



Identifying the Challenges and Discussing about Current Situation of the Iranian Pharmaceutical Industry Based on a Systematic Analysis of Experts' Opinion

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Abstract

Domestic pharmaceutical industry, as one of the strategic high-technology industries, has a significant impact on individuals' health. Despite its success in providing maximum medicine domestically, the industry, with its more than 110 active manufacturing companies in the form of semi-governmental holdings, private companies, and agile knowledge-based companies, faces challenges at the policy and operational levels. The challenges, situations, and some strengths of the industry would be identified in the present study using the scientific research method. To identify and review the challenges and status and also to explain the improvement strategies, in-depth interviews with 8 experts in the pharmaceutical industry in senior management positions in the manufacturing industry, regulators, and related syndicates planned and qualitative content analysis method using MAXQDA 2020 software platform applied to identify the challenges, situations, and strengths of the industry. According to the qualitative content analysis, challenges related to inappropriate policy-making, limited financial resources, and inappropriate pricing policies in the industry have been identified as the most important obstacles versus industry development, and on the other hand, the maximum supply of medicine in the country, appropriate knowledge

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base and desirable quality of some products are listed as strengths of the industry. Efforts to reform macro policies and industry strategies at the policy and regulatory levels, including private sector development, commitment to quality improvement, and the development of new pricing methods, are among the most important future solutions to cope with the challenges of the industry.

Keywords *Pharmaceutical Industry, Challenges and Strengths, Qualitative Content Analysis*

Introduction

The pharmaceutical industry is an integral part of every domestic healthcare system, with a high value and significance as a critical need and strategic asset. The role of medicine to prevent and treat diseases is best revealed by various economic, cultural, and social influences (Barouni et al, 2020). Pharmaceuticals are one of the most advanced, imaginative, and profitable high-tech industries (Rasekh et al, 2012). Pharmaceuticals are now one of the world's most important and largest sectors. One of the most important conditions for domestic growth is the existence of such an industry. The pharmaceutical industry is one of the most important industries in any part of the world because of its effects on public wellbeing and economies and its role in disease prevention as the health system's Achilles heel (Heidari et al, 2019). On the other hand, it is regarded as one of the most profitable and valuable manufacturing industries globally. After network and networking equipment, telecommunications utilities, and retail, the pharmaceutical industry is ranked third among the 53 most lucrative industries in the world. In addition to advanced knowledge of pharmacy, investing in various aspects of pharmacy, such as drug manufacture, manufacturing, storage, and distribution, necessitates managerial and economic expertise. The pharmaceutical industry provides effective representation and a better standard of life, but it also helps build economic strength (Elhami & Maleki,

2008; Heidari et al, 2006). Given the importance of defining and reviewing the domestic pharmaceutical industry's situation, challenges, and strengths in developing plans at the manufacturing industry's policy and operations levels, the current study employs a systematic approach to identify the industry's challenges and strengths.

Literature Review

In the last ten years, the global pharmaceutical industry has evolved dramatically. Pharmaceutical companies face new challenges due to globalization, increased competition, and the fight to capture a share of global markets (Rasekh et al, 2012). Growing healthcare prices, pricing policy, research and growth, pharmaceutical innovation, economic instability, socio-economic shocks, demographic shifts, emerging patient needs, regulatory reform, and market competitiveness are all macroeconomic challenges that the pharmaceutical industry is facing (Heidari et al, 2019). Corporate burnout, research, and development costs, and limited company size are only a few of the issues that have stymied the industry's growth (Kazemi et al, 2019). Iran's pharmaceutical industry faces declining reliance on government budgets, eliminating subsidized foreign exchange allocation, removing manufacturing restrictions and monopolies, rising consumer awareness and expectations for quality improvement, and the prospect of WTO accession, which opens the door to further market transfer. Iran's pharmaceutical industry is beset with difficulties. The poor structure of GMP in certain sectors of the industry is primarily to blame for these challenges. Pharmaceutical firms in Iran have an estimated lifespan of more than half a century, and their facilities and equipment are in desperate need of modernization. The lack of new investment in large-scale businesses is a significant impediment to upgrading manufacturing facilities. Semi-government companies, which control most of

Iran's pharmaceutical industry, are unable to make such investments. The creation of new drugs would be impossible for years due to a lack of effective research and development programs in pharmaceutical companies. As a result, the Iranian pharmaceutical industry's overall technological potential is restricted to the manufacture and formulation of generic drugs. There is also a chance that a lack of clarity and ambiguity in regulatory criteria for drug registration would allow companies to overlook ethical aspects of marketing (Cheraghali, 2017). Increased drug use, prescription prices, and a lack of a consistent drug policy in the pharmaceutical industry are all significant challenges (Davari et al, 2011). In addition to macroeconomic variables, factors such as population growth, increased government attention to the health sector (e.g., introducing economic development programs), cash incentives, and prioritizing health-related products and services can all be considered potential outlets for Iran's pharmaceutical industry (Heidari et al, 2019). Careful and long-term planning, tax regulation and banking system reform, insurance law and policy updating, and physician behavior change are all essential (Safari et al, 2018). Table 1 represents the most mentioned challenges in researches and articles.

Table 1.

Challenges in Former Researches

Challenges	Researches
Inappropriate policies	Varmaghani et al (2016), Shabaninejad et al (2016), Abolfazli et al (2019), Kian et al (2020), Doshmangir et al (2019), Cheraghali (2013), Danaei et al (2019), Safari et al (2018), Cheraghali (2017), Hashemi-Meshkini (2014), Ashrafi Shahmirzadi et al (2021), Rasekh et al (2012), Soltanzadeh et al (2017), Davari et al (2011), Sajadi et al (2019), Nassiri-Koopaei et al (2014), Ebadi farzadfar et al (2019), Shabaninejad et al (2014), Moghbeli et al (2019), Zaharee & Davami (2017)

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Challenges	Researches
Financing problems	Varmaghani et al (2016), Shabaninejad et al (2016), Kian et al (2020), Cheraghali (2013), Safari et al (2018), Cheraghali (2017), Rasekh et al (2012), Moghbeli et al (2019)
Improper pricing methods	Varmaghani et al (2016), Shabaninejad et al (2016), Kian et al (2020), Doshmangir et al (2019), Cheraghali (2013), Hashemi-Meshkini (2014), Ashrafi Shahmirzadi et al (2021), Soltanzadeh et al (2017)
Governmental industry	Shabaninejad et al (2016), Safari et al (2018), Hashemi-Meshkini (2014)
Generic scheme	Shabaninejad et al (2016), Hashemi-Meshkini (2014), Rasekh et al (2012)
Poor physical infrastructure	Shabaninejad et al (2016), Hosseinzadeh et al (2015), Danaei et al (2019), Cheraghali (2017), Moghbeli et al (2019)
Poor R&D support	Shabaninejad et al (2016), Kian et al (2020), Safari et al (2018), Rasekh et al (2012)
Human resource challenges	Babapour et al (2018), Hosseinzadeh et al (2015), Rasekh et al (2012), Shabaninejad et al (2014), Moghbeli et al (2019)
Quality challenges	Hosseinzadeh et al (2015), Doshmangir et al (2019), Safari et al (2018)
Political challenges	Safari et al (2018), Miremadi (2018), Bagheri Lankarani (2019), Kalateh Sadati & Bagheri Lankarani (2021)

Reviewing the related literature indicated that challenges about policies in Iran pharmaceutical industry is the most important barrier discussed in researches. Also financial challenges and unsuitable pricing methods caused a lot of problems for Iran pharmaceutical industries.

Method

The research goals were accomplished using a qualitative methodology and the qualitative content analysis process. Content analysis is any method that leads to the analysis, summarization, description, and inference of specific features of a text and the hidden meanings discovered in it in some cases and often allows the comparison of several texts. In qualitative content analysis, the hidden themes of the text and interviews are given more consideration,

and inference and meaning extraction are taken into account. Any type of communication content (lectures, book and article texts, newspapers, images, interviews, websites, and so on) can be analyzed using qualitative content analysis (MomeniRad et al, 2013). Apart from reviewing upstream papers, the key data collection method was an in-depth analysis of the domestic pharmaceutical industry's literature, problems and areas for development, and semi-structured interviews with 8 pharmaceutical industry experts. Twenty-two questions about the interview protocol were posed, as well as open-ended questions during the interview. Because of the specialized nature of the study, experts were chosen using purposive and judgmental sampling methods, as well as the snowball method on occasion. The interviewees were documented, and the key and relevant points were taken notes during the interview. Then the interviews were incorporated in text format to prepare the details for review and coding. In addition, using the MAXQDA 2020 program, research was carried out by coding based on conceptual similarities and the development of final categories. The continuous comparison of data with one another, obtained in light of the researcher's theoretical sensitivity, is an important point in qualitative content analysis. Researchers' theoretical sensitivity refers to the researcher immersing himself or herself in study data for an extended period to achieve a detailed understanding (Goulding, 2002). The researcher sees the final pattern and classes by rotating between types, codes, and data in this process (MomeniRad et al, 2013). As a result, after each interview, the researcher starts to identify concepts, assign appropriate labels, and similar group concepts together (Noroozian et al, 2019). The researcher regarded the cases in this analysis using the four parameters for evaluating qualitative research outcomes. These were reliability (defined as implicit or explicit properties summarized in data), dependence (defined as following a particular method from beginning to end of coding, proper

recording of steps and methods of combining, integrating, and summarizing data), transferability (defined as the comprehensiveness of data analysis for transferability in other contexts), and credibility (defined as original/reliable data) (Zhang & Wildemuth, 2009).

Findings

The data in this study were coded after an examination of the upstream documents and an interview. The theoretical codes were retrieved by coding using the permanent data comparison process, and 8 expert interviews were coded similarly. Table 2 shows the coding system and classifying categories, sub-categories, codes, and concepts representation model and the related challenges, strengths, and final categories about Iranian pharmaceutical industry listed separately in table 3.

Table 2.

Coding and Classifying System Representation Model

Item	Related Classification Representation Model
Category	
Related Sub-Category	
Related Code	
Related Initial Concept	

Table 3.

Coding and Classifying of Categories and Concepts Pertaining to the Iranian Pharmaceutical Industry's Challenges, Situations, and Strengths

Knowledge challenges
Poor KM in the governmental and policy-making sector
Failure to conform to the knowledge map in industry and the governmental sector
Poor modeling of globally recognized best practices

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	Poor platform for modeling of foreign products
	Restrictions on comprehensive industrial information
	Poor performance of TTAC system
	Highly complex process of developing new molecules
	Customer having little knowledge about medicine
Knowledge strengths	
	Numerous experts in the industry
	Educating hundreds of students using state-of-the-art pharmaceutical science
Environmental challenges	
	Growing environmental degradation and pollution
	Increasing number of diseases caused by environmental degradation
Attitude-cultural challenges	
	Cultural attitude of resistance to change
	Approach to domestic drug consumption
Inappropriate pricing methods	
	Pricing policy failing to comply with quality and GMP
	Lack of compliance between profitability and pricing policy
	Industries unwillingness to correct the pricing system
	Insurers failing to commit to high drug prices
Manufacturing status and challenges	
Manufacturing status	
	Health system accounting for 9% of GDP
	\$70 per capita of domestic drugs
	Maximum supply of drugs nationwide
	Necessity a global supply of drugs nationwide
	Legal requirement to supply certain raw materials domestically
Manufacturing challenges	
	Poor domestic context in technology manufacturing
	Industrial sector lagging behind in the field, infrastructure, technology, and knowledge
	Limited technology and machinery to exploit graduate knowledge
	Limited access to technology warranty
	Precedence of manufacturing climate
	Applying old manufacturing technology in the private sector

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Disrupted drug supply system
Poor technological manufacturing capacity in general manufacturing medicine
Need for imports
Drug shortages
Challenges posed by the international pharmaceutical system
Threats posed by imports to domestic manufacturing
Multinational corporation's monopoly
Complex process of marketing new molecules
Significant effect of international companies on the global pharmaceutical system
Quality status and challenges
Quality status of drug manufacturing
Appropriate quality of certain products
Private sector's significant progress in state-of-the-art knowledge and technology
Relative progress in producing machinery for manufacturing pharmaceutical raw materials
Quality and competitive manufacturing of high-tech drugs domestically
Quality challenges of drug manufacturing
Patients' highly limited right to take quality medicines
People's lack of trust for Iranian medicine's quality
Considerably reduced product quality
Lack of domestic technology manufacturing capacity
Poor quality of certain products
Lack of quality promotion despite quantity promotion
Lack of supervision on the quality of raw materials
Lack of access to international quality resources
Supply of a substantial part of raw materials abroad
Dependence on foreign corporations for manufacturing active ingredient
Lack of quality controller system
Poor quality of raw materials
Supply of materials from lower-quality sources
Limited financial resources of the industry
Lack of compliance of profitability and compliance with GMP requirements
Financial resources supply problems

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	Restricted exports to countries that do not abide by regional regulations
	The need for the outlay of foreign currency of import of raw and intermediate materials
	Current export lacking the power to earn foreign currency
	Industry's improper trade balance
	Industry's very long debt collection period
	Difficult bank financing
	Incompatibility between rising manufacturing costs and profitability
	Low industry's profit margins
	Financial costs of development
	Significant increase in the costs of access to technology
	Private companies' limited financial resources for improvement and development
	Necessity of sharing high annual profits in the private sector
Lack of export attitude in the industry	
	Trivial contribution of Iran's pharmaceutical market value in the world
	Lack of a commercial attitude in the pharmaceutical industry based on herbal medicine
	Loss of regional market (countries with no regulations)
	No need to register drugs in underdeveloped countries
	Limited export to countries with certain regulations
	No grounds for export to European countries
	No grounds for export to countries with certain regulations
	Profitability of export to countries with certain regulations
	Earning of foreign currency by export to countries with certain regulations
Inappropriate policy-making	
	Overlooking drug manufacturing capacity based on herbal medicine
	Disrupted health system
	Economic-currency corruption of export of drugs and raw materials
	Lack of a strategic attitude to the raw material industry rather than a mere economic attitude
	No effective communication between industry and university
	Difference in academic projects and industrial requirements
	Low attractiveness of the industry to graduates
	Graduates not attracted to the industry

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	Overlooking certain graduates in the industry
	Limited knowledge sharing between industry and university (academic institutions)
	Insurer's improper functioning
	Tax system problems
	Structural problem with Ministry of Health and Medical Education
	Structural problem with Food and Drug Administration of The Islamic Republic of Iran
	Complex processes
	Food and Drug Administration stakeholders dissatisfaction
	Improper industrial management structure
	Low managerial stability in the industry and policy-making sector
	Politicization in industry
	Inconsistency between policies and operations in the industry
	Failing to implement the Health system transformation plan properly
	Failing to manage the privatization process optimally
	Limiting domestic (internal) regulations
	Disrupted communication at the domestic institutions level
	Inconsistency between domestic regulations and international licensed manufacturing laws
	Lack of a forward-looking attitude
	Uninspired monotonous industry
	Iran Food and Drug Administration involved with daily problems
	Policy instability
	Extremely high government involvement

According to content analysis and coding, developing a knowledge management system in the domestic pharmaceutical industry and policy-making sector has gotten little attention. However, due to political and economic constraints, a good forum for joint cooperation and comparative modeling based on reliable reports from leading industrial companies worldwide was unavailable, and the required domestic model was scarce. The

method of creating new molecules is often complicated and time-consuming. Furthermore, since this sector is strategic, managers are not chosen solely based on economic, industrial, or scientific structures and criteria, and the industry's information map is not recorded. Since 2013, the design and implementation of the Food and Drug Administration (TTAC) authentication monitoring system and the systematization of commercial documents and licenses, and the tracking of health-related products have been on the agenda. It has not, however, been properly run due to the issues raised by the interviewees. Transparency in drug manufacture and distribution is a problem. It is worth noting that, due to a lack of adequate awareness among consumers (patients and drug users) about the quality of drugs and successful pharmaceutical materials, as well as information from manufacturing firms, development based on consumer needs and knowledge has received little attention in the field of industry. The good infrastructure for educating students and the availability of seasoned experts in the sector are two of the domestic pharmaceutical industry's knowledge fields' strengths. However, some young scientists and experts' willingness to emigrate has been one of the industry's issues because of technical shortcomings that it causes. Domestic pharmaceutical products will be exposed to improvements and threats resulting from environmental pollution and its negative impact on human physical and mental health. Pollution of the air and soil endangers people's health. Noise pollution is another pollutant that has negative psychological consequences. The content analysis of the interviewees' comments reveals that pharmaceutical manufacturing is incompatible with the current and potential phase of environmental degradation and its physical-psychological consequences. Policy-makers and manufacturers are confronted with complexities in the fields of approach, infrastructure, and development due to developments and changes in the market, which are the most significant

obstacles in the area of attitudes and resistance to change in the future. On the other hand, drug consumerism has become very common among society's members, leading to a strategic mistake in the manufacturing sector regarding domestic actual drug use. Because of the industry's strategic role in the health system, pharmaceutical companies have often collected foreign exchange at government rates. According to their goods at various rates (allocated by the government, NIMA), the currency has been distributed to pharmaceutical companies, making the drug pricing system complicated. Furthermore, the drug's cost was not commensurate with the nature of the drugs, and there was no option to price the drug using the same criterion as international products. It is worth noting that, in recent years, the price of medication has risen due to an increase in the exchange rate, which has slowed the consumption of medicine in society. The cost of manufactured drugs and the pricing mechanism is disproportionately high, limiting the industry's profitability. The role of insurers in limiting commitment to high-priced drugs has also posed a challenge to the manufacturing system. It is worth noting that the Ministry of Health, Treatment and Medical Education's policy-maker, printer, buyer framework, and pricing mechanism are primarily focused on strategic and governance parameters, with solely economic metrics receiving less attention. The domestic key drug manufacturing strategy focuses on maximum domestic production, global supply, and avoiding importing comparable drugs into the world. As a result, 97 out of 100 pieces of medication in the world are manufactured domestically, according to the review of the interviews' quality. The age of manufacturing spaces, the age of development methods, the weakness of the ability to produce infrastructure, and the construction of advanced processing machinery and equipment, particularly in the technology sector, are all challenges in drug production. Due to a lack of domestic manufacturing, the importation of pharmaceutical

raw materials and certain drugs is unavoidable, and production is reliant on imports. On the other hand, disruptions in the production and distribution systems and imports into the country have posed challenges in the planning of pharmaceutical products. The strategies of multinational companies and the world's leading pharmaceutical industry, developed under the guise of sanctions against the government, have made it impossible for the country to access certain high-quality medicine and pharmaceutical raw material and join the international pharmaceutical market for high-quality domestic goods. Imports of related domestic drugs, on the other hand, have posed a threat to domestic demand. Over the last few years, relative developments in pharmaceutical manufacturing by knowledge-based companies based on modern science and technology (nanotechnology and biotechnology) have been important. Some domestically developed drugs, especially in agile knowledge-based companies, have been of high quality and are exported. Any private firms have succeeded in manufacturing machines and appliances. Despite recent relative improvements, the majority of domestic pharmaceutical goods are of poor quality, one reason being the availability of pharmaceutical raw materials from less trustworthy suppliers (China, India, etc.) at the international pharmaceutical level, attributed to restrictions and industry-leading firms' reluctance to cooperate with domestic businesses. The structure of controlling the consistency of domestically manufactured drugs and imported raw materials, on the other hand, is not highly formal, according to interviews' content review. Foreign exchange difficulties, lack of a proper trade balance, unfavorable profitability, and a collection time of nearly 400 days are among the industry's main financing challenges. Obtaining banking facilities is largely complex and time-consuming. High-dividend policies for private holdings (TOICO, Shafadaro, Barakat, and others), which account for more than 70% of the domestic pharmaceutical system, divert resources

needed to develop lines, machines, and other industries. Nevertheless, it is worth noting that the imposition of sanctions has dramatically raised the cost of technology and technical improvements. According to the interviews' content analysis, the domestic pharmaceutical industry's strategy, background, mechanisms, and capacities are not ready for export. The majority of current exports to countries with fewer regulations are made in the region with minimal foreign currency earnings. Exporting to countries with special drug supply controls is not feasible due to a lack of consistency and international prohibitions and sanctions. As a result, drug companies have shifted their focus to domestic and small exports and foreign currency earnings. Improper policy-making and weak performance of policy-making agencies are the most significant problems in the domestic pharmaceutical industry. Economic-industrial development processes have been threatened by policy uncertainty, public sector over-ownership of production, and systemic and institutional problems in related bodies such as the Ministry of Health and Medical Education, the Food and Drug Administration, and insurance firms. Bureaucratic complexities have hampered industry growth in executive and production processes and politicization in the appointment of industry managers. On the other side, the industry is facing current (daily) financial, manufacturing, and logistics difficulties due to overlooking upstream documents and general policies, e.g., Article 44 of the Constitution on privatization, the role of society in industrial growth, and the unfavorable execution of part of the Health Transformation Plan, and foresight. Meanwhile, industry confronts additional challenges due to improper policy-making to create an efficient institutional partnership between industry, government, and academia in pharmaceutical companies and drugs and the unattractiveness of the industry for university graduates and young scientists. Furthermore, some of the economic corruption in drug and raw material

imports, which has harmed the industry's reputation, is due to policies and regulatory mechanisms that are ineffective. According to content analysis and by identifying and classifying concepts and categories associated with the status and challenges of the domestic pharmaceutical industry, the domestic knowledge, and scientific infrastructure is highly favorable, with numerous professors, experts, and scholars with in-depth knowledge and reputable scientific papers. The most significant challenges faced by the domestic pharmaceutical industry in policy-making have also been defined, as the government is the dominant structure of the pharmaceutical industry, as well as institutional/structural challenges, e.g., poor and optimal performance in relevant institutions such as the Ministry of Health, the Food and Drug Administration, insurance companies and organizations. In the domestic pharmaceutical industry, the ages in which manufacturing structures are built are often seen as major challenges and the lack of modern technology, particularly for the public sector. Insufficient attention to quality and lack of scope to provide high-quality resources and raw materials of foreign sources, lack of stage and the necessary focus on exports of products, lack of financial resources to the sector, and the lack of reasonable financial costs for developing current industries and a lack of an optimum and economical pricing system is necessary for the manufacturer. High-tech drugs are being produced throughout the country in specific diseases, cancer, kidney, blood diseases, etc. The only specialized and committed staff has achieved this. Experts' main strategies to address the current unfavorable situation include the development of export attitudes, the promotion of private sector development and the reduction in government ownership, the review of policy, the changing pricing and support structure in the field of medical and scientific management, quality management and knowledge management.

Conclusion

As one of the domestic strategic industries with advanced technologies, the domestic drug manufacturing sector is critical to the domestic health system. Improper policy making and quality infrastructure, cultural and knowledge challenges, limited funding resources to solve the existing problems and future evolutions, the absence of export approaches and attitudes, a price system, and the challenges posed by them currently represent the main challenges, according to the content analysis of the opinions of expert experts of various fields of industry. The political and economic sanctions have caused some of them to adversely impact the pharmaceutical industry, primarily run by public and private sectors. As a result, regulatory reform, privatization, and the decrease of government and private sector ownership in the area of drug manufacture, and the growth of private firms through knowledge-based companies will solve significant problems and help the industry shape a bright future. This research should be undertaken with a primary emphasis on individual medicines and the environment of knowledge-based firms in this regard.

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