Original Article

# Factors affecting pharmaceutical industry enforcements in Iran and selected countries

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## Abstract

The pharmaceutical industry has a significant share in national production of the countries. Therefore, the present study aims to identify the main dimensions and components of enforcing the pharmaceutical industry by the illustration of selected countries to stand against economic shocks. This is a comparative study which was carried out in 2019. Compared Selected countries are separated into two main classifications. First category is referred to turkey with similar characteristics to Iran. The other group is consisted of pioneer countries in pharmaceutical industries. USA, Britain and Ireland. Data analysis was based on a framework analysis. Findings of the study indicated that Iran needs to allocate more funds to the R&D unit to obtain self-sufficiency and strengthening accommodated with building centralized infrastructures in which coordinates these centers. This will also act to avoid wastefulness. In this regard, Iran can idolize countries such as Ireland and Turkey as a model. Despite the sanctions and domestic issues Iran should make more efforts in this regard. Drug rules and regulations need to be updated correspondent to difficulties such as domestic and foreign factors.

**Keywords:** Factor, Pharmacy, Law Enforcement, Health, Iran

## Introduction

Being generative in the health sector, especially in production of advanced technologies such as medicine, is directly affected by price shocks and fluctuations and more importantly the international sanctions [1]. The recession and severe inflation in prices originated from raw materials can have a devastating effect on the country's economic structure but the extent of outcomes within different organizations or political-economical systems might vary [2]. Some countries have better resisted to external and internal destructive factors and are less likely to be damaged. Meanwhile in other vulnerable countries, it leads to social and economic issues [3]. In recent years, Iran's pharmaceutical industry has faced numerous problems due to international sanctions in terms of raw materials imports for drug production uses. Otherwise accessible expensive foreign drugs, hard approaches to new technologies such as nanotechnology and biotechnology, decline in financial investment and an increase in risks of investments have encountered [4]. These issues have proved as important parts in all aspects of the pharmaceutical industry since needs of sustainable resources and viable investment for the purpose of intergenerational policies implementation in fields of health which is essential to change the structure and processes in fields of economy if the increase of the economic resistance is aimed. Related to speech, in recent years, issues related to strengthening economy, politic and science arenas has gained its noticeable attention in Iran [5]. However, so far, very few specific studies are conducted in the country to criticize country's pharmaceutical industries, from the perspective of a resilient economy [6]. Therefore, the present study aims to correspondently compare the factors affecting the solidity of pharmaceutical systems in Iran and other selected countries in year 2019, reinforce the knowledge in this area.

## Experimental

- Descriptive adaptation.
- Variety of health organization in countries is considered
- Use of expertise experiences.
- Criteria of selecting the mentioned countries was Having a cohesive and advanced pharmaceutical industry with authentic evidence in possession.

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- Similarities in social-economic-cultural aspects compared to Iran.

Compared Selected countries are separated into two main classifications. First category is referred to turkey with similar characteristics to Iran. The other group is consisted of pioneer countries in pharmaceutical industries. USA, Britain and Ireland.

Items to be compared in this agenda are:
Pharmaceutical system or industry, evaluation and development, law and regulations and inspecting scientific and health shocks in the pharmaceutical industry. Table References are adapted from: Pub Med, Scopus databases, Google scholar search engine, Ministry of Health website and Department of Health, World Health Organization website, World Bank website and OECD library website. Data analysis was based on a framework analysis. Based on extracted information, differences and similarities between countries were compared.

## Result

Each country is mentioned with isolated items.

### • Pharmaceutical system or industry:

The US Food and Drug Administration (FDA) were formed in 1902 by the US Congress to establish the modern pharmaceutical industry [7]. The United States is the largest market for biological drugs, accounting for about a third of the global market. Total U.S. drug sales accounted for $ 333 billion, accounting for 1.9 percent of GDP and 10.7 percent of total health care spending. Generic drugs sell for $ 70 billion (21% of total drug sales), exclusive drugs for $ 244 billion (70% of total drug sales) and OTC drugs for $ 19 billion (6% of total drug sales), and per capita drug sales are $ 1,036 [8]. Two unique aspects of the pharmaceutical industry are: 1) investment in research and development 2) patent system [4]. In terms of drug sales, the UK ranks fifth in the world after the United States, Japan, Germany and France. The UK's pharmaceutical sales volume accounts for 7% of total global sales. The pharmaceutical industry plays an important role in the country's economy. The British industry is in a legal environment. Research, production, licensing and product sales methods are under full supervision. Medicines are produced by a very large and successful industry. In general, this industry is the third most profitable economic activity in the country after tourism and finance [9]. NHS is the UK's leading buyer of pharmaceuticals [10]. Turkey is the 29th largest market in the world and the second largest in Central and Eastern Europe. The pharmaceutical industry in this country has a production structure in which, is consisted of high-level technologies and machines. Approximately 31,000 people are employed this sector [11]. Four factors have been the main cause of the growth of the pharmaceutical market in Turkey. These factors are included as: increasing drug prices, increasing drug volume, increasing sales distribution and new products [12].

INTOSAI-Donor Cooperation (IDC), the United States Agency for International Development and the European Commission (EC) which ensures the provision of medicines prepared through the main package of health services (BPHS) [13] are principally under World Bank's surveillance

The modern pharmaceutical industry in Iran had its starting point by authorizing and approving products and affairs from multinational pharmaceutical companies and importing Active Pharmaceutical Ingredient (API) and formulizing them in a localized manner. The First modern pharmaceutical company in Iran was established by the non-governmental sectors about 70 years ago. Iran's pharmaceutical industry was under changes and influences of the revolution in 1979. Self-sufficiency and independency were the two main government's goal and criteria. Since the influence of this policy was applied, all multinational pharmaceutical companies left the country, and the new government nationalized almost all pharmaceutical companies. In recent years, health care expenses in Iran have increased as calling for high-tech biopharmaceuticals by both physicians and patients has been frequent demand.(see table 2). In the United States, budget is spent by government to encourage and promote research and developments of pharmaceutical products in favor of public health. To enter this field, in order to accept the outcomes, rejects, and risks, along with the government finding, as a priority, a company must carefully consider the demand and recommendations. When there is a reception system (acceptance), government can fund the pharmaceutical companies to develop and investigate to avoid options being suspended in this field [14]. Research and development facilities in the UK are in world-class, and British companies have a long noticeable history of successful drug development. The UK pharmaceutical industry invests around 33.3 billion a year in research and development. The industry spends more resources on health care research in the UK; that's about six times more than the Ministry of Health, five times more than medical charities and Eight times more than the Medical Research Council[2] (MRC). By this status, it is apprehended, the industry spends most of the finance on health care researches in the UK. The pharmaceutical sector accounts for 65% of health-related research and development, and almost 40% of all industrial research and development expenditures in UK, equivalent to 10 million per day [15]. While global investment in research and development of innovative drugs is $ 120 billion per year, Turkey's share is only $ 60 million, representing only 0.039 percent of global research and development. Moreover, producing new molecules (nuclear research) has never been carried out in Turkey [16]. The Turkish government intends to increase Turkey's research funding and development to 3 percent on GDP and increase exports to $ 500 billion. By this perspective making Turkey one of the world's top ten health care economies till 2023 [17]. Research and development has been Iran's Achilles heel in pharmaceutical national system [18, 19]. Research and development facilities in Iran are divided and separated. This fragment implies that each pharmaceutical companies have their own research and

development unit, but these researches don't correlate with needs of society and more to be pointed, they overlaps in many cases, which ads additional costs to the country's health system. Also, in Iran, there isn't any essential infrastructures to conduct pharmaceutical researches and development [20].

- Regulation Enforcement

It is often hypothesized in the United States that in order to control the cost of medicines, it is vital to import cheap drugs from Canada. Pricing control mechanisms used by foreign governments may include international reference pricing (IRP). In this way, the government values a drug by comparing its price to the portfolio quota of selected countries. And TRP (therapeutic reference pricing) pricing is where a government designs drugs that are aimed to be used in certain conditions as a criterion for treatment. Also it is where the maximum refund and pricing for the mentioned group is delineated and determined. Ensuring the quality of the medicine is done by the process of discovering the medicine and its compounds are considered with corrections, fighting the diseases and reducing the drug side effects in favor of patients. Of course, before initiating the clinical trials, novel drugs are deliberately and carefully reviewed and rechecked by the FDA. Clinical trials of new drugs are done in three stages. The first step involves testing the safety of the drug in a small group of 20 to 100 healthy and normal volunteers. In second stage, 100 to 500 patients voluntarily Participate in surveilled and controlled trials to determine the drug's effectiveness in treating the disease.

The final step as the third stage is to study the efficiency of the medicines. The drug is tested and compared in each 1,000 to 5,000 patients. The comparison of the side effects is included [7]. The main mean of economic legislation in the UK is transpired by Pharmaceutical Price Regulation Scheme (PPRS). (PPRS) has managed a rate of return on investment in drug sales for NHS and it is aimed to equalize the rate of return to that of the entire UK industry. The 17 to 21 percent was agreed as the rate in the 1993 agreement. Pharmaceutical Price Regulation Scheme is a mechanism to determine and delineate the profits of pharmaceutical companies by selling their produced drugs to the NHS.

The main objectives of PPRS are:

1- Ensuring safety and effectiveness of drugs provided for NHS with a reasonable price
2- Promoting a viable profitable industry in which, has the ability to estimate costs of researches in sustainable development and leads to the access of new and advanced future drugs.
3- Promoting an efficient competitive development, supply and carrying out medicines to the pharmaceutical market in UK and other countries [21].

About the way of quality assurance, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), which is the main importance of British issued license executive, is responsible. It is also responsible to confirm clinical trials. If necessary, the Committee on the Safety of Medicines will be assisted to receive consultations. By merging these two mentioned organization, Commission for Human Medicines is formed. Medications may be approved for use in the UK nationally (directly through the MHRA), through a centralized approval system such as the European Medicines Agency (EMEA), or through a cross-border diagnostic method. Under a centralized program, companies directly request EMEA for licenses [15]. The price of medicine in Turkey is regulated and determined by the General Directorate of Pharmacies and Ministry of Health's Pharmacies. The final price of the product is determined by the lowest prices provided by drug manufacturers among the five EU members (France, Spain, Italy, Portugal and Greece). If price for a product wasn't declared by the reference countries, it is calculated by deducting mark ups (profits and overhead costs) and VAT from the retail price of the pharmacies. In cases where the factory price of a product is lower than the reference country (for products imported to the reference countries), the price in the country is taken as the reference price. If the product is available only in one of the reference countries, the factory price in that country is adapted as a reference. In cases where the product is illegal and banned in any of the reference countries, the cheapest factory price in any other member state of the European Union is taken as the reference. If the product is strictly prohibited in the European Union, the country where it originated from will be selected as the reference. Pricing the products that are only available in Turkey, is determined by negotiation between the Ministry of Health and the company or factory [22]. For generic drugs, prices are set at 80% (it might vary to 70%) of the original product price [23]. quality assurance is the responsibility of the general drug policy as well as the issuance of licenses for products and providers with the Ministry of Health (MOH). General Directorate of Pharmaceuticals and Pharmacies (GDPP) is responsible of registration, authorization, drug pricing, legal classification, monitoring the pharmaceutical advertisements, as well as inspecting pharmaceutical manufacturers, wholesalers and retailers in pharmacies. Decisions are made by process in which a committee after another, with considering requirements, confirms its approval [24].

In Iran, the pricing of manufactured and imported drugs centralized in the pricing commission of the Statistics and Planning Department of the General Directorate of Drug Monitoring and Evaluation of the Food and Drug Administration [25]. To begin the Pricing of imported drugs, the office receives the pricing form of imported drugs and other drugs related to customs imports. Then determines the prices of imported drugs based on factors such as reference price, import history of the same drug, import history of similar drugs and so on… In general, however, the pharmaceutical industry in Iran has always been accompanied by severe streaked surveillance in price [25]. About the quality assurance, the Pharmaceutical Production and Import regulations (1989) provides a set of rules to ensure the quality of pharmaceutical products on the market. According to

Article 12 of this law, establishing a pharmaceutical company, is in need of both license from the Ministry of Health, and license from the Ministry of Industry. Importing products must also be licensed and issued by the Ministry of Health. Moreover, products on the market must be randomly sampled and sent to laboratories for post marketing quality assessment. According to law, the import of active pharmaceuticals by domestic producers must also be supervised and approved by the Ministry of Health.

- ### Industry's confrontation with economic and health shocks

Pricing and innovation in health care, with the goal of quality enhancements, the federal government has allocated up to $ 20 billion to provide infrastructure and health information technology programs. With the aim of improving clinical cares and clinical trials determines and declarations, reducing medical errors, and increasing the sharing of patients' clinical outcomes and side effects, EMR / EHR implementations was done among patients and providers [26]. The US pharmaceutical market is also being varied by its domestic constitutions, laws and regulations. Regarded to this extent, lately, pharmaceutical companies have agreed to spend more than $ 13 billion to settle and justify US accusation of fake marketing, including promoting unapproved drugs by Food and Drug Administration [27]. Drug prices and expenditures are rising in the UK. with the UK facing an increase in the costs of prescription drugs in primary care, most of them are caused by the National Health Service (NHS). The increase in drug expenses, could be due to increase in prices, introducing the new pharmaceutical products into the market, and an escalation in the size of drug usage in comparison with the past [28]. To cope with this situation, the British government has used two attitudes: influence of consumer's behavior and that of provider's behavior. The approach to "consumer behavior" refers to items that affect the patient's demand, the patient's cost and franchise, and the over-the-counter and out of prescription drug market. Methods of influencing patient's demand range from providing patient costs (franchise) to expanding the market for out of prescription and over-the-counter OTC drugs and the amount of OTC drug coverage covered by insurance. Familiarizing drugs and advertising it, provides alternative means to influence a patient's needs [28]. In influence of provider's behavior, Items related to repayment decisions, monitoring of drug prescribing activities and financial incentives are discussed. After 1992, Turkey faced one of the most serious economic problems in history. In reaction to this emergency, the Turkish government began to indulge learning the use of existing resources in a more effective way. One of the earliest stages was the creation of a list of drugs and vitamins, and it was released by the Ministry of Finance [29].

Government agencies, such as the Social Security Administration and the State Railways, hold a list of drugs with repayments of it, which provides generic drugs or cheaper drugs for consumers [30]. The increase of pharmaceutical costs through the country was another challenge the Turkish healthcare system faced. The Turkish government has used regulations to cut down the expenses, which has been an alternative solution to this circumstances. However, since the beginning of 2013, with the entry of new drugs into the refund list, costs began to remarkably increase [22]. After the revolution happened in Iran. Problems such as the eight-year war with Iraq and subsequently US sanctions were met. These sanctions have affected many productions and service sectors of the country. the provision of medicine and the supply of raw materials was considered as late effects of the sanctions [31]. Although about 97% of Iran's pharmaceutical needs are prepared by domestic manufacturers, when companies are unable to simultaneously supply and prepare all the components of the drugs on time, their production and sales cycle will be disrupted and the producing chain will be dislocated. Although drugs are unconditionally exempted from sanctions under any circumstances, many international companies, due to payment restrictions, have by far not been able to deliver orders to Iran [18]. Looking forward to improve the drug accessibility and money savings for plasma-derived medicines (PDM), since 2005, Iran has devised a successful plan. The program focuses to send plasma produced by the country's Blood Transfusion Organization to a contractor and final products will be distributed in the local market and returned to the country [32]. The price differential and variation emerged between imported drugs and products from this program have caused remarkable savings for Iran's healthcare sector [33].

## Discussion

As one of the major global health care providers, the drug has outstanding distinguishable features that signifies and separates its place from different parts of the health system. This has led governments to make the issue of medicine major and magnify its role in their policies.

- ### Pharmaceutical system or industry

The pharmaceutical system is translated into a set of individuals' affairs and activities whose purpose is exploring and improvement, clinical trials, drug registration, manufacturing and packaging, importing, supply chain and distribution [34]. These components or subsystems are not equally advanced and sophisticated in all countries, and within a country, some of these infrastructures have received more attention. Taking United States as an instance, it has the largest market for biological drugs, accounting for about one third of the global market. One of the reasons why the United States has achieved this level, is because of the spiritual ownership system in the United States, which supports scientific innovations in three manners: patents and data protection, devising the most reliable authentic and accurate science-based monitoring system, the largest scientific research center under academic management, and decades of funding the public research, and strong capital markets. The United Kingdom is also the world's third largest direct exporter of drugs and medicines. Britain is indeed, one of the most important research and development sites in the arena

of medicine, and this is one of the reasons why it has been fertile in the fields of medicine. Turkey and Iran have many cultural and social similarities, but the economic status has been different for these countries over the past decade. In 2003, Turkey applied the health Transformation Plan with the aim of organizing, financing and providing health services in a more efficient, effective and equal attitude [35]. This plan also had an effect on pharmaceutical market and has increased the value of the pharmaceutical industry in Turkey, as well as the policies of this plan have caused changes in the supply and demand of medicine in Turkey [35]. It has moreover enhanced indicators such as increasing equivalence and ease of access in Turkey [36]. In recent years, Iran has faced problems in importing drugs and pharmaceutical raw materials. However, despite sanctions, the pharmaceutical industry in Iran has gradually grown between the years 2001 – 2012. In spite of being far from developed countries however, Iran has gained the level of competing other countries. Due to long-term sanctions, old structure and lack of participation in international markets, the pharmaceutical industry in Iran does not possess valid international certificates. The fact that Iran is potential to produce and distribute drugs and medicines is undeniable, to obtain international certificates and improve quality more efforts needs to be made by Iranian pharmaceutical companies with the intention of having greater shares in markets [18]. Adjacent countries of Iran such as Iraq and Afghanistan, have weak pharmaceutical industries. They are held as consumers. They can hypothesize to be considered as Iran's target market.

## • Research and Development

Research and development is one of the main importance of any industry that creates competitive benefits and development productivity [37]. Nevertheless, both heavily invested countries and reluctant countries are existed related to the communication. The United States, has set a wide range of government budgets to promote research and development of pharmaceutical products that contributes to public health. With the increase in investment in this sector, India as an example has become one of the most powerful pharmaceutical industries in the world and has benefited from competing with other pharmaceuticals [38]. Of course, there are exceptions; Ireland is one of the powers in the field of pharmaceuticals that the budget for research and development of the pharmaceutical industry is much lower than other countries with which Ireland can compete [39]. Lately, Turkey has also spent extravagant fortunes on research and development in the pharmaceutical industry. Regarded to this, Turkey has taken measures such as devoting budgets for applied research, releasing and broadcasting scientific knowledge, allocating subsidies for research and development, forming cooperation of universities with research and development centers by creating a strong relation amongst, creating investment opportunities for private sector meant for research and development [16]. Even though research and development is one of the achievements of the pharmaceutical industry, in Iran, less attention is being payed to this importance and has evolved as one of the unfulfilled tasks of pharmaceutical industry [39]. Other controversial challenge which involves Iran, is the out of order researches and irregularity of this industry. Also the irrelevancy of researches being far from the society needs is another issue. To elaborate, each pharmaceutical company has its own idea of researching and development units, and there is no interconnectedness that embodies as a central research and development center. Another factor that has deteriorated researches and developments in Iran is the procedure of drug pricing. This subject is processed under the surveillance of the government. And in most cases the research and development expenditures in drug pricing are not considered to be taken into account, thus consequently being ignored [20]

## • Regulation Enforcement:

A major problem of pharmaceutical industry in numerous parts of the world is the security of quality and safety of drugs which fake manufacturers bring about [40]. Sales of forged drugs and products devastates financial resources, postpones cure, increases drug ineffectiveness, and leads to death eventually [41]. Another problem the health systems deals with around the world is the increase in pharmaceutical charges, which un case of preventing, the necessity of being regulated needs to be attended.

In Countries like United States, regulations on drug quality and safety are basically applied by government which by protecting the public safety, prevents and delays the entry of new drugs into the market. The government motivates securing healthy and effective drugs. United States policy is that; innovative drugs must be approved by the FDA. [14]. As One of the drawbacks of this method, the long process of new drug entering the market may discourage manufacturers. But on the bright side drugs enter the market with minimized risks and maximized competence and effectiveness. On the other hand, in UK this process requires less time-consuming. The UK has set up a centralized commission for human medicines to launch a unified drug endorsement and approval mechanism. By this approach, the United Kingdom became one of the countries with the lowest rate of absorption and new drugs entrance in Europe [15]. Likewise, In Turkey, focusing on this duty is undertaken by the Ministry of Health. The Ministry of Health responsibly reviews new drugs evaluates the existing drugs as well. This emphasis saves money, time and energy in quality controlling. This system also reduces the consumed time for an imported drug to be licensed. The drug standard in Iran correspondent to international standards of the British Pharmacopoeia (BP) and the American Pharmacopoeia (USP), and pharmaceutical companies operate in association with international pharmaceutical standards. Albeit, it should be noted that the quality of pharmaceutical products relies on important elements such as additional raw materials, drug type and packaging, and the approach of modern technology. Following the sanctions imposed on Iran, as well as the disvalued currency, most factories are looking forward to have cheap raw materials that will deteriorate the quality of

the production. So it is comprehended, not all the imported drugs are necessarily imported from the best pharmaceutical companies due to these factors. There is no existence of any approaches in the United States of America to improve the evaluation of health care fare that should be considered in the structure of the pharmaceutical industry, health insurance, and the international drugs market. Concentrating on procedures that have been operative whether in US markets or worldwide can aid drug price controls in the US and provide a reliable future market [4]. But Britain uses a specific method in drug pricing. The main form of economic legislation in United Kingdom is Pharmaceutical Price Regulation Scheme (PPRS). But like others, it is otherwise perfect. Breaches can be concerned:

- PPRS is solely dedicated to companies that offer branded products to NHS.
- -The price of generic drugs is not monitored by PPRS
- The price controls of drugs are indirect [42].

In Turkey in 2004, controlling the price of drugs for human use was declared in parallel with the HTP health transformation program. Given this, Turkey has moved from cost-based pricing system to external reference pricing system and the refund commission became in charge of issuing the agreed list of drugs. In addition, VAT on medicines was decreased from 18% to 8%, and subsequently as a conclusion, discount contracts were settled by authorities of pharmaceutical industry and the government [11]. In 2005, agreed lists were introduced to three social security organizations. Then united into a single list defined by their equivalent groups [11]. In Iran Pricing is arranged by the pricing commission of the Statistics and Planning Department of the General Directorate of Drug Monitoring and department pf Evaluation of the Food and Drug Administration. Research and development costs in pricing is deliberately denied which causes the neglectfulness of manufacturers and companies, which contradicts the Iranian pharmaceutical market, effecting the world and the region.

- ### Industry competing with economic and health shocks

Economic crises became a significant strategic issue lately. All economic sectors have sought to establish a mechanism and framework to stabilize and endure simultaneously. They are taking an innovation-based approach as an alternative approach to strengthen functional fundamentals [43, 44]. Countries such as United States of America and United Kingdom were less prone to critical conditions, such as civil war and sanctions in comparison with other countries. Main difficulties of these countries have always been associated with domestic economy and growth of health expenses which was accompanied by drugs. This has been perceptive for the progressing of medical equipment and the explanation of long lifespans. Preventing the increase of pharmaceutical expenses has been key factors in these countries. These countries have adapted to choose strategies that affect individuals' demands, such as making an allowance for franchisees for drugs, repayment decisions, monitoring drug prescriptions, and creating financial enthusiasm for providers [21, 28, 45, 46]. On the other hand, after the economic crisis in 1992 in Turkey, successfully implemented the Health Alteration Plan and carried out mechanisms to control drug expenses. Among the countries in this, Iran Forced to shut down factories has consequently increased the unemployment and reduced the purchasing power in society, which has also affected their health expenses. Iran has managed to recover pharmaceutical industry, but some raw materials still have to be carried in to gain satisfactory qualification and security in pharmaceutical products [47]. Iran's economy has been through currency fluctuations, the risk of international factors (international developments) and the risk of domestic mandatories such as tariffs, targeted subsidies and a constant rise in energy prices. In such an environment, a suitable structured model must be specialized in pharmaceutical industry to be less affected by internal and external factors.

## Conclusion

A study the pharmaceutical industry in different countries in comparison with Iran revealed, Iran needs to allocate more funds to the R&D unit to obtain self-sufficiency and strengthening accommodated with building centralized infrastructures in which coordinates these centers. This will also act to avoid wastefulness. In this regard, Iran can idolize countries such as Ireland and Turkey as a model. Despite the sanctions and domestic issues Iran should make more efforts in this regard. Drug rules and regulations need to be updated correspondent to difficulties such as domestic and foreign factors.

**Table 1.** The Classification of the Dimensions and Final Components of Strengthening the Pharmaceutical Industry in Selected Countries

| Dimensions under study | Components |
|---|---|
| Pharmaceutical System | Context |
| | Pharmaceutical market |
| | Export and import of medicine |
| | The status of drug production in the country |
| R&D | Intellectual Property |
| | R&D costs |
| Regulation Enforcement | Cost control policies |
| | Quality insurance |
| The Industry's confrontation with economic and health shocks | Public environment |
| | Environmental Challenges |

**Table 2.** value of import and Export in the Pharmaceutical Industry in Selected Countries

| country | Value of Export (US$) | Value of Import (US$) |
|---|---|---|
| USA | 48.35 Billion | 115.63 Billion |
| UK | 30.08 Billion | 30.27 Billion |
| Turkey | 1.17 Billion | 4.36 Billion |
| Iran | 187.85 Million | 1.57 Billion |

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