000 film-coated tablets.
- All production procedures are managed According to the cGMP guidelines, FDA and WHO, with the most up to date production machinery and equipment right from granulation down to packing and cartooning, based on the international standards EP, BP, USP.
- It has export to more than 15 countries all over the world.

Certificates & Standards

Quality Management "ISO 9001:2008 ", Environment Management "ISO 14001:2004 " and Occupational Health System & Safety" OHSAS 18001:2007 "have been stabilized at Farabi by the MIC institute of England.. Also stabilized laboratory management "ISO 17025:2008" by the NACI center.

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CinnaGen Company

Brief Overview

CinnaGen Pharmaceutical Group was founded in 1994 with the goal of manufacturing hi-tech products in biotechnology and related fields. Today the company produces more than 100 different products and is the biggest bio-pharmaceutical manufacturer and biotech exporter in the region.

Products/Services

Cinnagen's product portfolio is divided into four main groups, which include: Neurology & Ophthalmology, Oncology & Hematology, Endocrinology & infertility, and Autoimmune & Immunology. The company's main focus is on advancing biosimilar candidates in the areas of Immunological diseases, MS, Infertility, Diabetes, Kidney diseases, Osteoporosis, Hormone disorders and Oncology as well as providing contract research development services.

Industrial achievements and awards and Export

- This group has eight subsidiary companies and five manufacturing sites that obtain GMP certification from the European Union.
- CinnaGen allocates and invests big part of its annual revenue in R&D (about 20%) to achieve and create new biopharmaceutical drug
- development of high-tech medicines in a world-class environment
- The company has a constructive scientific partnership and collaboration with Fraunhofer institute (Germany), Boku University (Austria), British Colombia University (Canada), UGA Biopharma (Germany), Medical university of Tehran (Iran), Shahid Beheshti medical University (Iran) and other several research institutes.
- CinnaGen is the biggest exporter of biotech products in Iran and the middle-east
- CinnaGen is the biggest exporter of biotech products in Iran and the middle-east
- CinnaGen ilac has been established in 2019 and this company is the first full cycle manufacturing site to produce biosimilars in Turkey.

Certificates & Standards

- Integrated management system (IMS) in compliance with ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007, ISO10015:1999 and ISO 10002:2014

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Tadbir Kalaye Jam Company (Tekaje)

Brief Overview

Tadbir Kalaye Jam Company (Tekaje) was established in 1998 as an import-export company and started its activity in the production of pharmaceutical products in 2009 and today has been able to develop a portfolio of products in the fields of CNS, Urology, Antidepressants, PE, Diabetes and medication supplements to support health and prevent disease. Also, Tadbir Kalaye Jam Company (Takajeh), after many years of cooperation with manufacturers of raw materials and excipients, is known as one of the main suppliers of API and Excipients to Iranian pharmaceutical companies.

Products/Services

The company products are divided into four main groups in the field of Antirheumatic, Vitamin and Mineral, Multiple Sclerosis, Phosphate Binder, Anti-Depressants, Antifibrotic Agent, Anti Anginals, Anti Psychotics, and etc.

Certificates & Standards

- Quality management system standards in accordance with ISO9001: 2015
- Environmental management system in accordance with ISO14001: 2015
- Occupational safety and health management system in accordance with ISO45001: 2018
- Customer satisfaction and complaints management in accordance with ISO10004: 2018 and ISO10002: 2018 standards

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Kharazmi Pharmaceutical Company

Brief Overview

Kharazmi Pharmaceutical Company was established in December 1962. In 1996, with the development of production lines and products, it was transferred to 9 km of Karaj special road.

Products/Services

- Analgesics Anti-inflammatory Drugs and Antipyretics
- Antibacterial Drugs
- Antidepressant
- Antidiabetic Drugs
- Antiepileptic
- Antifungals
- Antihistamines
- Antimalarials
- Antimigraine Drugs
- Antiprotozoal
- Antineoplastic
- Anxiolytic Sedatives Hypnotics and Antipsychotics
- Bronchodilator and Anti-asthma drugs
- Nutritional Agents and Vitamins
- Gastrointestinal Drugs

Industrial achievements and awards and Export

Kharazmi Pharmaceutical Company is located on a land with an area of 24,000 square meters and has 3 separate buildings in operation with production and office use. The production unit has been constructed in an area of 7000 square meters in 2 floors and all the production lines of this company include making all kinds of pills, capsules, syrups, oral drops, ointments, sprays and oral antibiotics in accordance with GMP rules.

Certificates & Standards

- BS OHSAS 18001:2007
- Integrated Management System (IMS) Based on Pas 99:2006
- BS EN ISO 14001:2004
- GMP Certificate

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Actoverco Company

Brief Overview

Actoverco has been investing the production of biotechnology drugs since 2012, and the result of this investment is the construction of the Actoverco Biotech factory and the production of drugs needed for patients with MS and cancer. Additionally, the second phase of the Biotech line was also launched to produce biosimilars for the treatment of cancer and special diseases.

Products/Services

The products of Actoverco in Actoverco 1, Actoverco 2, Actoverco Biotech (biosimilar products), Actero (the most equipped site for oncology products), AtiPharmed (the only GMP certified corporation regarding hormonal drugs), Alborz Zagros (the only site with OEL5 for hazardous drugs), Actoverco Cellgene (personalized medicine), Actobiochem (active pharmaceutical ingredients) and Nexus (supplements) results in production of drugs in the field of cardiovascular, neurology, asthma and allergy, diabetes, oncology, MS, urology, gynecology and infertility, organ transplantation, supplements, gastroenterology, hyperlipidemia and metabolism, analgesics, psychiatry, skin, hair and beauty and infectious diseases and COVID-19.

Industrial achievements and awards and Export

- Today, by employing more than 2000 country's efficient young people in 15 medical fields with more than 320 pharmaceutical products possessing highest standards approved by domestic and international organizations, Actoverco has been able to develop the greatest and the most experienced private pharmaceutical group in Iran and the Middle East.

- At present, the pharmaceutical sector with 43,000 square meters of production space and 18 production lines of tablets and capsules with a capacity of more than 7 billion per year, 5 production lines of vials and pre-filled syringes with a capacity of 60 million, the largest production line of ampoules with a capacity 50 million, 3 production lines of lyophilized products with a capacity of 5 million and 4 production lines composed of bioreactors with a capacity of 2000 liters and presence in more than 15 medical fields and production of pharmaceutical raw materials and supplements have reached the determined goals of the beginning; furthermore, with the assignment of the new goals, it has again started the fundamental changes in the pharmaceutical and therapeutic environment of the country.

Certificates & Standards

- ISO 9001:2015
- ISO14001:2015
- ISO45001:2018
- GMP certificate

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Takgene Group

Brief Overview

Takgene Group was established in 2004 as a science based company in order to produce different kind of probiotic products. This company is the sole company in the country that is dedicated to produce various types of functional microorganisms for food industry.
Takgene Company has managed to get all the needed approvals and licenses from Ministry of industry, mine and trade and Ministry of health as well as food and drug administration and veterinary organization in Iran.

Products/Services

Takgene products could be divided into 5 major categories:

- Human probiotic supplements
- Livestock probiotic supplements
- Food probiotics
- Dairy starters and probiotics
- Cosmetic products

Industrial achievements and awards and Export

Takgene Research and Development Unit, benefiting from more than 10 years of purposeful research by top experts, has collected over 700 strains of lactic acid bacteria native to Iran. These strains were evaluated according to international standards and were marketed after carrying out meticulous laboratory and clinical studies with the cooperation of prestigious domestic and international universities and obtaining the necessary licenses.

Certificates & Standards

All the products are manufactured in clean rooms under international standards and guidelines such as ISO 9001 and GMP. With a production capacity of 6000 tons annually, Takgene can compete with best producers in Europe.

- ISO/TS 22002-1:2009
- ISO 22000:2005
- ISO 9001:2008

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Tissue Regeneration Corporation

Brief Overview

TRC (Tissue Regeneration Corporation) is a leading global bio implant processing and producing company providing surgeons with safe biologic implants using its latest technology and advanced processing science. Two decades' experience and commitment to delivering a higher standard, TRC bio implants are used in a wide variety of applications such as cardiovascular, sports medicine, general surgery, spine, orthopedics, maxillofacial, dental implant and trauma procedures.

Products/Services

TRC bio implants are in 4 categories: Cardiovascular, Orthopedic, dentistry, and Neurosurgery, which are being produced under global standards.

Industrial achievements and awards and Export

- The company's products have been distributed in nearly 20 countries for more than 1 million patients.
- Its products are processed in Kish island; a 10,000 square meter plant with 1,800 square meter clean rooms which are class 10 to 10,000.
- The company has an official distributor in Turkey with trade name of BIOGENIX BONE

Certificates & Standards

- TRC is accredited by ministry of health and also granted for Medical Device Quality Management System ISO13485:2016 & ISO1400:2015 and OHSAS18001:2015.
- FDA QSR 21 CFR 820 (cGMP)
- TRC adheres to strict policies and procedures that were devised in line with the guidelines and standards of the FDA and UK codes of practice for productions of human derived therapeutic materials.
- Their work is consistent with the fundamentals of both national and international quality standards and ethical principles, specifcally they obey all AATB and FDA rules in cellular and tissues based products.

Tissue Regeneration Corporation

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Pooyesh Darou Biopharmaceuticals Company

Brief Overview

Founded in 1997, Pooyesh Darou Pharmaceuticals today is one of the most well established biotechnology companies through the Middle East. With 6 recombinant biopharmaceutical products helping patients in the country, Pooyesh Darou Pharmaceuticals became regional leader in the effort to develop and apply the most advanced capabilities in biotechnology to address a range of unmet medical needs. The company sterile manufacturing facility includes an 11000 sq. ft. production site. Their aseptic fill and finish manufacturing facilities are capable of filing over 13 million low volumes parenteral sterile unit per year and utilizes five high-speed filling lines and two lyophilizers.

Products/Services

- **API Products:** GENERIC NAME, interferon alfa-2b, filgrastim, erythropoietin, peginterferon alfa-2a, pegfilgrastim, interferon alfa-2a
- **PIPELINE:** erythropoietin, Peg-erythropoietin, Human menopausal gonadotrophin Human Chorionic gonadotrophin, Somatropin, streptokinase, Follicle stimulating hormone, Interferon beta-1a, Peg-Interferon beta-1a

Industrial achievements and awards and Export

- Pooyesh Darou Pharmaceuticals has acquired technology exclusively from the ICGEB (United Nations' International Center for Genetic Engineering and Biotechnology, Trieste-ITALY) to manufacture recombinant-DNA-based therapeutic proteins, the endogenous hormones and leukotriene that control essential body functions. The company is the first in Iran to use these genetically modified bacteria and cells to produce basic endogenous proteins.
- The company collaborat with the best experts in the fields such as ICGEB in Trieste-ITALY, Primm labs (GLP certified laboratory) in Milan-ITALY and the National Institute for Biological Standards and Control (NIBSC) in London-UK.
- Pooyesh Darou Pharmaceuticals manufacturing spaces' elements such as building materials, space design, facilities and flows, have considered all the environmental regulations and meet all quality criteria for manufacturing biological products.
- Pooyesh Darou Pharmaceuticals' QC laboratories are equipped with all necessary reagents and equipment to perform complete QC tests for biological products. The latest versions of pharmacopeias such as USP and BP are being used for the QC analysis of their all row materials and products.

Certificates & Standards

- The Aseptic Manufacturing Facility of company maintains a static and operational Grade A (ISO Class 5) environment.
- Their production site meets and exceeds standards for ISO 9001:2008, ISO OHSAS, 18001:2007 and ISO 14001:2004.
- The company manufacturing facilities adhere to strict cGMP protocols and are compliant with national and international regulatory agencies.

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Danesh Banyan Bio-Fermentation Company

Brief Overview

Danesh Banyan Bio-Fermentation Company started its activity in 2013 in the Faculty of Pharmacy of Tehran University of Medical Sciences. Bio-fermentation Company has succeeded in designing a very efficient method in the production of probiotic products with the spray drying method, which has been registered with patent number 63124.

All biofermentation products, in addition to obtaining the necessary licenses from the Food and Drug Organization and the necessary standards for the production of drugs and natural supplements, also have a safety management system certificate, a quality management system certificate, and a HACCP system certificate from D.A.S. England.

Products/Services

The factory currently produces more than 25 pharmaceutics for different purpose which are divided into 4 main groups including:

- Drug: Broca®, Zimosil
- Probiotics:
  - Women: Lactovage cap, Lactovage tap, loctoFem
  - Kids: Kidy Guard, Kiddy Locket, Pedilact, BB Care, Baby East
  - Family: familact, dallyeast, colperIBS, lactoGum, familact 2plus, famiLact veg, geriLact 2plus, geriLact, lactoCare
- Vitamin-and-mineral: vitaLact, biobion, Doctor Gumfi
- Natural: Rojovit, Rougewit

Industrial achievements and awards and Export

- Annual production of 300 million types of supplements and drugs in solution form and 100 million in drop form.
- Annual production of 500 million types of supplements and drugs in powder form, 2 billion in capsule form, and 1 billion and 560 million of vitamins and mineral salts in tablet form.

Certificates & Standards

- Health and safety management Systems ISO 45001:2018
- Food safety management Systems 22000:2018
- Environmental management Systems ISO 14001:2015
- Quality management Systems ISO 9001:2015

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