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A Study of the Economic Obstacles to the Development of the Pharmaceutical Industry in Iran

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Abstract

Purpose: The production and discovery of medication for every patient and the acceptable quality of drugs are among the principles tightly related to societal health. Hence, the pharmaceutical industry is a major strategic industry in every country, and removing the obstacles to its development must be a priority.

Design/methodology/approach: The present research addresses the economic obstacles to the growth of the pharmaceutical industry in Iran. The descriptive survey was used as the research method. Moreover, the statistical population included all the chief managers in the Iranian pharmaceutical industry. The sample size was determined to be 58 using the purposive sampling technique, and simple random sampling was selected as the sampling method. The research data were collected via the library and field methods, with questionnaires being used as the collection tool. The reliability of the questionnaires was determined to be 0.903 using Cronbach's alpha method, and their validity was determined using the Lawshe content validity ratio, based on which the content validity was confirmed by experts. In addition, the research data were analyzed using SPSS software and statistical, descriptive, and inferential tests.

Findings: The results provided a comprehensive description of the economic obstacles to the Iranian pharmaceutical industry in the form of three major groups: pre-production, production, and post-production obstacles. Furthermore, the role and significance of these obstacles were verified by field experts so as to facilitate resolving them via nationwide plans.

Keywords: Pharmaceutical Industry, Development, Economic Obstacles, Economic Sanctions, Currency Exchange rate.

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1. Introduction

Food and medicine are among the most fundamental needs of human beings. Nevertheless, there is a major difference between the two. While being necessary for survival, food is not unique and can be found in different forms everywhere and can be obtained naturally or through industrial processes. In other words, food is a basic good with numerous alternatives. A type of food in shortage can be replaced by another type. Moreover, low-quality food is not harmful to health in the short term, and its adverse effects can be compensated for later. On the other hand, medication lacks such characteristics. In other words, it is both irreplaceable and scarce, and if a needed medication is not administered with sufficient quantity and quality, recovery will be delayed, and the patient may even die. As a result, the pharmaceutical industry is of critical importance. This industry can be of great benefit to the society when obstacles to its development are removed.

The present research aims to identify the economic obstacles to the growth of the pharmaceutical industry in Iran and provide a perspective to decision-makers in this field so as to facilitate overcoming these obstacles. The innovation of this work is its attempt to gather and analyze these obstacles in one study.

2. Literature

2.1. Local research literature

Basmanji et al. (2015) addressed the obstacles to the pharmaceutical industry after the Islamic revolution of Iran and attributed these obstacles to the general management, political, and economic system (1).

Seyedi et al. (2020) stated that the growth of the pharmaceutical industry is hindered by a group of environmental conditions. These obstacles include government interference in pricing, numerous circulars, and foreign sanctions (2).

Mohammadian et al. (2020) considered pharmaceutical branding an important method for helping to maintain a trademark against generic products after obtaining a patent. According to the authors, a strong trademark can benefit from considerable consumer loyalty and enjoy high sales even after patent expiry (3).

Beigbour (2021) believed that the Iranian pharmaceutical industry can enter international competition given its status in the provision of medication; the advent of recombination, biotechnology, and nanotechnology; and the local production of 97% of the required medicine. However, this depends on the ability of the authorities to help growth in this industry by adopting correct measures and eliminating cumbersome local regulations (4).

2.2. International research literature

In research about the significance of competition, the secretariat of the United Nations Conference on Trade and Development (2015) mentioned that competition in the pharmaceutical industry can encourage brands to produce new and improved medication and encourage generic companies to provide less expensive alternatives (5).

In a study related to India, Festa et al. (2021) expressed that the Indian pharmaceutical industry has encountered issues such as a drop in exports and a rise in prices. Moreover, maintaining competitiveness and market share in this sector depends on the companies' ability to obtain patents, which requires considerable expenditure in research and development (R&D) and knowledge creation. The most important point is recognizing intellectual property rights as the natural factor that promotes pharmaceutical R&D (6).

According to Teramae et al. (2020), R&D productivity is continuously decreasing, and the conventional pharmaceutical trade model is becoming obsolete. In order to sustain growth, pharmaceutical companies must increase their revenues through a continuous supply of new products and optimize their costs by increasing productivity (7).

Barbosa et al. (2016) believe that pharmaceutical companies have experienced turbulence and must create the capability of change in their organization in order to counter this situation and achieve better performance. In addition, the pharmaceutical industry must employ qualified experts due to the need for providing high-quality products that guarantee health and, hence, increase production costs (8).

According to Daemmrich (2009), regulations have a significant impact on the industry's outcomes, determining its success or failure. Daemmrich further suggests that several factors contribute to these challenges faced by both the industry and lawmakers. These include public scrutiny regarding the cost of medicine, health issues arising from product withdrawals due to adverse reactions, and criticism regarding the inadequate delivery of medication to patients in developing nations (9).

Talor (2016) mentioned in his research that the pharmaceutical industry has a number of unusual characteristics, both in its structure and in the nature of its commercial operations. These characteristics are less known outside the industry but affect the process of providing new medication to the patient. According to the author, the pharmaceutical industry is involved in issues most of which do not seem to have clear solutions (10).

Stevens et al. (2017) stated that innovative approaches based on participation, intellectual property, and pricing help stimulate innovation, promote healthcare services, and reduce worldwide healthcare inequalities. They believe that no single approach is sufficient and that the beneficiaries must play a more active role in promoting knowledge and technology transfer to ensure the production, licensing, and distribution of critical medication in low- and medium-income countries (11).

According to Barbieri et al. (2017), the increase in age and revenue in the so-called emerging countries influences both the global demand and the supply organization for medicine. Moreover, the reorganization of supply and demand for health-related products is necessary (12).
According to research by the World Health Organization (WHO) (2011), policymakers around the world continuously endeavor to strike a balance between health policy goals (such as access to economical and critical medication) and pharmaceutical industry policy goals (such as improving innovation and local R&D). According to this research, particular tensions emerge, notably in the areas of pricing and reimbursement (13).
Fardazar et al. (2019) divided the national pharmaceutical policies into four groups: research and development, imports and exports, drug supply, and drug provision and distribution. Then, they addressed the upcoming challenges and claimed that the Iranian pharmaceutical sector has management and administrative differences with that abroad, leading to considerable lags (14).
Biggar (2001) examined issues related to competition and regulations in the pharmaceutical industry. Regarding insurance companies, he maintains that health insurers seek to control medicine prices using various policies such as cooperative payment mechanisms, where multiple individuals or organizations contribute to the cost of a particular treatment, approved medication lists, and maximum reimbursement levels for different drugs (15).

3. Theoretical background

The medicinal system, i.e., the processes of producing, importing, distributing, prescribing, providing, and consuming medicine, is one of the most important health chains in a country. The pharmaceutical sector of Iran suffers not only from special problems but also from every single defect and issue in the overall management, political, and economical systems in the country (1).
After the Islamic Revolution, fundamental changes occurred in the direction of the Iranian pharmaceutical industry. The consequences of this re-direction include governmental centralization in policymaking and planning for the pharmaceutical industry. In the first few years after the revolution, medication was considered an essential good requiring full state control and support. Many pharmaceutical companies were taken over by the government, and medicine imports were conducted only by the public sector. During these years, the medicinal system of the country was established based on a generic model. In other words, each medicine was given a single designation, with no distinction between drugs produced by different companies. Furthermore, pricing was performed in a prescriptive manner, and a fixed profit margin was determined for all the links in the pharmaceutical chain, including the producer, the distributor, and the pharmacy. The combination of strong governmental support for the public pharmaceutical industry and the strict pricing mechanism resulted in unrealistic prices in the drug industry compared to other industries (2).
The present research seeks to identify the obstacles to the growth of the pharmaceutical industry in three groups.

3.1. Pre-production obstacles

3.1.1. Financing obstacles

Borrowing issues:
Securing liquidity from banks has always been a major concern of the pharmaceutical industry in Iran. Some sources claim that a major reason for drug scarcity is the lack of sufficient liquidity in companies for paying customs.
On the other hand, if a bank partners with the owners of a company by providing capital, it will share the profits and losses. Since banks refuse to take the risk of possible losses, they usually refrain from such investment partnerships (16).

Issues with selling shares in the stock market (primary market):
In general, the provision of liquidity for investment in Iran is mostly bank-oriented rather than capital-oriented. In other words, most people invest their savings in banks and are less likely to buy shares of manufacturing companies. Hence, investors do not significantly depend on selling shares in the stock market for growth and mostly attempt to borrow from banks, a situation that has its limitations.

Limits on foreign investment and partnership:
Two points must be taken into account in attracting foreign investment: (a) the interest rate in the host country must be higher than that in the investing country; (b) there must be economic, political, and military security in the host country, accompanied with observance of ownership rights (17).
The sanctions currently placed on Iran prevent foreign investment in the country, except for a few cases. This has adversely affected all industries, including the pharmaceutical industry.

The impossibility of monetary and financial exchange with foreign producers due to sanctions:
Concerns due to sanctions by the United States, exchange rate fluctuations, money transfer problems, and issues with opening letters of credit (LC) for importing medicinal ingredients are among the problems related to liquidity supply for procuring these ingredients. According to a report by the Iranian Foreign Ministry on the manner of execution of the JCPOA, dated July 16, 2016, i.e., six months after the implementation of the JCPOA, a major obstacle to the establishment of brokerage and financial

relationships between many banks and financial institutions around the world on the one hand and Iranian banks and institutions on the other hand is the concern for penalties related to these regulations by the US.

Currency shortage in the integrated currency exchange system (ICES):
Despite the actions taken to regulate trade-related currency exchange, challenges still remain. The exertion of export restrictions for recovering the foreign currency due to exports, the study of problems and obstacles to currency exchange in trade with regional countries, the insufficient supervision and deviation in currency supply by the Central Bank, economic sanctions, the dependence of the currency resources on petroleum revenues, the large number of responsible institutions influencing currency exchange related to foreign trade, the large number of circulations, and the unpredictability of trade are among these obstacles (18).

Changes in the preferential-to-ICES exchange rate:
The exchange rate of 42000 IRR per US dollar had such a devastating effect on the economy that the thirteenth Iranian administration decided to correct this rate once and for all. If the ICES cannot meet the demands of manufacturers and importers, referral to the free currency market will fundamentally endanger the production sector (19).

Impossibility of credit purchases from local and international companies:
Due to the sanctions in recent years, other countries cannot issue credit cards for natural and legal persons in Iran. Hence, credit purchase of pharmaceutical ingredients and equipment from outside the country is impossible. Inside Iran, credit purchasing has been made possible only for a few household necessities.

Delays in allocating foreign-currency-based funds to ingredient imports:
Currently, companies that need foreign currency for procuring ingredients become involved in the bureaucratic procedures of the Central Bank and the Food and Drug Administration and may be delayed up to several months. This delay is extended to the production chain. Nevertheless, if a single exchange rate is used for the pharmaceutical industries, pharmaceutical companies will no longer be delayed by the Central Bank, and capacities can be better exploited with an increase in agility.

4.1.2. Institutional and legal obstacles
Bureaucracy in obtaining business licenses: Business licenses are issued by the government to ensure the eligibility of the owners of commercial/economic businesses. A problem arises when the licensing activities are not in line with the regulation goals. This increases the time and cost of starting a business, making the licensing process a cumbersome task (20).

- **Limits on the drug list:**

The national drug list was being prepared from about three years ago up to early last year. It was revised this year by adding 21 drugs needed by patients with special or refractory diseases in the spring and 9 additional drugs in the fall of 2022. According to many drug experts and producers in the country, the long blocking of this list deprived many patients of new drugs and treatments. In addition, the refusal to allow new drugs to enter this list led to less competition and R&D and a smaller drug market.

Presence of a large number of state companies in the pharmaceutical industry:
About 66% of the pharmaceutical industry in Iran is held by three holdings: the Social Security Organization, the Execution of Imam Khomeini's Order, and the National Development Investment Group. Clearly, the full implementation of the Privatization Law in this industry can promote healthy competition in the private sector and contribute to the development of this industry (21).

- Weakness of ownership and drug patent laws: In general, intellectual property rights affect two main areas in the pharmaceutical industry: (1) observance of invention rights, elimination of competition, and the availability and prices of new drugs and (2) R&D incentives (i.e., the role of intellectual property rights on motivating the discovery and marketing of new medication).

4.1.3. Technical and structural obstacles in production Outdated status of part of the pharmaceutical industry:
The pharmaceutical industry has significant issues in terms of production. The measures necessary for the development of this industry in Iran to keep up with international progress, especially innovations such as biotechnology and nanotechnology, have not been taken. In addition, the final price resulting from worn-out production line equipment and low production capacity compared to the nominal capacity in some production units has contributed to the unfeasibility of production (22).

Shortage of R&D centers in this sector:
The level of R&D in every country can be identified from the share of the research budget in its gross domestic product (GDP). Based on statistics published in November 2020 on the Statista website, South Korea ranked first in the share of GDP allocated to R&D at 4.35%, followed by Finland, Japan, and Sweden at 3.5%, 3.5%, and 3.2%, respectively. In 2018, the research budget of Iran was 0.65% of the GDP. This percentage reached 0.58% in 2019 and 0.43% in 2020. This shows a descending trend in the allocation of budget to research activities (23).

Shortage of local ingredients:
From about 1450 active molecules in the drug list of Iran, 13.8% are produced inside the country. This has led to a 25%-30% saving in foreign currency exchange in this area. However, the majority of this reduction is due to the production or discovery by the police of the active ingredients of narcotics, such as opium. In addition, the main focus of the active ingredient industry is on systemic antibiotics, cardiovascular drugs, and digestive drugs. Other active ingredients are imported and hence affected by currency exchange problems and sanctions (24).

4.2. Production obstacles

4.2.1. Institutional and regulation issues

Instability of producer regulations:
Among the requirements of continued economic stability and safety is the stability of the law. This means that the regulatory provisions related to economic stability must be themselves stable. Frequent revisions in the rules, regulations, and circulations by the government reflect their hasty preparation in the first place. Therefore, a clear perspective of the economy is a key point in providing calm, stability, and security in this field in economic terms (25).

Shortage of local part manufacturers: This issue can be attributed to two reasons: (a) lack of local technology and skill for the production of parts required for the pharmaceutical industry and the necessity of supporting R&D centers and knowledge-based companies and (b) uneconomical nature of part manufacturing due to the limited number of drug production centers and the variety of production equipment, which results in very high production costs and reduced demands for the locally produced equipment.

Issues in subsidizing the pharmaceutical industry:
In 2018, the government decided to allocate government-sponsored foreign currency to basic goods, including medicine, in order to prevent an increase in the price of drugs. However, players across the pharmaceutical industry, especially small firms, strongly opposed this method by stating that government-sponsored foreign currency leads to corruption (35). In the "Darooyari" (medicinal support) plan, drug subsidies are provided to insurance companies, following corrections in the foreign currency policies related to locally produced drugs. As such, the margin due to the increase in prices is paid by the Planning and Budget Organization to insurance companies and then to pharmacies, and changes in drug prices will not affect patients (26).

Inappropriate pricing system for medicinal products;
The Food and Drug Administration manages the pricing system identically for all producers and all medicinal products. According to the pricing rules, the price of generic drugs is determined based on drug analyses and cost documents. If a company uses the generic brand name for a drug, it will be 15%-30% different from generic drugs. Also, if the locally produced drug is similar to the drug bearing the brand name, the prices of the two drugs will be up to 70% different (27).

4.2.2. Structural issues in production

Delayed supply of local and imported ingredients:
According to players in the pharmaceutical field, local suppliers largely meet the needs of producers for ingredients. However, local suppliers cannot fully meet the requirements due to their limited resources. They even have delays in delivering materials, which adversely influences the production of pharmaceutical companies (28).
In addition, due to economic, financial, and banking sanctions, some exporters of high-quality ingredients are unwilling to sell these materials to Iran, and procuring these materials from unofficial channels around the world bears risks such as high costs.

The limited supply of imported spare parts due to sanctions:
Sanctions play a significant role in the reduction of the import of spare parts used in the pharmaceutical industry. As a result, these parts must be imported from unofficial channels. The cost of procuring parts in this way is considerably higher than imports through official channels. Nevertheless, the Iranian parliament approved a law in 2022 allowing the import of pharmaceutical and medical parts and equipment free of customs duties and import tariffs, which was a positive step (29).

Redundancy of production capacity in the pharmaceutical industry:
Since the GDP is the base of every economy, an increase in GDP improves a country's capability to produce pharmaceutical products and increases trade between two countries (30).
In the early 1990s, the Iranian parliament allowed pharmaceutical factories to dedicate their excess capacity to produce and supply drugs at the exchange rate determined by the Ministry of Health and Medical Education. These drugs were priced as suggested by the producers and confirmed by the Ministry of Health and Medical Education (31).

4.3. Post-production obstacles

4.3.1. Institutional and regulation issues

Lack of an efficient supervision system for drug distribution:
A study of the medication distribution network revealed the following issues: inappropriate distribution of drug amounts, inappropriate distribution timing, ignorance of new management methods in drug distribution networks, and the absence of comprehensive studies on distribution network planning in drug distribution companies (32).

Ineffective measures against local and imported drug trafficking:
Based on statistics reported by the Minister of Health and Medical Education, there were 3.6 billion Euros worth of medicine and medical equipment imports. This number reached 3 billion Euros this year, indicating savings worth 600 million Euros. However, part of the local drug products are trafficked out of the country, and the corresponding exchanged currency does not enter the economic cycle (33). The use of the preferential exchange rate during drug production and the use of the ICES foreign currency has led to a difference between the allocated and the free-market exchange rates, has made the pricing of pharmaceutical products more realistic, and has significantly reduced the motivation for trafficking locally produced drugs outside the country or into the local black market.

Issues with improving the quality of exported products:
The quality of pharmaceutical products in a country is the main factor driving the competitiveness of these products with those of other countries. Studies show that the obstacles to improvements in the quality of exported drug products can be attributed to the quality of the active ingredients and the additives, the drug type and packaging, possession of advanced technology, and possession of the GMP certificate, among other factors (22).

Issues with obtaining the GMP certificate:
Good Manufacturing Practices (GMP) is a system ensuring that products are continually produced and controlled based on quality standards. Currently, all industries with different levels of involvement in the pharmaceutical area are GMP-certified and observe the minimum requirements. However, upgrading and updating equipment is difficult since relationships with foreign countries are restricted by sanctions (34).

1.3.2. Post-production structural issues

Sanctions on shipping and e-sale companies and trade restrictions:
The US Federal Reserve passed sanctions against the Islamic Republic of Iran Shipping Line Group and 18 subsidiaries on September 10, 2008, based on Executive Order 13382 under charges of carrying nuclear and missile-related materials for the Iranian Ministry of Defense and Armed Forces Logistics. Based on these sanctions, the bank accounts and assets of all these companies were frozen, and all American institutions were forbidden from trade relationships with them. Even companies insuring shipping cargo belonging to the Islamic Republic of Iran or supplying gasoline to Iran were included in the sanctions list (35).

Weaknesses in branding and competing with foreign products:
Based on a study, the senior and executive managers of some companies, who are the main decision-makers in these companies, are not fully aware of the process and prerequisites of using trademarks for their products despite knowing its advantages. This is because it has not had any effect on the macro-strategies, organizational structure, and, most importantly, the workforce within their companies (36).

Delays in collecting debts from distribution companies:
Delayed payment of debts by public centers to distribution companies under contract with producers leads to delays in debt collection by the producers. As a result, producers face shortages of liquidity, which adversely affects the procurement of ingredients and equipment for production (39). Moreover, delayed debt collection wastes opportunities for investment and revenues, timely payment of debts to use discounts, and purchasing of goods and ingredients. In addition, the integration and smooth cash flow of the supply chain face challenges, leading to deteriorated performance (37).

Unfair competition between public and private companies in drug marketing:
Important points in the codes of ethics of well-known pharmaceutical companies are fair competition with other companies, prohibition of gifts except in special cases, observance of commercial standards, prohibition of an agreement on discount ceilings and customer selection, and agreements on price increase with competitors. These points are related to competition rules and stating them can prevent violations of competition regulations in the pharmaceutical industry and minimize interventions by supervisory bodies on competition in this industry (38).

5. Methodology
The present research is applied in terms of objective and constitutes a descriptive survey in terms of data collection. Based on the research variables, the population consists of senior managers in the pharmaceutical industry. The research variables are either independent or dependent. An independent variable is one that affects the dependent variable

positively or negatively. The economic obstacles were considered to be the independent variable in this research. A dependent variable is a variable that the research seeks to explain or predict the variation of. The dependent variable in this research was the development of the pharmaceutical industry in Iran.
The main tool used in this study is a questionnaire containing 35 questions. It is worth mentioning that the questionnaire must be answered by people fully familiar with the fundamental issues in the industry. For this reason, this questionnaire was presented to 58 experts and senior managers in the pharmaceutical industry. The criteria were rated using the Likert scale: from "strongly agree" to "strongly disagree". Moreover, the content validity was confirmed by experts.

Factors evaluated in the questionnaire

Main construct	Component	No. of questions
Pre-production obstacles	Financing obstacles	16
	Institutional and legal obstacles	
	Technical and structural obstacles in production	
Production obstacles	Institutional and legal obstacles	9
	Structural obstacles in production	
Post-production obstacles	Institutional and legal obstacles	10

In addition, the reliability of the questionnaire was measured using the internal consistency method. The most important indicator of internal consistency is Cronbach's alpha method. Cronbach's alpha is a criterion used to evaluate the reliability or internal consistency of a set of scales or test items. In other words, the reliability of a questionnaire refers to the degree to which the questionnaire consistently measures the intended constructs or variables, and Cronbach's alpha is a measure of the strength of that consistency (39). Those who use the SPSS software for data analysis can measure the reliability of their measurement tool using Cronbach's alpha method, which can also be calculated manually using a formula. However, as a rule of thumb, the value of Cronbach's alpha must be at least 0.7. In this research, the reliability of the questionnaire was calculated and confirmed using Cronbach's alpha method.

Reliability of the questionnaire

Main construct	Component	Cronbach's alpha	Overall Cronbach's alpha
Pre-production obstacles	Financing obstacles	0.798	0.903
	Institutional and legal obstacles		
	Technical and structural obstacles in production		
Production obstacles	Institutional and legal obstacles	0.685	
	Structural obstacles in production		
Post-production obstacles	Institutional and legal obstacles	0.791	
	Structural obstacles in post-production		

6. Data analysis

In order to improve the accuracy and reduce the error in manual calculations, the SPSS software, which is a powerful tool in data analysis, was used for this purpose.

6.1. Descriptive analysis of the demographic features

In terms of descriptive statistics, the data relating to the distribution of the responders to the demographic features and other features considered in the questionnaire are mentioned. With respect to inferential statistics, the method used for testing the hypotheses is the one-sample t-test. Hence, the Kolmogorov-Smirnov test was used to establish the hypotheses and determine the normality. Moreover, the Friedman test was employed to rank the dimensions and components of the economic obstacles to the development of the Iranian pharmaceutical industry.

Description of the demographic variables

No.	Variable	Levels	Frequency	%
1	Gender	Female	11	19
		Male	47	81
2	Marriage status	Married	53	91
		Single	5	9
3	Academic qualifications	Bachelor's degree	2	3.5
		Master's degree	7	12
		Professional doctorate	21	36
		PhD	28	48.5
4	Age	20 to 29	0	0
		30 to 39	13	22
		40 to 49	16	28
		50 to 59	21	36
		60 and higher	8	14

No.	Variable	Levels	Frequency	%
5	Work experience	1 to 5 years	1	1
		6 to 10 years	5	9
		11 to 15 years	9	16
		16 to 20 years	10	17
		More than 20 years	33	57

6.2. Descriptive analysis of the variables

Descriptions of the variables are important because the hypothesis testing results are obtained based on the data and indicators from these variables. The research data possess interval scales. The central tendency and dispersion indicators were used to describe the variables, as shown in the following.

Descriptive indicators for all the variables

Research variable	Quantity	Mean	Median	Standard deviation	Normality indicators		Minimum	Maximum
					Skewness	Kurtosis		
Pre-production obstacles	58	4.064	4.063	0.374	-0.446	1.108	2.81	4.94
Production obstacles	58	3.994	4.056	0.544	-1.112	1.952	2.22	4.89
Post-production obstacles	58	3.890	3.800	0.456	-0.158	-0.055	2.60	4.80
Financing obstacles	58	4.175	4.250	0.368	-0.554	0.010	3.13	4.88
Institutional and legal obstacles	58	4.007	4.000	0.619	-0.416	-0.102	2.20	5.00
Technical and structural obstacles in production	58	3.862	4.000	0.765	-0.390	-0.276	1.67	5.00
Institutional and legal obstacles	58	4.048	4.200	0.581	-1.108	1.683	2.20	5.00
Structural obstacles in production	58	3.927	4.000	0.682	-1.131	2.475	1.50	5.00
Institutional and legal obstacles	58	3.905	3.875	0.601	-0.585	0.792	2.00	5.00
Structural obstacles in post-production	58	3.879	3.833	0.489	0.149	-0.443	2.83	5.00

The following results are obtained from the above table, which includes various central tendency and dispersion indicators.

A. All the variables had a mean above the median (i.e., 3), indicating the good status of these variables.

B. The skewness and kurtosis of the normal distribution are equal to zero, which indicates the normality of the data distribution. Moreover, if the skewness and kurtosis of a variable are smaller than -2 or larger than 2, the corresponding distribution is not considered to be normally distributed. The results show that all the variables can be considered normal.

C. The data distribution can be guessed from the mean, median, and a comparison between the two. If the mean is considerably larger than the median, the data are right-skewed, and vice versa. Based on the values presented in the table, the mean and median are close to each other. Therefore, the data distribution can be considered symmetric and normal.

6.3. Hypothesis testing

6.3.1. Kolmogorov-Smirnov test

Before the hypothesis testing, the normality of the data distribution must be analyzed using the Kolmogorov-Smirnov test in order to select the statistic type for the hypothesis test. The statistical hypotheses related to the normal distribution are as follows:

H_0: The data have a normal distribution.

H_1: The data do not have a normal distribution.

If the data have a normal distribution, parametric tests such as one-population, two-population, or multiple-population mean tests and linear regression can be used. In contrast, if the data are not distributed normally, non-parametric tests can be utilized. Non-parametric tests are usually used in the case of data with abundance. According to the performed evaluation, since the significance level of the economic obstacles to the development of the Iranian pharmaceutical industry is larger than 0.05 and the Kolmogorov-Smirnov statistic is between +1.96 and -1.96, the null hypothesis is confirmed, and the normality of the data distribution is accepted.

Main hypothesis test:

Economic obstacles to the growth in the pharmaceutical industry

Main hypothesis test results

One-sample t-test (test value = 3)						
Variable	T-test statistic	Degree of freedom	Significance level (two-tailed)	Confidence interval 95% of the mean difference		Result
				Lower bound	Upper pound	
Pre-production obstacles	21.648	57	0.000	0.9652	1.1620	Approved
Production obstacles	13.906	57	0.000	0.8511	1.1374	Approved
Post-production obstacles	14.857	57	0.000	0.7697	1.0096	Approved

Since the significance level of the obstacles to the growth of the pharmaceutical industry is smaller than 0.05 for the three dimensions, one may conclude that the mean of these three dimensions is significantly different from 3. In addition, because the upper and lower bounds for the "pre-production obstacles", "production obstacles", and "post-production obstacles" are positive, the mean of this variable is larger than 3. As a result, given the upper and lower bounds of the last row of this output, one can say that these three dimensions are among the most important factors preventing the growth of the pharmaceutical industry in the country.

Hypothesis testing of the economic obstacles to the growth in the pharmaceutical industry based on the indicators

Main hypothesis test results for individual indicators

One-sample t-test (test value = 3)							
Component	Indicator	T-test statistic	Degree of freedom	Significance level (two-tailed)	Confidence interval 95% of the mean difference		Result
					Lower bound	Upper pound	
Pre-production obstacles	Financing obstacles	24.311	57	0.000	1.0778	1.2713	Approved
	Institutional and legal obstacles	12.389	57	0.000	0.8441	1.1696	Approved
	Technical and structural obstacles in production	8.584	57	0.000	0.6610	1.0632	Approved
Production obstacles	Institutional and legal obstacles	13.747	57	0.000	0.8956	1.2010	Approved
	Structural obstacles in production	10.351	57	0.000	0.7474	1.1060	Approved
Post-production obstacles	Institutional and legal obstacles	11.466	57	0.000	0.7471	1.0633	Approved
	Structural obstacles in post-production	13.682	57	0.000	0.7506	1.0080	Approved

Since the upper and lower bounds are positive for all the indicators of these three dimensions, the mean of this variable is larger than 3. Hence, given the upper and lower bounds of the last row of this output, one may conclude that these seven dimensions (financing obstacles before production, institutional and regulation obstacles before production, technical and structural obstacles before production, institutional and regulation obstacles during production, structural obstacles during production, institutional and regulation obstacles after production, and structural obstacles after production) are among the most fundamental factors preventing the growth of the pharmaceutical industry in the country.

6.3.2. Friedman test

The Friedman test is used to rank variables based on the highest effect on the dependent variable. This test, which is named after its inventor and the famous economist Milton Friedman, compares several groups in terms of the means of their ranks. This test was used in the present research to prioritize the dimensions, components, and economic obstacles to the development of the Iranian pharmaceutical industry.

H_0: The means of the ranks are identical.

H_1: At least two ranks have different means.

The Friedman test has two outputs. The first output (Table 4-16) consists of the number of data in each dimension, the value of the chi-square statistic, the

degree of freedom, and the significance level. Since the significance level is smaller than 0.05, the null hypothesis is incorrect, and the claim that the ranks of the dimensions are equal is refuted.

Results of the Friedman test based on the obstacles to the growth in the pharmaceutical industry

Variable	Mean rank	Rank
Pre-production obstacles	2.11	2
Production obstacles	2.22	1
Post-production obstacles	1.67	3

Hence, given the means presented in the table, at a confidence level of 95%, the "production obstacles" are the most important obstacle, and the "post-production obstacles" are the least important obstacle to the development of the pharmaceutical industry in the country.

7. Conclusion

The present research attempted to identify and describe the economic obstacles to the growth of the pharmaceutical industry in Iran in the form of a concept map and have them confirmed by experts in this industry. These obstacles were divided into three groups: (1) pre-production obstacles, (2) production obstacles, and (3) post-production obstacles. This classification is itself an innovation of this research, which endeavored to open a new perspective to the managers in this industry so that they can resolve these obstacles by categorizing them and ranking their adverse effects on the development of the industry.

Finally, the statistical analysis results found the following to be the main obstacles to the growth of the pharmaceutical industry in Iran:

- Issues with borrowing from banks
- Shortage of liquidity and failure of the government to pay its debts to distribution companies
- Limitations on foreign investment and partnership with foreign companies
- Impossibility of currency and financial exchanges with foreign suppliers due to sanctions
- Shortage of foreign currency flow due to the violation by some exporters of their foreign currency commitments
- Problems in the allocation of budget to the pharmaceutical industry
- Changes in the preferential-to-ICES exchange rate
- Impossibility of credit purchases from foreign and local companies
- Bureaucracy and the loss of competitive production opportunities
- Issues with adding new drugs to the national drug list
- The presence of numerous public and state companies in the pharmaceutical industry
- Weakness in the laws supporting pharmaceutical ownership and patent rights
- The presence of numerous local producers and the small market share of each producer
- The use of worn-out equipment in the pharmaceutical industry
- Shortage of R&D centers in this field
- Shortage and low quality of locally produced ingredients
- Instability of regulations relevant to producers
- Lack of support for local manufacturers of parts and equipment for the pharmaceutical industry
- Insufficient subsidies allocated to the pharmaceutical industry
- Improper pricing system
- High final cost and low marginal profit (due to the allocation of non-preferential foreign currency)
- Delayed supply of local and imported ingredients
- Limitations on imported spare parts due to sanctions
- Shortage of fuel and energy and outages in utilities
- Redundancy of the production capacity
- Lack of an efficient drug distribution monitoring system
- Inefficient actions against local and imported drug trafficking networks
- Issues with improving exported drug quality
- Issues with obtaining GMP certification
- Problems in the local transportation system
- Increase in the cost of international transportation
- Sanctions on shipping (e-sale) and trade restrictions
- Weaknesses in branding and competing with foreign companies
- Delayed debt collection from distribution companies
- Unfair competition of public and semi-public companies with private companies in drug marketing

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