

Investigating the Growth Trend of Biomedical Production in Iran and Futurology to Achieve the Horizon of 1404

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Abstract

Background Biomedical drugs have been considered by many countries due to their important effect and high value. In the upstream documents, achieving a share of 3% of the global market of these drugs is set for 1404. The purpose of this study is to calculate the growth rate of biomedical products, their import rate and suggest strategies to reach the specified horizon.

Materials and Methods This research consists of two parts, quantitative and qualitative, in which the exploratory approach and the theorizing and typology model have been used. In the "quantitative" section, according to the country's pharmaceutical statistics, the growth trend of production and import of biopharmaceuticals over the past decade was calculated. The next step was performed "qualitatively" using the data research method of the grounded theory. First, information about the country's biopharmaceutical market was collected through interviews with 25 experts in this field. Then the "key templates" became the appropriate model.

Results The results of the present study in the qualitative section were the extraction more than 326 open codes which is presented in the form of a paradigm model. In the quantitative sector, Iran's global share was estimated at 0.5% to 0.7%, which is growing with an average numerical growth of 5.6% and 30% in Rial. The average global market growth was estimated at 8.2% per year.

Conclusion Considering Iran's 0.5% share of the world market, with the continuation of the current trend, it is not possible to achieve the set horizon and to achieve this horizon, we need a leap in pharmaceutical biotechnology.

Keywords Biopharmaceuticals, Import, Horizon 1404, Coding, Grounded Theory



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Introduction

With the advancement of science in all fields, including medicine and pharmacy, new topics emerged in this field, one of the most important topics is pharmaceutical biotechnology, that means using medical and biological sciences and its effect on man-made technologies (1). With the advancement of medical science in the past centuries, many infectious and contagious diseases became preventable and curable, but still no acceptable cure was found for chronic non-contagious diseases such as cancer, MS, autoimmune diseases and many genetic diseases. With the genesis of biotechnology in the world, a great change was made in the prevention, diagnosis and treatment of many of these diseases. Also, with the increase in world population and the need of this population for various food and medicine resources, increase in life expectancy, increase in the elderly population in the world and also the increase in the rate of chronic diseases, the world population needs more effective drugs. To meet these needs, the resources that available, certainly not enough and we must find new resources to supply these needs. Biotechnology is also very helpful in this issue and can help human beings to meet these needs. For this reason, this science has received a lot of attention in recent years and is developing more and more (1, 2). The traditional use of microorganisms to produce substances such as vinegar, yogurt and cheese dates back to more than 8,000 years ago, but their use in a new way, in the form of biotechnology, in the world is about 30 years old. The first institutes in Iran that start research and activities in this field are Razi Vaccine and Serum Research Institute (was launched at 1303) and Pasteur Institute (was launched at 1299) and the first specialized center for modern biotechnology, about two decades ago launched in the Scientific and Industrial Research Organization of Iran (1).

Considering the importance of the growth in the pharmaceutical biotechnology industry for scientific and economic growth of the country, the comprehensive scientific plan of the country for the year 1404 in this field has been determined to reach a share of 3% of the global market. To achieve this goal, we need to calculate the distance to the specified horizon and provide practical solutions to achieve these goals. If the issue of growth and development in the field of biomedicine production not to be considered and remains unknown, in addition to creating problems in the field of prevention, diagnosis and treatment of diseases and depriving a large number of patients of new treatments, the country in the today word, that the arena of invasion of new

technologies is lagging behind, huge amounts of currency will be taken out of the country, and also the ground for the growth of specialists in this field will not be provided, and finally we will face the phenomenon of migration of experts. While with practical solutions to help the growth of this field, in addition to specialists, many people will also be indirectly employed, and the country is taking an important step in the direction to a non-oil economy and developing a knowledge-based economy (3). The production of biopharmaceuticals may initially cost more than other drugs, but not producing them will cost the country and the people much more in the long time.

According to a study conducted by Dr. Tabatabaeian et al, it can be said that there are different components of this network in Iran, but there are some deficiencies in them. In the case of manpower, for example, the number of specialists is sufficient for the needs of the country, but it is necessary to increase the skills of these people in various fields, including the commercialization of ideas. Investors are also reluctant to invest in ventures and find it difficult to invest in this area. If these problems are solved and investor attraction and commercialization capacity in the country increase, the ground for further growth in this area will be provided. There are also policy problems in this area, such as defects in property laws, as well as problems in cooperating with other countries due to international pressures and cumbersome laws in areas such as starting a business. The important point is that the existence of the necessary components alone is not enough and there should be a good relationship between them, but in our country, due to the newness of this industry, this effective relationship is not enough and most components operate independently (1). According to research by Dr. Saberi et al., Who check out a ten-year period from 2002 to 2012 in the U.S. biomedicine market, the top sales were for cancer treatment products, including monoclonal antibodies. The second place was occupied by drugs related to autoimmune diseases, which is headed by Anti tnf alpha. The third best-selling drugs in this field is diabetes drugs, which include insulin analogues, and it is the only drug category that has a stable double-digit development in the ten years check out in this study (4).

According to this information, for the faster growth and development of this industry, we can prioritize production to these products to achieve maximum profitability in the shortest time.

Another study aimed at reviewing and identifying development and investment strategies used by leading countries in the global biopharmaceutical market was conducted by Dr. Moorkens et al. In 2017. This descriptive study



checks the mentioned indicators in the top 25 biopharmaceutical companies in 2015. These strategies include: 1- Resource development 2- Efficient investment 3- Investment in the new generation of biopharmaceuticals 4- Development of biosimilars 5- Investment in developing countries in this field 6- Cooperation between companies and Factories. It is important to note that none of these companies relied on a single strategy and put the use of several strategies on the agenda. One of the most common strategies used by these companies is their collaboration (5).

Material and Methods

The method of this study consists of two parts: quantitative and qualitative. Quantitative theoretical study is prospective (6) and qualitative study is observational (non-interventional), descriptive (7) which identifies the challenges of biomedical production over the past decade and suggest practical solutions to reach the specified horizon. The data of this research were collected from two methods: field method (qualitative section interviews) and library (quantitative section statistics). Study of domestic biomedicine production statistics and their import status in Iran as well as the global market through data available in reputable national and international databases such as the country's pharmaceutical statistics (8), comprehensive scientific map of the country, 20-year vision document, document National healthcare development, reputable international sites such as Statista (9) took place. In the next step, which is related to the field of qualitative and futurology studies, to obtain more comprehensive information in this field with a group of experts in this field (25 technical assistants and CEOs of biomedical companies, academics as well as legislators in this area), a semi-structured interview was conducted to check the topics in a more specialized way. Library studies have also been helpful in this area as needed. After extracting the mentioned information, the data analysis was divided into two parts: quantitative and qualitative. In quantitative part, a statistical study was performed to calculate the growth trend of production and import status of biopharmaceuticals in Iran. Then, the possibility of achieving the horizon of 1404, which is to reach a 3% share in the global biopharmaceutical market, was checked according to the global market growth situation in this area. In the qualitative section, the challenges that exist in the field of production of these drugs in the country have been studied. This information was also collected through interviews with experts in this field. Finally, according to the interviews, solutions were proposed for the achieving to

Horizon 1404, considering the current situation in the country.

To analyze qualitative data (Horizon 1404 Futurology section), we first proceeded through the grounded theory paradigm and using MAXQDA2020 software (10). Then, for a more detailed study of this section and more accurate futurism, ten of the most frequently proposed solutions are entered into MICMAC software (specialized futurism software) and based on structural analysis with scenario writing method, which is the most common futurism method for highly variable systems the data were ranked (11).

We also used Excel software to determine the growth trend of production and import of biopharmaceuticals (quantitative part).

To ensure the validity and reliability of the research, the interview questions were approved by several experts. In evaluating qualitative studies, statistical experts referred to the criteria of reliability, transferability and authenticity (12). To achieve these, the following steps were taken:

Implementation of interviews and continuous analysis along with data collection during the interview, review of how the interviews were coded by other experts to ensure the correct coding and lack of taste of the researcher's understanding of the content of the interviews, as well as to achieve greater reliability, researcher results has shown and confirmed her analysis to the interviewees.

Results

According to the annual growth rate of numerical production of domestic biopharmaceuticals, which is calculated based on statistics published in the "Pharmaceutical Statistics of the country" and has been approved by experts in this field (graph3) can be obtained from 1389 to 1399 production of this Drugs have been developing with an average annual numerical growth of 5.6 percent, which in recent years this growth has been faster than in the past and in the second 5 years under study this rate has reached 6.2 percent.

Comparing the official statistics of the Food and Drug Administration in the Rial section of biopharmaceuticals and the global market statistics of these drugs, which was published on Statista (9), we found that Iran's current share of this market is between 0.5 to 0.7%.

Observing the growth trend of biologics in Rials during the past decade (graph 1), we found that from 1389 to 1392, there was a mild growth in terms of Rials. In 1393, we are observing a jump of almost 100%, and from 1394 to 1399, a mild increase in rial growth can be observed.

According to Figures 2 and 4, we found that in this area, both in Rials and in the numerical sector, domestic products have a larger share of imports. This ratio is on average 73% to 27% in the numerical production section, and 70% to 30% in the Rial sales section.

According to the statistical information obtained from the Statista site (9), which has provided the volume of the global market for biopharmaceuticals, the annual growth rate of the global market in this field has also been calculated and the following numbers have been obtained:

The average annual growth of the global biopharmaceutical market has been 8.2%, which has accelerated in recent years and has reached 10.2% in the second 5 years. Comparing the average annual growth rate of domestic biopharmaceuticals and the global market, we find that this rate is 68.3% of the global average for Iran.

According to the global market statistics and the average growth rate, the volume of this market in 2025 (equivalent to 1404) with a simple average method, is estimated at 3.71 billion US dollars (9). So, the dollar equivalent of a 3% share of the world market would be about 0.11 billion US dollars, which we should achieve in 1404. Of this amount, 1.8 percent is related to the domestic market and 1.2 percent is related to the export of these drugs.

Discussion

In this study, the growth trend of production and sales of domestic biopharmaceuticals and their import status, comparison of production and import, as well as the global biopharmaceutical market situation were studied and according to the current situation and the challenges ahead, strategies to achieve 3% share of the global market was suggested based on interviews with experts in this field. The results of this study showed that our current market share is between 0.5 to 0.7 percent, which is a long way from the horizon set for 1404 and we need to grow 4 to 6 times to achieve it.

Also, the average annual growth of biomedical production in the country is 68.3% compared with the growth of the global market. Therefore, by continuing the same process, reaching the specified horizon will be out of reach. The country's domestic planning and policies must be such that there is a leap in the production of this field to be able to give us 3% share of the global market. Factors such as the closure of the Iran drug list (IDL), international sanctions and limited target market, irrational drug pricing in the country that reduces the desire of investors to enter this field, currency supply problems and export and import problems The cumbersome

administrative bureaucracy in the country, Old and outdated drug laws are all challenges and obstacles that hinder the progress of the craftsmen in this field.

Removing these problems requires macro-national policies to solve these problems and solutions such as empowering insurances to pay a larger share of the price of medicine, which leads to reasonable pricing along with no double pressure on the patients, It also helps the opening of IDL because one of the reasons for the closure of IDL is the inability of insurances to pay for new drugs, which attracts more investors, developing accelerators that make ideas faster conversion to the new product. Also support the biomedical industry and facilitate in this field, increase the growth rate of this field and enable get to the 1404 horizon.

One of the government's most challenging actions in previous years was to ban the import of drugs that have a production line in the country under the pretext of supporting domestic production. This action has pros and cons, which was quite evident in the present study. However, based on studies and observations of decreasing imports in recent years, and at the same time not having enough leaps in growth and observing the same slow growth trend, we found that this policy has not only failed to increase the production of biopharmaceuticals in the country, but also caused problems for patients and their lack of access to their medications. This monopoly also reduces the quality of domestic products and destroys the competitiveness in the international market. As a result, Iranian products in the global market lose the ability to compete with foreign samples and are eliminated from the market. As a result, this policy has not been a good way to support domestic production. It seems that with the presence of foreign drugs along with domestic drugs in the market, we can keep the quality of domestic products high so that we have a Convenient location in the global market and give patients the right to choose any drug they want and to consume.

According to the graphs of the ratio of domestic production to import of biopharmaceuticals during the past decade (graph 2 and 4), we have seen that both in Rials and in the numerical part, the share of imports is decreasing.

Based on the findings of the qualitative section extracted from the interviews, one of the most important reasons is the country's policies on do not import of drugs that have similar to domestic (which was mentioned earlier) and also the closure of IDL and do not import of new drugs, so that the growth of imports of biopharmaceuticals in Rials has been negative for some years.

Also, banking sanctions and currency transfer problems, problems in purchasing up-to-date equipment and essentials, and the reduction of international relationship were other factors in reducing the import rate of these drugs in recent years. In the Rial section, currency policies and rate changes have a direct impact on the conditions and growth rate of this market.

- Observing the increase in the average annual growth rate of the global market during the second 5 years of the study, we find that the growth rate of this industry in the world is increasing in recent years, and if we do not remove the obstacles in the country, not only will we not achieve the set goals, but we will lag behind the world scientifically and economically, and the country's patients will be deprived of access to new and efficient drugs, or we will be forced to pay for these drugs at great cost.

- According to the findings of a quantitative part of the research, we find that The growth process of this drugs is slow in the last ten years, and although in the second 5 years of the study, we moved more quickly to the specified horizon, But we are still far from maximum growth and we are not ready to reach the set horizon.

Considering the current share of 0.5 to 0.7 percent of Iran in the world market and the average growth of 68.3 percent compared with the world market, with the continuation of the current trend and the current problems, Experts in this field do not consider it possible to reach the set horizon

The findings of this research in the quantitative section are completely new and no similar research was found for the domestic market. In the qualitative section, the challenges and problems of biomedical production include the lack of commercialization potential of specialists, cumbersome domestic laws (mentioned in the section on intervening conditions) and the importance of macro-national policies in this area, with research by Dr. Tabatabaeian and Collaborators (1) are consistent.

Also, another problem of this industry, which was extracted from the interviews, is that the

According to the information obtained from the quantitative section and finding the distance that exists with the targeting done in this area, according to the interviews, we will study the conditions of the domestic market and the challenges of this industry, and finally by presenting a paradigm model, we offer practical solutions to reach the horizon of 1404:

Causal conditions: events that precede the phenomenon in terms of time and affect it.

Challenges of the pharmaceutical biotechnology industry:

unwillingness of investors to invest in this field and also the lack of coordination between different parts of the legislation is consistent with the research of Dr. Kheir Andish et al (3).

Conclusions

According to the statistical information extracted from the official statistics of the Food and Drug Administration (8) and calculating the distance with the horizon set for 1404, as well as interviewing with experts in this field and reviewing the challenges of this industry, finally the following proposals are made to achieve a 3% share of the global market:

With the opening of IDL, the elimination of supportive currency and the allocation of income from it to insurance companies in order not to put double pressure on patients, turning the country's universities into 3rd and 4th generation to increase the commercialization capacity of domestic specialists and reduce cumbersome bureaucracies And inhibitor laws, we can hope to achieve the set goals in the near future.

Ethical Considerations

There was no ethical consideration to be consider in this research.

Conflict of Interest

The authors declared no conflict of interest.

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Authors' contributions

Conceptualization, methodology, resources, and investigations: all author; writing original draft: Seyyedeh Hannaneh Hosseinzadeh Moghaddas; writing review and editing: Seyyedeh Hannaneh Hosseinzadeh Moghaddas and Ali Razzazan; supervision: Hossein Rastegar and Majid Annabi.

In this section, management problems, sanctions and financial problems accounted for the highest percentages, respectively.

Underlying conditions: Factors that already exist and affect the solutions.

Strengths and successes:

According to experts in this field, the development of biotechnology knowledge in recent years, competitiveness in the global market and export of biopharmaceuticals, as well as the positive and growing situation of companies producing these drugs are the most

important strengths of the country's biotechnology industry.

Solutions: based on actions and reactions to control, manage and deal with the phenomenon. In this part, government support, reliance on the power of domestic experts, expansion of international relations and reform of macro-national policies were the most important strategies that experts pointed out.

Intervention conditions: Conditions that facilitate or limit solutions in a particular area.

Government facilitation and support, legislators' demands, including increasing product quality and producer responsibility, as well as honesty in work, are conditions that, in the opinion of the interviewees of this study, facilitate solutions. The governmental economy, sanctions, and

structural complexity of the Food and Drug Administration and the ruling bureaucracy also limit the solutions that suggested.

Outcome: The results of the solutions.

Finally, according to this study, the consequences of applying the proposed solutions include the country's progress in the field of pharmaceutical biotechnology, maximum export, preventing patient confusion and migration of specialists and creating maximum access for patients in the country.

Figure 1 is a paradigm model of the above results.

According to the results of the interviews, the most important factors that influencing the growth rate of biopharmaceuticals are the following in order of importance:

Table 1. Most important factors

Effective factor	PERCENTAGE OF IMPORTANCE
Facilitation and government support	46/6
Sanctions	33
Rely on internal power	6/9
Macro-national policy	6/2
Corporate liquidity crisis	4/2
Non-competitive domestic market	3/1

Respectively, the most important sub-categories related to each section include the following:

- Facilitation and government support

Table 2. Facilitation and government support

Effective subcategory	Impact percentage of 100	Impact percentage of the main category
Reasonable pricing	54/2	25/3
Elimination of supportive currency	33/3	15/5
Help to open the IDL	12/5	5/8

- Sanctions

Table 3. Sanctions

Effective subcategory	Impact percentage of 100	Impact percentage of the main category
Currency supply problems	51	16/8
Problems of export and import of medicine	41/5	13/7
Problem of financial transfer and equipment	5/6	1/9
Lagging behind the global growth rate	1/9	0/6

- Rely on internal power

Table 4. Rely on internal power

Effective subcategory	Impact percentage of 100	Impact percentage of the main category
Launch the accelerators	43	2/9
Leave the way for trial and error	28/5	2
Setting up science and technology parks and growth parks	28/5	2

- Macro-national policy

Table 5. Macro-national policy

Effective subcategory	Impact percentage of 100	Impact percentage of the main category
Industry development	80	5
Independent and strong monitoring system	20	1/2

Findings from Mic Mac software futurology:

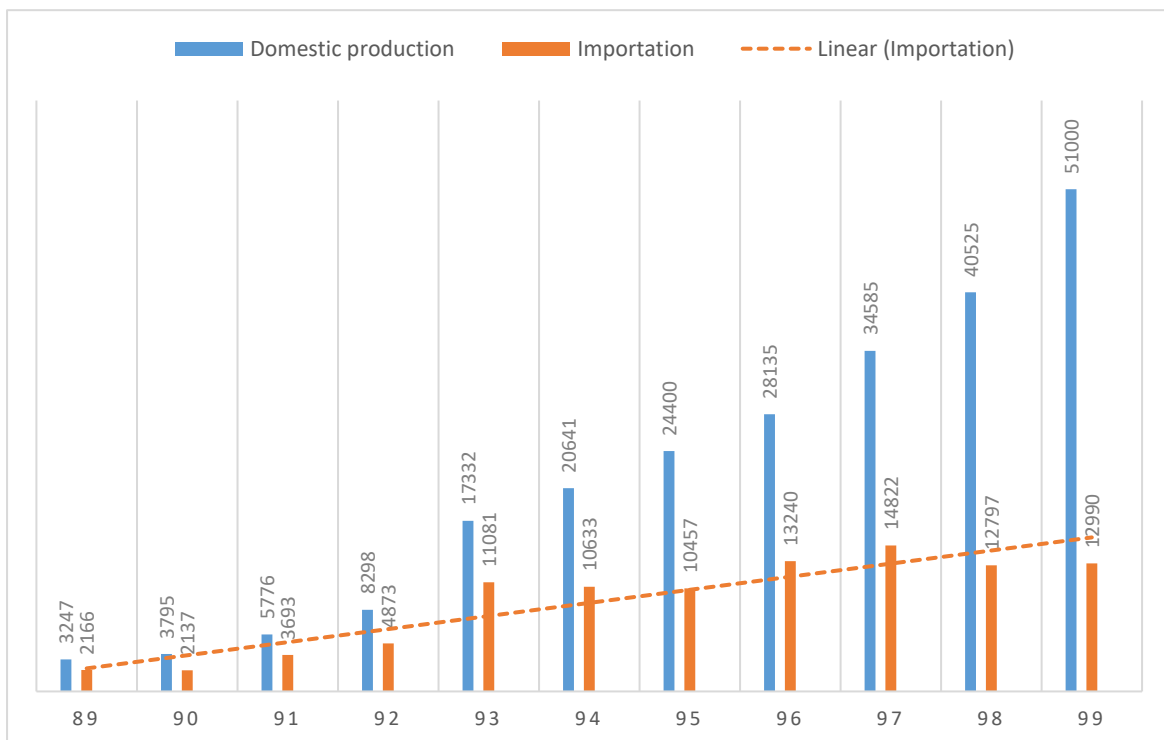
According to the structural analysis of Mic Mac software, the most important factors are:

Table 6. Mic Mac analysis

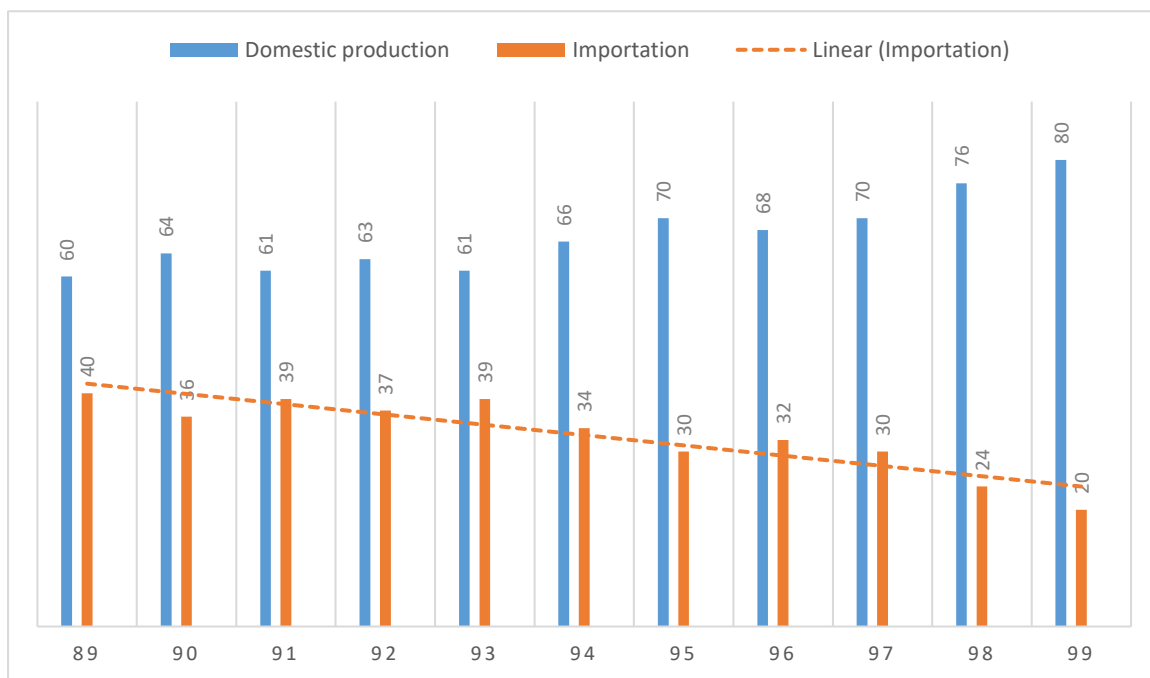
Effective factor	Impact percentage
Facilitation and government support	29
Sanctions	20/5
Rely on internal power	10
Macro-national policy	9/6
Reasonable pricing of medicine	9/3
Supportive currency problems	8/5
Problems of export and import of medicine	4/2
Help open the IDL	3/9
Corporate liquidity crisis	3
Non-competitive domestic market	2

Figures

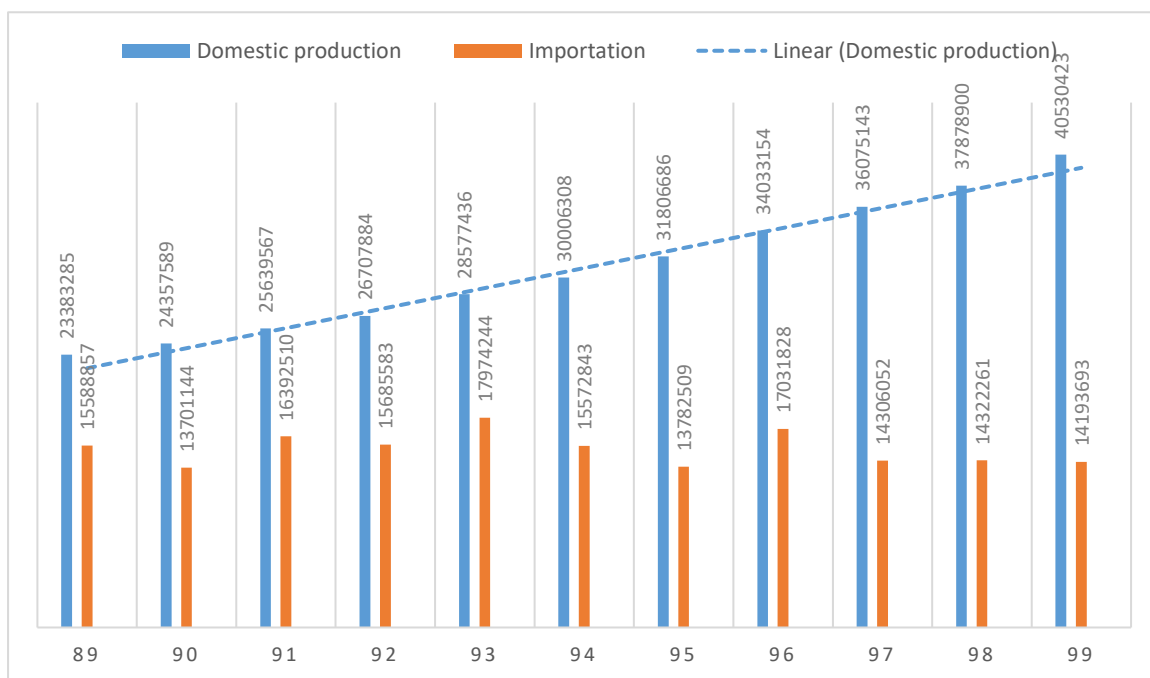
Graph 1. Comparison the amount of Rials of domestic production and import of biopharmaceuticals from 1389 to 1399 (billion Rials)



Graph 2. Rial ratio of production and import of biopharmaceuticals from 1389 to 1399



Graph 3. Comparison the numerical trend of domestic production and import of biopharmaceuticals in the country from 1389 to 1399



Graph 4. Numerical ratio of production and import of Biopharmaceuticals from 1389 to 1399

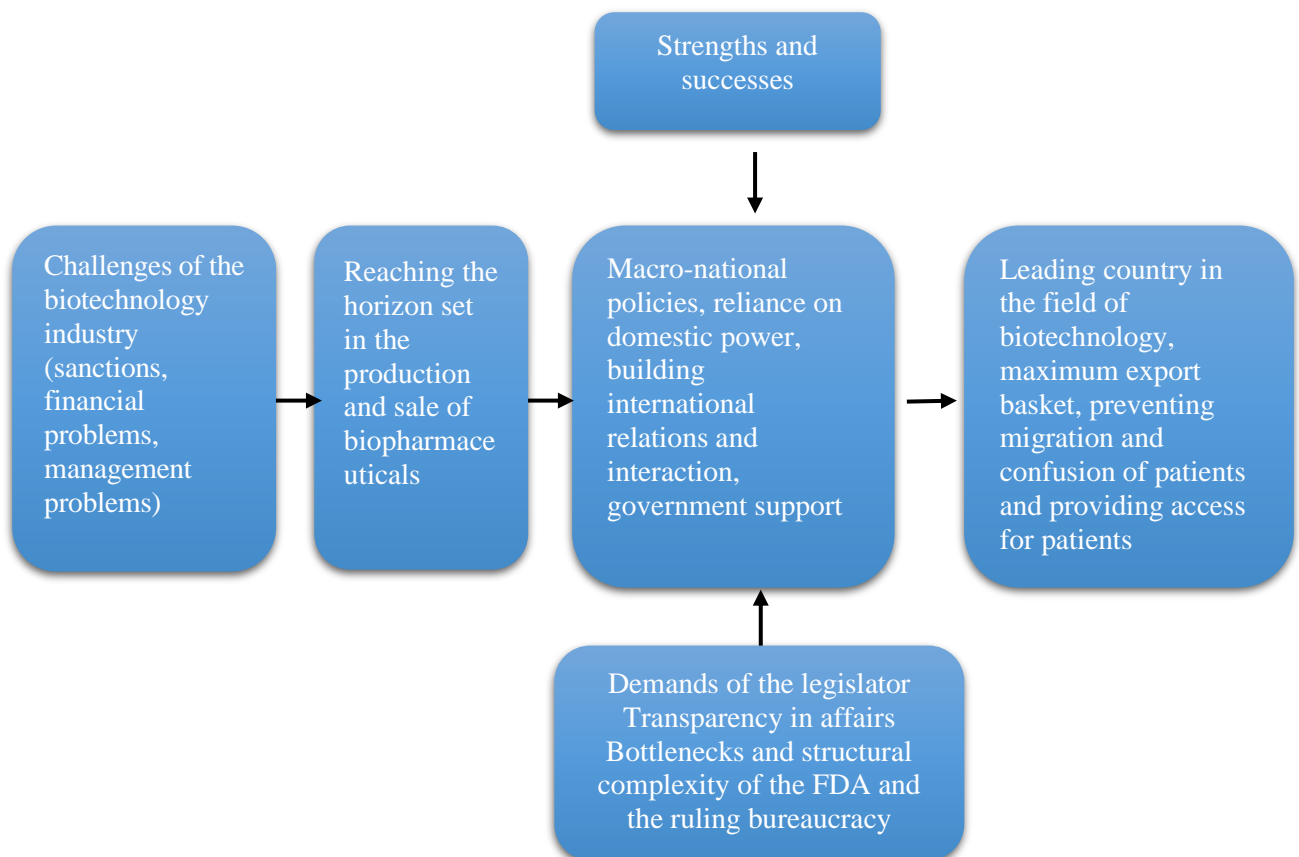
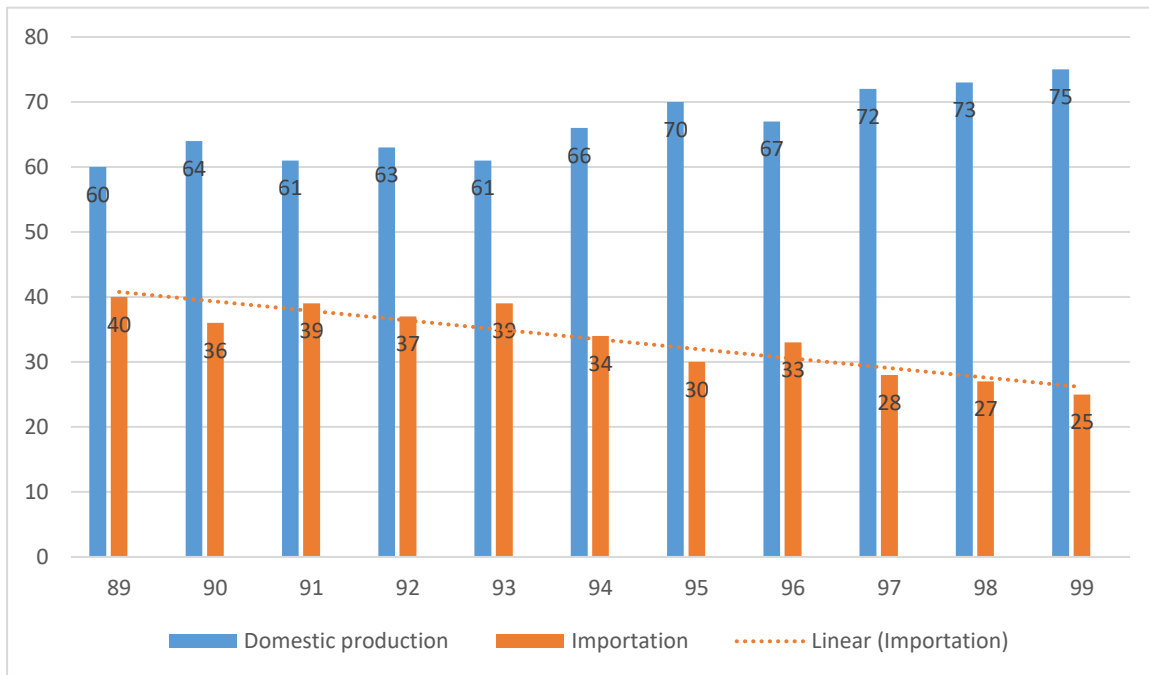


Figure 1. Research paradigm model

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