TECHNOLOGICAL TRANSFORMATIONS: THE CASE OF INDUSTRY 4.0 IN TURKISH PHARMACEUTICAL INDUSTRY

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ABSTRACT

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The completion of the technological transformation of all sectors, especially the production sector, is one the most important factor for their survival in today's world where competition is rapidly increasing and new technologies are developing beyond traceability. In order to stay in the race, adapting and internalizing the new technologies that came into our lives with industry 4.0, which recently emerged and became a current issue in a short time, became a necessity. Given the importance of technological transformation, pharmaceutical industry that is one of the world's largest industries and growing continuously (İEİS, 2016), needs to keep pace with this transformation. Through semi-structured interview data from pharmaceutical companies located in Turkey, this study aims to measure the technological readiness of Turkish pharmaceutical companies for the technological transformation within the scope of industry 4.0. Thanks to the interview data examined in five main headings which are awareness, technological situation, pricing and reimbursement processes, changes in the private sector and expectations from the public sector, the situation of the pharmaceutical industry in Turkey in the context of industry 4.0 is determined and the policy recommendations are made for the completion of the technological transformation.

Keywords: Industry 4.0, pharmaceutical, pharma 4.0, technological transformation, policy

ÖZ

TEKNOLOJİK DÖNÜŞÜMLER: TÜRK İLAÇ SANAYİNDE ENDÜSTRİ 4.0 UYGULAMASI

İlhan, Ömer
Yüksek Lisans, Bilim ve Teknoloji Politikası Çalışmaları
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Üretim başta olmak üzere tüm sektörlerde teknolojik dönüşümünün tamamlanması, rekabetin hızla arttığı ve yeni teknolojilerin takip edilemez bir hıza ulaştığı günümüz dünyasında şirketlerin hayatta kalmaları için en önemli faktörlerden birisidir. Yakın zamanda ortaya çıkıp kısa sürede gündem haline gelen endüstri 4.0 ile hayatımıza giren teknolojilere uyum sağlamak ve bu teknolojileri içselleştirmek yarışın içinde kalmak için bir gereklilik halinde gelmiştir. Teknolojik dönüşümün önemi göz önüne alındığında, dünyanın en büyük endüstrilerinden biri olan ve her geçen gün büyüyen ilaç sanayinin (İEİS, 2016) bu dönüşüme ayak uydurması şarttır. Türkiye'de faaliyette bulunan ilaç firmaları ile yapılan yarı yapılandırılmış mülakat verileri doğrultusunda, bu çalışma ile Türk ilaç firmalarının, endüstri 4.0 kapsamındaki teknolojik dönüşüm için hazırlıklarının ölçülmesi amaçlanmaktadır. Farkındalık, teknolojik durum, fiyatlandırma ve geri ödeme süreçleri üzerindeki etkiler, özel sektör tarafındaki değişiklikler ve kamudan beklentiler olmak üzere beş ana başlıkta incelenen mülakat verileri sayesinde Türk ilaç sanayinin endüstri 4.0 konusundaki durumu tespit edilerek, politika önerilerinde bulunulmuştur.

Anahtar Kelimeler: Endüstri 4.0, ilaç, pharma 4.0, teknolojik dönüşüm, politika

To My Wife

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First and foremost, I would like to thank my supervisor, Prof. Dr. Erkan ERDİL, not only for his valuable guidance and support throughout the research but also for his priceless contributions to this thesis.

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Finally, I would like to thank my wife and my family for their constant support.

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LIST OF ABBREVIATIONS

3D	Three Dimension
AİFD	Association of Research-Based Pharmaceutical Companies
APC	Automated Process Control
ASELSAN	Military Electronics Industry
BCG	Boston Consulting Group
EFPIA	European Federation of Pharmaceutical Industries and Associations
ICT	Information and Communication Technologies
İEİS	Pharmaceutical Manufacturers Association of Turkey
IMS	Information Medical Statistics
IoT	Internet of Things
İSO	Istanbul Chamber of Industry
ISPE	International Society for Pharmaceutical Engineering
IT	Information Technology
M2M	Machine to Machine
MES	Manufacturing Execution System
MH	Ministry of Health
MIT	Ministry of Industry and Technology
NGO	Non Goverment Organisation

OECD	Organisation for Economic Cooperation and Development
PhD	Doctor of Philosophy
PPP	Public Private Partnership
R&D	Research and Development
RPA	Robotic Process Automation
SIG	Special Interest Group
SMEs	Small and Medium Sized Enterprises
TEPAV	The Economic Policy Research Foundation of Turkey
TMMDA	Turkish Medicines and Medical Devices Agency
TÜBİTAK	The Scientific and Technological Research Council of Turkey
TÜSİAD	Turkish Industry and Business Association
US	United States of America
VAT	Value Added Tax
WMS	Warehouse Management System

CHAPTER 1

INTRODUCTION

In recent years, the impact of new technologies on society is felt more than ever. The necessity to keep up with this rapid change is inevitable. The completion of the technological transformation of all sectors, especially the production sector, is the most important factor for their survival in today's world where competition is rapidly increasing and new technologies are developing beyond traceability.

At this point, the first issue we face is industry 4.0. The number of people researching this subject is increasing day by day. The most important fact is that it is impossible to survive without internalizing the technologies that came into our lives with industry 4.0. Today, we are talking about the fourth industrial revolution triggered by digital technologies. We observe that nine technologies, such as smart robots, big data, the Internet of objects, 3-D printing, and the cloud, play a crucial role in triggering this revolution. The concept of Industry 4.0, which emerged with this revolution, is now defined as the integration of parts of value chains with each other beyond their own automation. Furthermore, as befits the name, industry 4.0 is accepted to be a revolution. Schwab (2017) states that revolutions have come with new technologies that leads to significant changes in both economic and social structures. Therefore, we should perceive industry 4.0 as a fundamental phenomenon in terms of social developments.

According to a detailed survey conducted by Boston Consulting Group (BCG) in 2015, the widespread implementation of Industry 4.0 is expected to have significant impacts on the German economy over the next 10-15 years. A cost-reducing effect of 90-150 Billion Euros is mentioned as a result of an industrial productivity increase corresponding to 15-25% of production conversion costs (BCG, 2015). The concept

of industry 4.0 which raised in Germany for the first time, ensure a process that provides not only an increase in productivity, it is a journey that leads to higher value added, creating its own economy, fundamentally changing established value chains, and most importantly, reaching a more important point in the need for qualified manpower (TÜSİAD, 2016).

Given the importance of technological transformation, it is essential that the pharmaceutical industry as one of the world's strategic industries (İEİS, 2018) should keep up with this transformation. The pharmaceutical sector has a great social importance and has the potential to make a significant contribution to the economic development of a country due to its unique sectoral characteristics. In the pharmaceutical industry, which is an information and technology intensive sector (Gambardella et al, 2001), technological changes have accelerated recently. In this context, when the Turkish pharmaceutical industry is examined, it is seen that the sector produces just generic pharmaceuticals and performs pharmaceutical filling.

It is necessary to follow the technological developments at the global level and to take the steps to ensure technological transformation for the Turkish pharmaceutical sector in order to take part in highly competitive economies. Industry 4.0 has many opportunities to be one of the most important factors in the development and increase of competitiveness of the Turkish pharmaceutical industry.

Being the world's 17th largest pharmaceutical market, the Turkish pharmaceutical industry includes pharmaceutical manufacturers and importers, pharmaceutical stores and pharmacies (İEİS, 2019). Being a high-tech sector with the highest concentration of research and development, including long and costly product development processes, being subjected to many arrangements and denials from basic research to presentation of the pharmaceutical makes the pharmaceutical industry quite different from other sectors. In this respect, it is very important to reveal Turkish pharmaceutical companies technological positions and measure how they are ready for technological transformation in the scope of industry 4.0. Therefore, it is important for Turkish pharmaceutical industry to adopt the new

technological transformation and by taking the advantage of it to strengthen the competitiveness.

In this context, the main purpose of the thesis will be to measure the technological readiness of Turkish pharmaceutical companies for the technological transformation within the scope of industry 4.0 and to make policies that are needed to ensure the transformation. The main focus is on the manufacturing side of the industry, while it has many other processes such as R&D, distribution, marketing etc. A qualitative methodology is adopted in this thesis and the data is obtained through semi-structured interviews to be able to respond to the research questions below:

- Is the Turkish pharmaceutical industry ready for technological transformation in the scope of industry 4.0?

- Which policies should be made to ensure the transformation?

When the answers to these questions are found, the first study in this field will be done. To the best of our knowledge, there is no study measuring the readiness of the pharmaceutical sector for technological transformation within the scope of industry 4.0 in Turkey.

The thesis consists of four chapters. Chapter 2 introduces the main points of the pharmaceutical industry and the concept of industry 4.0 and its components. Later on to capture the relation between the industry 4.0 and the pharmaceutical industry, Pharma 4.0 will be introduced in Chapter 2. Chapter 3 introduces the research context, the methodology and the processes of data collection and analysis. It also highlights the data structure obtained through semi-structured interviews. Further, the findings of the research are introduced in Chapter 3. Finally, Chapter 4 comprises the concluding remarks and possible policy recommendations.

CHAPTER 2

LITERATURE REVIEW

2.1. Pharmaceutical Industry

The pharmaceutical industry is an industrial field that provides therapeutic treatment by producing synthetic, vegetable, animal and biological chemical substances used for therapeutic, preventive and diagnostic purposes in human and veterinary medicine in accordance with pharmaceutical technology. One of the greatest social responsibilities of today's governments is to deliver health care services to their citizens in a quality and effective manner in order to protect and sustain public health. The fulfillment of this responsibility is only possible with a strong and effective pharmaceutical sector. Besides providing significant contributions in terms of economic development, it is also necessary to have a pharmaceutical industry capable of producing pharmaceuticals that meet the needs of the country in the face of factors such as war, epidemic diseases and possible embargo. (MIT, 2016)

In addition to this, the sector provides high value-added products due to its involvement in intensive R&D activities. R&D activities in the pharmaceutical sector that allocates the most resources to R&D in the world are extremely important for sustainable economic growth. (TEPAV, 2015) The pharmaceutical sector is an industry with the potential to provide significant contributions to the economic development of an individual country in terms of its own sectoral characteristics as well as having a great social significance. The industry is at the forefront of the sectors with the highest R&D intensity. Pharmaceutical products are high value-added products that are developed because of long and costly research and development activities.

In the pharmaceutical industry where the technological changes are very fast, the products produced are under patent protection. The pharmaceuticals that make difference due to the production technology, the activity or the type of treatment can provide serious market share to patent holders in a short period. Hence, having an effective and strong pharmaceutical sector will contribute to the increase of R&D activities, export and economic development by creating value-added and high-tech products.

Another feature of the sector is that there are many serious regulations and rules in almost every field. Pre-clinical and post-clinical studies have been regulated by steps such as regulatory, production, pricing and sales, standards set by international organizations, legal regulations of countries and serious regulations within the framework of social security policies. In addition to intensive R&D activities, these regulations are among the causes that increase pharmaceutical development costs and prolong investment processes.

2.1.1. Pharmaceutical Industry Value Chain

The pharmaceutical development or research process begins with a pre-discovery basic research phase. In this process, scientists try to understand the disease at the molecular level and identify valid target molecules. Once the necessary knowledge is accumulated about the mechanisms and effects that cause the disease, scientists identify biological targets or targets for potential new drugs. After the basic research, the discovery phase is started. The goal in this phase is to identify or improve a drug molecule candidate by clarifying the relationship of the selected target or targets to the disease and its effect on it. Candidate molecules that have successfully passed early reliability and optimization studies are carried to the next stage of preclinical studies.

Preclinical studies involve the identification of safe starting dosages before optimizing candidate molecules are tested on humans. In preclinical studies, laboratory tests and animal experiments are conducted to test the safety profiles of candidate molecules and to assess their effectiveness with toxicology.

With the completion of drug discovery, pharmaceutical companies begin clinical trials that another important step in the drug development process. Clinical trials consist of experiments on patients or healthy people. Because people are involved in the process, it is necessary to obtain permission from the competent authority of the country in order to start clinical trial. Clinical trials comprise of three basic phases. Each of these research phases, called Phase I, II and III, is aimed at verifying the information obtained from the previous phase and eliminating possible problems. In other words, in order to be able to pass the next phase, positive results must be achieved in those phases.

Phase I studies include reliability tests on 20-100 healthy volunteers. In Phase II, there are studies that measure the efficacy of the drug on a group of 100-500 patients with the illness developed for the treatment. If the results are come true expectedly, the phase III is passed, which is much wider and longer. In Phase III clinical trials, the efficacy and safety studies of the drug are continued on a population of approximately 1000-5000 patients. Phase III disease is considered the most important stage to decide whether the drug is effective and safe both in the short and long term. The other goal of the Phase III is to see if drug is superior to its competitors. Phase III clinical trials are the longest and most costly studies compared to other stages. After Phase I, II and III clinical trials, the developer company applies to the authorized body of that country with a file containing the results, analyzes and studies of all these phases in order to obtain the drug license. However, clinical trials that have been carried out after obtaining drug registration and entering the market are called Phase IV stage. Firms that develop drugs to introduce possible new adversities or side effects of the drug, which is being used by more and more people with the entry into the market, are obliged to observe the process and inform the competent authority at various intervals. These studies, which are made after the license acquisition, are also called pharmacovigilance studies.

The time from the early stage of the research to the mass production and the entrance stage of the market varies from 10.5 to 15 years on average. “Gassmann et al. (2005) estimated that pharmaceutical firms require, on average, 13.2 years bringing new drugs to market.” (Jeon et al., 2015). In the process, in addition to pharmaceutical

companies, universities, research centers and competent public institutions are involved. Studies have shown that the cost of drug research and development process is US $ 1.3 billion. However, DiMasi et al. (2016) point out that with increasing failure rates, this figure should be calculated considering the failure opportunity costs and it is about US $ 2.6 billion when calculated accordingly.

25% of the total R&D cost is spent on basic research and preclinical research while almost 60% is spent on clinical trials (Ding et al, 2014). The fact that production and licensing processes constitute only 6% of the total cost puts emphasis on the importance of R&D activities in a new drug development process.

It is possible to divide roughly two classes of products in the pharmaceutical industry. The new products developed because of the process described above and entering the market for the first time are called reference or original drugs. "The original drug is an international term used for new medicines based on long-term research and clinical studies based on a patented molecular basis, proven to have a positive effect on a particular disease" (Konca et al., 2015). Patents for reference drugs have a protection period of 20 years. On the other hand, it is called generic drugs that have entered the market after the end of patent protection of the original drug, have the same characteristics as the original drugs and have been scientifically proven to have the same effect. Generic drugs should have the same formulation and pharmaceutical form, containing the same active ingredient as the reference drug. Generic drugs are produced without long and costly expenses, so their prices are much lower than the original drugs. Therefore, generic drugs entering the market after the end of the patent of the original drug can increase their market share in a short period because the costs are much lower.

If there is not any profit for a limited period, new drug developers cannot meet R&D and regulatory agencies approval costs and incentives to develop new medicines will substantially reduce. Therefore, drug patent protection is particularly important regarding technical development (Oral et al., 2017).

With the development of technology, production methods are changing in the pharmaceutical sector as it is in many sectors. Especially, it can be said that the

technological developments in the field of biotechnology are the most widely used in pharmaceutical industry. Biotechnology can be defined as any application that uses living organisms, biological systems and processes to achieve a new product / process or to develop a product / process for a specific purpose. However, conventional drugs are small, relatively simple molecules that are usually produced as a result of chemical synthesis processes. Biotechnological drugs are drugs made from or made up of active substances such as proteins (growth hormone, insulin, antibodies) and other substances produced by living organisms (such as cells, viruses and bacteria). Since the final product needs to be purified from thousands of other molecules in the living cell or organism, the production process is complex and requires advanced technology.

Another stage special to the sector is pricing processes that can be seen as the last stage of the process. The price elasticity of the drug demand cannot be said to be high since drugs increase the quality of human health. Therefore, pharmaceutical manufacturers are able to take advantage of this low demand flexibility and offer high prices for products that they spend too much and that cannot be substituted. Price adjustments made in the pharmaceutical sector are designed both to regulate this incomplete competition in the market and to make it easier for each individual in the community to obtain the drugs. When examining drug price regimes worldwide, it appears that there are many policies ranging from completely free pricing to policies where the price is determined entirely by the government.

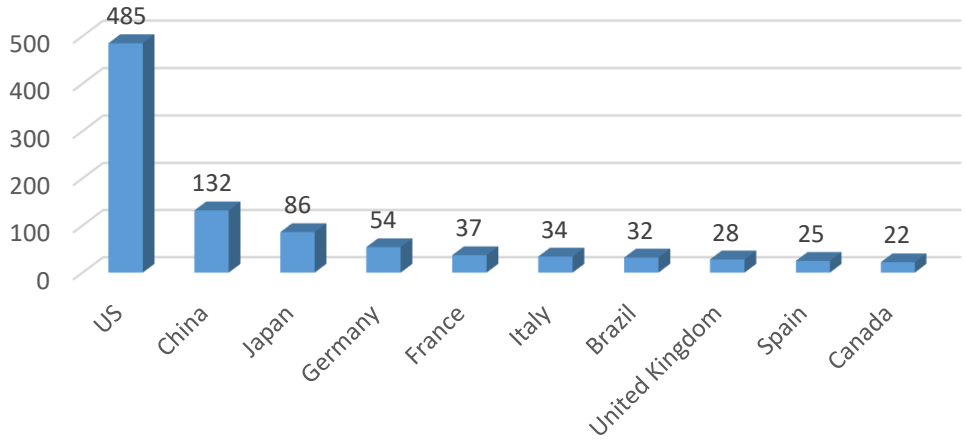
2.1.2. Pharmaceutical Industry in the World

Factors such as increasing world population and average life expectancy, new diseases and new treatment methods, demographic changes and the requirements of being a welfare state constantly increase the need for health services and pharmaceutical industry. In addition to the mentioned social benefits, the pharmaceutical industry is a knowledge-intensive industry with high value-added products, with a potential to contribute positively to countries' economic development, technology transformation and foreign trade performance. These social

and economic benefits have played an important role in the growth of the world pharmaceutical industry and its market.

According to Information Medical Statistics (IMS) data, the global pharmaceutical market has grown by an average of 6% since 2005, reaching a market volume of US $ 1.08 trillion in 2015. According to the IMS Institute for Healthcare Informatics (2014), global drug market size is expected to exceed US $1.3 trillion by the end of 2018 and now it reached US $1.2 trillion in 2018 (İEİS, 2019).

Figure 1. World Pharmaceutical Market, 2018 (billion US dollars)



Source: İEİS, 2019

As it can be seen from the Figure 1, The United States has the largest pharmaceutical market with a market size of 485 billion US dollars in 2018. One of the main reasons why the US has such a big market is that the US does not control the price of drugs in the pharmaceutical sector and that the free market economy rules in the sector are valid. The US is followed by China and Japan respectively. The fact that countries such as China, Brazil, Russia and India ranked lower in 2006 in the order of pharmaceutical market size, shows that the market has an expansion towards developing countries.

With a market size of over US $ 1 trillion, economies of scale is significant since the pharmaceutical industry uses high technology in drug development and production

processes, involves long and risky R&D activities, high cost of investments and many regulations. This has led to multinational companies having 95% of the global pharmaceutical market (IMS and Statista, 2014).

2.1.3. Global Trends in the Pharmaceutical Industry

Products and production processes are constantly changing with technological developments. There is a period in which markets and investments are shaped both quantitatively and qualitatively within the framework of these technological changes. It would not be wrong to say that pharmaceutical industry, which is technology intensive and has a lot of intramural competition, is affected from these changes much more and rapidly than the other sectors. Therefore, while setting policy, global trends in the sector should be studied carefully. Global trends that significantly affect the pharmaceutical industry can be grouped under different headings, in general, increasing R&D activities, biotechnology sector position, changing business models and sector locations in developing countries.

As mentioned previously, the cost of developing a drug exceeds $ 1 billion. A large part of the cost is constituted by basic research and clinical studies. Pharmaceutical companies which want to compete with the generic drugs that are entering the market every day and improve their product portfolio and keep their market share, have been increasing the number of R&D projects day by day. The number of these projects in the sector, which has been on a steady upward trend, reached 11.307 in 2014. Despite the increasing number of projects, studies show that the success rate of drug R&D activities is decreasing. This decline can be attributed to the fact that the projects are usually based on complex and challenging diseases such as cancer (TEPAV, 2015).

Conventional drugs give their place to biotechnological drugs. Global biotechnological drug market has been growing rapidly in recent years. Biotechnological drugs, which had a market of US $ 46 billion in 2002, reached a market value of US $ 163 billion in 2012 (Statista, 2019). On the other hand, the share of biotechnological drugs in total drug spending in the world in 2002 was 11%, compared to 18% in 2012 (Statista, 2019). Biotechnological drugs, which are more

complex, costly and large-molecule products than conventional drugs, offer more effective and safe treatment options and cure diseases that have not previously been treated. For this reason, innovative drug manufacturers can market their products at high prices and achieve significant gains with high demand. The leading companies in the global pharmaceutical market seem to shift their R&D activities and resources towards biotechnological products.

Differences in biotechnological drugs from conventional drugs also change the way the industry works. Recent developments such as accelerating genomic sequence analysis in life sciences and biotechnology, as well as widespread application of bioinformatics, allow elaborating studies on complex disease mechanisms and leading to personalized treatment. These new scientific approaches have led to in-depth basic research and the need for information infrastructure to change the business models of large pharmaceutical companies in the R&D process. The number of small entrepreneurs working in the life sciences and biotechnology-focused subfields has increased steadily. Small and medium-sized enterprises are inadequate in the clinical phasing and commercialization of these basic research outputs, although the success rates of basic research and discovery stages are higher than those of major pharmaceutical companies. Therefore, collaborations and mergers/acquisitions, between large pharmaceutical companies and small biotechnology companies have increased in this context.

2.1.4. Pharmaceutical Industry in Turkey

"One of Turkey's new growth strategies is to perform the transformation process to high-tech. In the transition to the information economy, the pharmaceutical sector is of great importance in this context. The pharmaceutical industry offers the opportunity to make Turkey's production and export sophistication splash. The way to use this opportunity is to transform the existing pharmaceutical industry with new technologies and to become a technology developer." (TEPAV, 2015)

Turkey's pharmaceutical sector is import-dependent in various stages of production and increases the current account deficit. Generally, generic drug production and

drug filling operations are performed in Turkey. On the other hand, there is no original or biotechnological drugs produced in Turkey. Recently, there have been several biosimilar drug production initiatives. Since drug industry involves emerging technologies such as biotechnology, it can gain a more important ground in Turkish economic development.

Turkey's technological priorities should be parallel to worlds'. The most important component of the new growth strategy should be to accelerate technological leap. A technology-oriented, selective industrial policy is the most important need to speed up the transfer of new technologies and to increase exports of advanced technology. The pharmaceutical industry is the best candidate to be one of the prominent sectors of the new growth strategy because of the opportunity it offers for the transfer of biotechnology (TEPAV, 2015).

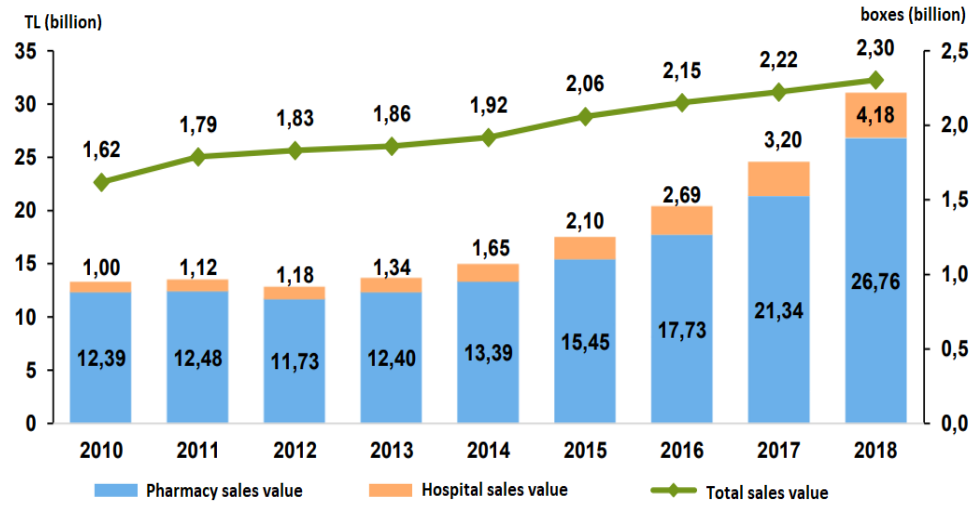
Turkey has recently transitioned from a low-tech structure to a medium-tech structure. However, the share of advanced technology is still very low. It is critically important to increase the share of advanced technology products in production and export so that they can reach their targets in the coming period and increase their competitive power in the global markets. Although the economic integration in the last 30 years has diversified production and exports, it has not yet achieved the transformation of quality. There is a need to diffuse new technologies that increase the quality of exports and to increase the share of advanced technology sectors in production and exports.

2.1.4.1. Position of the Turkish Pharmaceutical Industry

Turkey is the 17th largest pharmaceutical market in the world (İEİS, 2019). It consists of drug manufacturers and importers, pharmacy warehouses and pharmacies. Turkey's pharmaceutical market reached 30.94 billion value-based and volume of 2.3 billion boxes in 2018 (İEİS, 2019). When the growth rates of pharmaceutical industry in Turkey between 2010-2018 periods are considered, the increase in the value of the

market is about 131%; on the other hand, it is about 42,3% on a box basis (Figure 2).

Figure 2. Turkish Pharmaceutical Market, 2018



Source: İEİS, 2019

When we examine Turkish pharmaceutical sector in terms of economic actors involved in market, there are 71 pharmaceutical manufacturing firms (56 domestic), 77 drug manufacturing plants (60 local) and 12 raw materials facilities (6 local) in Turkey by 2015 according to Ministry of Health (MIT, 2015). In addition, there are many importing companies that offer drugs imported from abroad in Turkish market as a result of drugs registration process. When these are added, number of firms in the sector is 332 (295 domestic). Besides, there are 516 pharmacy warehouses, 85 representative pharmacies and over 24.000 pharmacies (MH, 2018).

When the concentration of the pharmaceutical industry in terms of the number of enterprises is examined; Istanbul, Ankara and Kocaeli stand out, while Istanbul, Kocaeli, Tekirdağ, Kırklareli and Ankara are in the first place when net sales figures are taken into account. It is seen that 60% of the market is located in Istanbul and more than 90% is in Marmara Region regarding net sales of the pharmaceutical industry (MIT, 2015). The list of the Top 500 Industrial Enterprises announced by the Istanbul Chamber of Industry (İSO) involves four pharmaceutical companies. On

the other hand, all of the world's 10 largest pharmaceutical manufacturers, which are the determinants of the global pharmaceutical sector, make sales to Turkish market. The first three of them US Pfizer, Swiss Novartis and France's Sanofi firms also carries out production in their plants in Turkey (AİFD, 2018).

Table 1. Original-Generic Product Breakdown in Turkey, 2010-2018

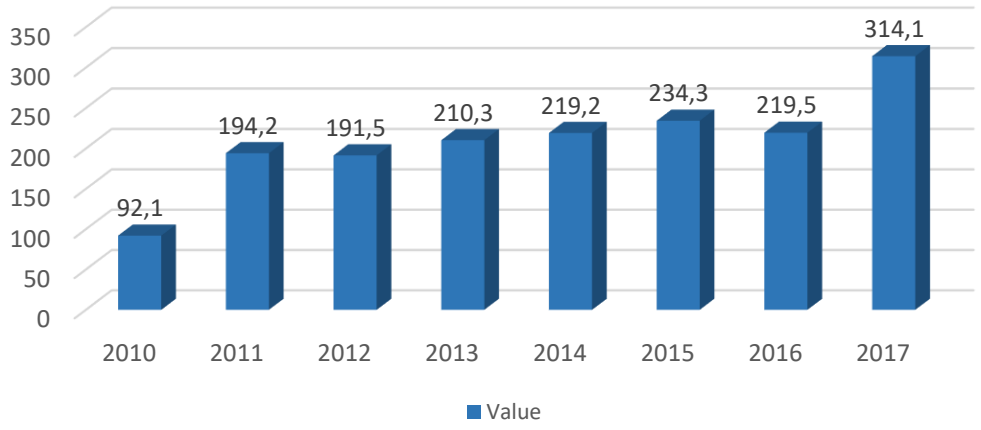
	ORIGINATOR PRODUCT				GENERIC PRODUCT			
	2010		2018		2010		2018	
	Import	Local	Import	Local	Import	Local	Import	Local
Box	38%	62%	37%	63%	5%	95%	2%	98%
(mn)	287	464	349	586	44	824	31	1.339
TL	77%	23%	74%	26%	10%	90%	4%	96%
(mn)	7.186	2.128	15.603	5.416	426	3.652	426	9.491

Source: İEİS, 2019

Although a significant portion of the pharmaceutical production is directed to the domestic market, pharmaceutical raw materials and finished drug exports are made in small quantities. The pharmaceutical sector export, which stood at US $ 474 million in 2009, showed a gradual upward trend until 2015 and reached nearly US $ 1,2 billion in 2018 (İEİS, 2019). On the other hand Turkey imports of pharmaceuticals is a more balanced trend in the period 2009-2016 and is approximately US $ 5 billion in 2018 (İEİS, 2019).

When we look at imported/manufactured discrimination of reference/generic products (Table 1), while there is a shift to import in reference drugs, it is to domestic production for generic ones. While 62% of in box basis and 23% in value of reference drugs produced in Turkey in 2010, these rates were 63% and 26%, respectively in 2018. On the other hand, 98% in box basis and 96% in value of generic drugs are produced in Turkey by 2018. This shows that Turkey is dependent on abroad for its more value-added and therefore more expensive reference drugs, and produces less value-added and cheaper generic products in the country.

Figure 3. Pharmaceutical Sector R&D Spending in Turkey (mn TL), 2010-2017



Source: İEİS, 2019

The pharmaceutical sector, which realized 92,1 million TL total R&D expenditure in 2010, increased its expenditure and reached to 314,1 million TL in 2017 (Figure 3). In addition, the share of R&D expenditures of pharmaceutical sector in R&D expenditures of total manufacturing sector is 5.82% (TurkStat, 2019). These rates are considerably below those of the leading countries of the global pharmaceutical industry.

Generic drugs constitute the main area of activity of Turkish pharmaceutical industry. In addition, studies are more often done for developing different combinations of molecules, different dosage forms, or generic products, rather than finding a new molecule or developing a new drug. There is no new molecule developed in Turkey yet.

A drug must be licensed to be marketed in Turkey. The licensing procedures for drugs are made according to the provisions of the "Regulation on the Regulation of Medicinal Products for Human Use" prepared within the framework of harmonization studies with European Union legislation. Turkish Medicines and Medical Devices Agency (TMMDA) has been authorized to granting of licenses and permits to drug sales, pricing, classification and examination.

The Ministry of Health determines the maximum prices by taking the necessary precautions to ensure that the medicinal products for human beings reach the consumer on appropriate terms. In the pharmaceutical sector, which is subject to intensive regulation, prices have been set within the framework of the reference price system since 2004 and are now set out in the Decree No. 2017/9901 on the Pricing of Medicinal Products for Human Use.

The reference price is the lowest official warehouse-selling price, excluding discounts, of the EU registered reference countries or the reference to the market in which the product is licensed and in the ongoing membership period. However, if the country in which the product concerned is manufactured or imported is outside the reference countries and there is an official warehouse price set in these countries below the reference country prices, the price in the country where the official warehouse selling price is lower is accepted as the reference price. At present, the cheapest selling prices of a drug in the reference countries of France, Italy, Spain, Portugal and Greece are set as reference. Additional discounts are introduced to the prices of the drugs entering the reimbursement list and finally the final retail price is reached by adding 8% VAT to the premium rates of the warehouses and pharmacists.

2.1.4.2. Localization Program

The drug localization program run by the Ministry of Health is not a direct support program but a program that has indirectly affected the drug industry and has recently been implemented. This program is a policy tool for the pharmaceutical sector. By this program, drugs imported from abroad are intended to be manufactured in Turkey gradually, considering security of supply in the market. Imported drugs were collected under 5 different groups according to the manufacturing rates and the number of equivalent drugs in the market. Starting from the first phase, it is proposed that foreign drug manufacturers are allowed to produce drugs in Turkey. Companies that do not commit to localization in their medicines are reported to the firm to be removed from the reimbursement list. It is planned not to be a direct production support but to increase the number of products produced domestically through the

reimbursement list. The Ministry of Health aims to reduce foreign trade deficit, increase domestic production, increase capacity utilization rates of existing factories and hence employment by means of drug localization program.

2.2. Industry 4.0-The Fourth Industrial Revolution

2.2.1. Historical Development

With the invention and spread of the printing press, the literacy rate increased, the scientific studies showed itself in every field, and according to the old periods, the world completely differentiated. In other words, scientific life illuminates the whole world and has created radical changes. In the second half of the 18th century, these developments and changes were maintained by increasing the importance of industrial revolutions. (Schwab, 2017)

The first revolution in history took place in agriculture. It is the first social revolution realized by human beings in the establishment of the agrarian society. When we look at the history of humanity, it is seen that there has been a very long period of transition from the agricultural revolution to the industrial revolution. The industrial revolution emerged as three major changes. The name of the first industrial revolution, which began in 1750-1890, is also known as the Age of Steam since steam engine is invented in the beginning of the period. In this period, the weaving industry developed and the changes in metallurgy were realized. This great revolution has enabled the mechanical production by the construction of railways and the contribution of steam engines.

Economy before the Industrial Revolution was based on the factors of production composed of human, animal and soil. Featured sectors were agriculture, animal husbandry, carpentry or smiting. With the Industrial Revolution, the effect of new inventions on production and the production of steam-powered machines gave rise to the mechanized industry enabled mass production. (Drath and Horch, 2014).

The second industrial revolution emerged in the late 19th century when electricity was used in production and electrical power guided the assembly lines. In the beginning of the second industrial revolution, the electrical systems installed in Ford Motor plants became more effective. Thanks to these systems, mass production was started and this led to a decrease in costs and prices due to the increase in production volume (Eğilmez, 2017). In this period, which is called Fordist Period, it was aimed to produce cheaper automobiles as a result of production with flexible and high efficiency (Weckbordt, 2015).

The second industrial revolution has also led to the dissemination of electricity, science-based chemicals, telegraphy, and the discovery of the telephone and communication technologies. In this industrial revolution, the importance of scientific knowledge emerged (Castells, 2013).

The spread of scientific information-based communication technologies has also triggered the emergence of the third industrial revolution, the next industrial revolution. With the onset of the third technology revolution, developments in nuclear, computer, microelectronics, laser and genetics have emerged (Akbulut, 2011). In the period when the mass production was done with electricity, the development of both the mechanical and the electronic fields, the devices that know the programming with digital technology and the information technologies have emerged.

In the mid-20th century, heavy industry and information technology developments were experienced and new economic terms such as information society emerged. This situation has made possible the development of fiber optics, chip technology and atomic energy, and microelectronic technology production (Yücel, 2004). Programmable machines developed in 1968 with the more active use of scientific knowledge led to the beginning of the third industrial revolution. In fact, with the use of computers, production became easier and the need for human labor decreased. In addition, the widespread use of the internet and the increase of transportation opportunities have affected the production positively.

When the three industrial revolutions are evaluated together, it is seen that the times between the breakthroughs are shortened and the need for labor is decreased in every new industrial revolution. Therefore, the substitution of human labor with capital has increased the power and importance of capital. In other words, the labor-intensive technology has been replaced by the capital-intensive technology and the industrial revolutions have emerged (Özkan et al, 2018).

Changes in the industrial revolution, mechanical and microelectronics developments have led to the formation of an information society. An information revolution has emerged along with the communication sectors and has been involved in computers. Japan and the US have made a rapid progress in this process and became a leader in the field of technology. This situation caused the developed countries to become an information society and affected their economic structures. Together with the information revolution, companies and institutions have entered into a restructuring process. With the acceleration of the globalization process, there has been a transformation that is compatible with technology all over the world and the formation of the information society has been ensured (Erkan and Erkan, 2007).

In the 3rd stage of the industrial revolution, producers have continued with their production understanding in the second stage of it. The basic goal in the background is to make life easier. Different machines and tools developed in different areas from household appliances to transportation. However, in the early 1970s, the automation of the electronics and information technologies, increased the automation of the production and brought the new dimensions to the advanced stages. Especially in the 1980s and 1990s, it has brought different approaches in production processes. The market has grown and became more competitive. In the face of these developments, industries have focused on specialization, and efficiency in production,

Computers are now very advanced, while the desktop, turned into the form of laptops now they are in our pockets. More importantly, computers have become more and more accessible to everyone without knowing any programming language. In the same way, the development of microchips has been realized rapidly and has contributed to this process. Of course, this process has gained even momentum with

the spread of the internet. With the addition of mobile technologies to these developments on computer and internet, a new and different period has been entered. The world has become smaller and the concepts of time and space have gained new meanings.

After these new developments, production patterns have changed and supply chains have expanded. With the development of computer programs, design activities have diversified. Computer-aided design, advanced technology production and increased automation in production, have opened a new era. Customer satisfaction has increased to a high level thanks to the designs made easily and rapidly in computer environment. Undoubtedly, this process has been added to the developments in other branches of science, interdisciplinary studies have increased; mechanical tools have been enriched with electronic elements. As a result, the structural features of the industry and all the processes have undergone significant transformations. Mass production has lost its meaning; consumer-specific production has come to the fore. Finally, the developments in information and communication technologies in the third stage of industrialization indicate that a period has ended and a new period has been entered. This rapid development, with a broad alliance of industrialization has entered the fourth stage, "Industry 4.0" (Özsoylu, 2017)

2.2.2. The Fourth Industrial Revolution-Industry 4.0

The Fourth Industrial Revolution, also called Industry 4.0, provides the interaction of virtual and physical production systems by revealing smart factories. In this way, products can be made more customer-specific which in turn creates an increase in consumer benefit (Schwab, 2017). This revolution makes the products more qualified and increases productivity and changes the customers' demands.

Furthermore, on the production side, industry 4.0 is a collective term that involves many modern automation systems, data exchanges and production technologies. This revolution is a set of values consisting of the internet of objects, services of the internet and cyber-physical systems. At the same time, this structure plays a major role in the formation of a smart factory system. This revolution will allow more

efficient business models to be created in the production environment, as each data will be collected and well monitored and analyzed (Özkan et al, 2018).

The fourth industrial revolution, which is still in its infancy, provides the basis for all actors involved in industrial production to communicate with each other, to reach all data simultaneously, and to create high added value through these data. With the spread of information technologies and automation, cyber physical systems have reached a new stage where dynamic data processing and value chains are connected to each other. With the integration of sensors, production tools and information technologies, industrial chains have formed beyond a single company (Özsoylu, 2017).

As can be seen from the developments, the fourth stage of industrialization is not limited to intelligent and connected machine systems, but also from gene science to nano technology, from renewable energy to different branches of health and social sciences. With the concept of Industry 4.0, information infrastructure has come to the fore and new concepts have been added to daily life. The concepts, which were previously known only, whose names were not known, were thought to be discussed only in the related fields of engineering, and came into daily life with the flow of Industry 4.0.

The biggest innovation that Industry 4.0 brings to the economy is the elimination of high efficiency / efficiency through software, which is not in the technology, by the brain, which is not in the technology and in the human. As a result of this, the economy was reflected as an increase in production and new job fields emerged. However, it is generally stated that the complexity of factory workers and interpersonal communication will remain in the shadow of change in production (Blum, 2016).

Although digitalization is not fully utilized in the production process, the rapid spread of mobile networks and the Internet, the use of machines with artificial intelligence and their further development and integration has led to the beginning of the fourth industrial revolution (Schwab, 2017). More clearly, this last industrial revolution has

significantly expanded the use of computers in production and highlighted the use of high technology (Eğilmez, 2017).

The fourth industrial revolution is developing much faster than other industrial revolutions. In addition, it brings together various technologies and causes serious paradigm shifts in the economy and society. This in turn transforms the whole society, countries, companies and sectors. The difference of this revolution from the previous ones is that the developments in technology are intertwined with each other, they act in a coordinated manner and all areas are affected together (Schwab, 2017).

In the Industry 4.0 conversion, sensors, machines, work pieces and IT systems are connected beyond a single enterprise along the value chain. Cyber-physical systems can interact with each other using standard Internet protocols; they can analyze the data to predict errors, build themselves and adapt to changes. Industry 4.0 enables faster, more flexible and efficient processes to produce better quality products at lower costs by enabling data collection and analysis between machines. With this contribution, it will change production efficiency and economy; it will encourage industrial growth and change the profile of the workforce (Rüßmann et al., 2015).

Industry 4.0 combines the strengths of traditional industries with the most advanced internet technologies. It incorporates technologies that enable the integration of smart products with intertwined digital and physical processes (Schmidt et al., 2015). The vision of Industry 4.0 is to realize the internet of objects and to provide a high level of flexibility and adaptation of the production systems in the factory context (Weyer et al., 2015). The cyber physical system consists of components that exchange information, trigger actions and control each other independently.

On the other hand, there is much debate about the negative effects of the industrial 4.0 revolution. Negative effects of new technologies on employment, growth etc. are also important issues to be addressed.

The globalization of the world economy allowed the liberalization of capital movements and the displacement of production (Özkan et al, 2018). Developed countries have shifted their production to countries where labor is cheap, mainly due

to cheap labor and tax advantages (Eğilmez, 2017). Thanks to globalization, investors in developed countries have reduced their costs by benefiting from cheap labor, while developing countries have been able to use their economic potential in such matters as growth and employment. However, the development of automation in production has reduced the importance of cheap labor in developing countries. This situation; This means that developing countries may lose this advantage and experience serious problems in employment and growth rates (Özkan et al, 2018).

John Maynard Keynes warned about widespread technological unemployment "*due to our discovery of means of economizing the use of labor outrunning the pace at which we can find new uses for labor*" (Schwab, 2017). However, the increase in income increases the demand for new products and services, and this results in the employment of unemployed workers in the fields of work to produce new goods and services (Kazdağlı, 2015). While technological advances have resulted in the substitution of capital instead of labor and the unemployment of the workers, the increase in demand for new products and services requires the emergence of new jobs and the employment of workers in these new jobs (Schwab, 2017).

In addition, increases in productivity that may arise in connection with the fourth industrial revolution in developed countries may lead to reduce the competitiveness of developing countries in global terms (TÜSİAD, 2016). Countries with high production costs, using the large scale of high-tech enterprises; countries with low production costs will strengthen their competitive positions in the global arena by using easier access to new technologies(TÜSİAD, 2016).

On the other hand, Yalçın (2018) states that transition to industry 4.0 at regional level; the difference in the level of socio-economic development between the regions will grow, the dual structure of the industrialization process has been replaced by the triple structure and regional dualism problem may lead to even more serious dimensions.

Schwab (2017) stresses that on a global scale; as men continue to dominate, the new industrial revolution, such as computer science, mathematics and engineering, increasing demand for specialized technical skills can further increase gender

inequality. When the imbalance in the use of information technologies cannot be solved within the framework of industry 4.0, it will deepen the gender gap by increasing the demand for information technologies and decreasing the participation of women in the labor force (Yalçın, 2018).

On the other hand, cyber-attacks are a major threat for both countries and companies due to the internet-based generation of new Technologies. For example, "Northeast Outage 2003", which affects 50 million people and has caused $ 6 billion in loss, was identified as a bug in the software used in the energy management system (Karabacak, 2011). Even if the transition to Industry 4.0 is fully achieved, deficiencies in cyber security measures will be a threat to the entire system (Yalçın, 2018).

According to the Frey and Osborne (2013), the world faces an immediate governance challenge while building new mechanisms to shape the development and implementation of new technologies. How to manage rapidly evolving technologies is a complex question: regulating it too quickly can reverse progress, but lack of governance can increase risks and create uncertainty that is of no use to potential investors and innovators (Fırat, 2017).

2.2.3. Nine Technological Factors Triggering Industry 4.0

2.2.3.1. Big data and analytics

Systematic data analysis is important in many ways, from the optimization of product quality to energy efficiency, the efficient use of machinery and equipment, and the development of service. In Industry 4.0, data from different sources are gathered for real-time interaction and decision-making that they are evaluated comprehensively. Production equipment and customer management systems are standardized (Rüßmann et al. 2015).

With the increasing use of electronic devices, the importance of big data is increasing. The big data concept is an important institutional power parameter and a new

business system or platform that offers a large number of resources from various sources to obtain added value and offers more features for collecting, storing and analyzing data in bulk.

According to Özsoylu (2017) big data offers very important opportunities. There are three significant values that can be achieved primarily: Reducing costs, improving decision-making, improving products and services. When interpreted with the right analysis methods, big data will provide the foundation for the enterprises to be more accurate in their decisions, to better manage their risks and to dare to innovative breakthroughs. Considering the fact that the right strategies can only be produced based on the correct information, the importance of big data for Industry 4.0 is also evident. Companies that use big data for accurate purposes will come to the forefront in the competition battle, productivity will increase, costs will be reduced, procurement methods will develop, customer relations and marketing insights will become more effective.

2.2.3.2. The internet of things (IoT):

The IoT provides a platform that enables devices to be remotely connected, detected, and controlled over a network infrastructure. It is known that a significant portion of the physical objects does not have a network connection. The IoT ecosystem and machine-to-machine communication (M2M) technologies are intended to monitor and control these objects on the network (Oral and Çakır, 2017).

The IoT, though not compromised, is defined as "a world-wide network of uniquely addressable objects, and a network of objects in this network communicating with each other through a specific protocol (Yetimler, 2019)." It is also possible to define a system of devices that communicate with each other through a variety of communication protocols, connect to each other, and create a smart network by sharing information (Özsoylu, 2017).

At a relatively small number of production facilities, machines and sensors are interconnected to create an embedded system. Along with the Internet of industrial

objects, more and more production vehicles will be connected to each other in a vertical and horizontal manner and will be in real time interaction (Rüßmann et al. 2015: 4). Sayar and Yüksel (2018) suggest that IoT can directly contribute to improving products, services, customer experience and security. Network sensors have the potential to transform conventional commercial-customer interactions in a non-previously designed form when integrated in various electronic devices and / or machines to exchange data or information in real time.

Today's construction is generally structured in the form of vertical automation pyramids, where sensor and field devices with limited artificial intelligence and automation control mechanisms are connected to the overall production control system. The Internet of Things, however, will allow even more devices, even semi-finished products, to connect to each other through standard technologies to take advantage of integrated data processing. In this way, the equipment in the field will be able to communicate with each other and, if necessary, with the central control systems. It will also enable real-time decision-making processes, eliminating the requirement for a single-handed analysis and decision-making process (TÜSİAD, 2016).

2.2.3.3. The cloud

Increasing the density of data transfer with Industry 4.0 will require more data sharing across cross-border facilities and company boundaries. The performance of cloud technologies will develop with a reaction time of several milliseconds. The sharing of machine data and functionality will be spread over the cloud and more data-based services will be provided for production systems (Sayar and Yüksel, 2018).

In the simplest form, cloud computing is defined as receiving services related to information systems from third parties (Özsoylu, 2017).

Thanks to the development of cloud computing technology, the availability of large data on the Internet has become possible. In line with these possibilities, the big data

definition which is one of the building blocks of Industry 4.0 has been applied in the industry.

TÜSİAD's study (2016) implies that companies are currently using cloud-based software for some enterprise and analytics applications. However, in the coming period, more data on products will need to be shared between facilities and companies. At the same time, thanks to the increase in the performance of cloud technologies, the response time will drop to a few milliseconds. As a result, the data and functions of the machines in the cloud platforms will increase and more services will be provided to the production systems based on data. Even systems that follow and control processes will not be surprised even to move to the cloud. Nowadays, manufacturing executive systems are already offering similar cloud-based solutions.

Regardless of whether we are talking about apps used simultaneously by millions of people, or improving medical care with intelligent pills, or mobile applications that deliver safety-critical real-time information, or breaking down local IT barriers so that staff can work together efficiently across national borders: All of this relies on the cloud to function.

The infinite amounts of data can only be collected and stored with the cloud technology. The significance of the cloud continues to increase for all industries. Nearly %71 percent of ICT companies use cloud solutions in 2015 shows that use of cloud technology is going to rise on over the next few years (Abolhassan, 2017).

2.2.3.4. Autonomous robots

Robots are expected to play the most active role in production in Industry 4.0. Since it is desirable to install more flexible tasks to the robots, robots should be more autonomous and more collaborative every day. They are expected to interact with each other and to work confidently with people. Thanks to the robots, production costs will be reduced and production capabilities will be wider in the future (Rüßmann et al. 2015).

Manufacturers in various sectors have been using robots for a long time in their operations. Robotic technology in the world is now becoming more autonomous, flexible and co-operative by improving its competencies and reducing the cost of ownership. In the following period, the robots will increase their interactions with each other, will work more safely with people and improve their learning abilities (TÜSİAD, 2016).

Autonomous robots can test, pick, pack, sort, build, inspect, or transport materials of various sizes and weights faster and more efficiently than ever. As technologies have advanced, robot setup and implementation is getting faster and easier than ever before. Learning models are becoming more intuitive, allowing any technician or employee to "train" an autonomous robot in a matter of minutes or hours.

2.2.3.5. Simulation

Simulations with Industry 4.0 are expected to be an integral part of their operations. Simulations present the physical world in production in virtual environments. Thanks to the simulations, machine settings, machine installations, layouts of production tools and equipment can be tested and optimized virtually (Rüßmann et al. 2015).

At the moment of design, 3D simulations of products, materials and production processes are utilized, but in the future, simulations will become more widespread in factory operations. These virtual models, based on real-time data, will provide the virtual reality of the physical world with machines, products and people. In this way, the operators will have the opportunity to test in the virtual world before setting the machine parameters for the following product on the production line, reducing machine installation time and improving quality **(**TÜSİAD, 2016).

2.2.3.6. Horizontal and vertical system integration

With Industry 4.0, companies, divisions, functions and capacities will be more compatible with cross-companies, universal data networks and machine-oriented value chains (Rüßmann et al. 2015). Horizontal integration across value networks is

the integration of different IT systems that are used in different stages of business planning processes, including the production stages involving the exchange of materials, energy and information between different businesses as well as different businesses.

Thanks to Industry 4.0 in which horizontal and vertical integration takes place, a change in production processes is quickly answered and a problem can be solved much more quickly when a problem is encountered. It can provide customer-specific and personalized production easing, increasing resource efficiency, optimization in the global supply chain.

2.2.3.7. Cyber security

The wide network and high-rate data sharing with Industry 4.0 will rapidly increase the cyber security demand of the companies. For this reason, large companies need an adapted risk management system and safety strategy for cyber security. Companies aim to develop operational safety and protection so that their earnings are not adversely affected.

Industry 4.0 technologies also trigger hackers with new ways of data theft. Therefore, large companies may believe that the threat of cyber risk will increase and solutions must be sought. Intelligent production systems, data sharing, and viruses that can disrupt large data networks can have very bad effects on companies' production facilities. However, large companies think that these risks can be prevented around advanced risk management and safety strategies.

The security of critical systems and production lines against cyber threats that will increase with the connection and communication protocols that come with Industry 4.0 is very important. The safety of machines and users when providing security; access management, advanced identity security, communication systems are based on (Rüßmann et al. 2015).

2.2.3.8. Additive manufacturing

With Industry 4.0, businesses will work with additive production tools such as the use of 3D printers. Small batch of specialized products such as complex or lightweight design with additive production methods can be easily produced (Rüßmann et al. 2015).

3D printers are machines capable of producing three-dimensional objects, each of which can be constructed with layers built on a previous layer. With the help of 3D printers, consumers will be able to be producers, workers and intermediary costs will be eliminated. Thanks to the three-dimensional production, rapid prototyping and model production will be possible, so the release of the products will accelerate, stock cost will be minimized and production will be cheaper (Özsoylu, 2017).

2.2.3.9. Augmented reality

In the virtual world, operators can interact with their machines and modify their parameters by clicking on a cyber-button. Operational data and maintenance instructions will be possible. Due to these advantages, companies will use augmented reality to develop decision making and business procedures (Rüßmann et al. 2015).

Systems that benefit from augmented reality support various services, such as selecting parts in the warehouse and sending repair instructions to mobile devices. Although these systems are in their early stages, they will benefit more from the enriched reality in the future in order to improve companies' decision-making and operation processes and deliver real-time information to their employees (TÜSİAD, 2016).

2.2.4. Industry 4.0 in Turkey

In a study conducted by TÜSİAD and Boston Consulting Group (BCG) in 2016; industry 4.0 applications in automotive, white goods, textile, chemicals, food and

machinery industries were examined. According to the study; information and material flow, integration with suppliers, simulation of the product and production process at the design stage, smart products that increase flexibility and predictability in production and production lines come to the forefront as opportunities. During the interviews with industry representatives, it is said to be observed that there is a high level of awareness about opportunities, and many industrial organizations have already begun to move forward at different levels of maturity in industry 4.0 applications. The common conclusion is that it is believed that the transformation process can be achieved only with the contribution of all stakeholders and the establishment of holistic policies (TÜSİAD, 2016).

According to the analysis conducted by BCG within the scope of the same study, industry 4.0 applications are expected to trigger an increase of up to 3% per year in industrial production. This GDP growth of 1% and above in Turkey means additional revenue growth and an additional 150-200 billion TL. In addition, it is estimated by the study that Turkish producers should invest approximately 10-15 billion TL annually in the next decade to incorporate the industry 4.0 technologies into the production process. Finally, it is expected by the study that with low-qualified employees replacing automated systems the rate of exposure to this change will be 20-30% at certain points of the value chain in the long term. However, the possible increase in production efficiencies in other countries with the fourth industrial revolution may reduce Turkey's competitiveness in a global sense (TÜSİAD, 2016).

On the other hand, according to a report published by TÜSİAD in 2017, in order to measure the digital transformation level of competence of companies that use technology in Turkey, to identify the areas of competence of technology supplier companies and to determine the point to be focused, a comprehensive research was conducted with 108 technology users and 110 technology suppliers companies.

According to the results of the study; there is a high level of knowledge and interest in digital transformation of companies, but the proportion of companies thinks that they are ready for transformation is relatively low. In addition, industrial companies are in the process of implementing pilot projects in the fields of digital transformation

and companies have low competence in determining strategic road maps in Turkey. The research suggest that digital transformation competency levels of large scale companies are higher than small ones and the biggest obstacles to digital transformation are high investment costs and uncertainty of return on investment.

In this context, the study driven by TÜSİAD suggests that leading the investments according to the target and prioritizing technology investments that are easily accessible and quick to apply, identifying the problems that may be encountered in the way of transformation and taking the necessary measures, the successful completion of institutionalization of domestic suppliers and the development of mechanisms to eliminate the communication gap between the supplier and user companies are the most important issues to be considered (TÜSİAD, 2017).

The former minister of Ministry of Industry and Science (MIT) Faruk Özlü (2017) states that in the Turkish industry, the majority of which is composed of SMEs, the added value of employees in manufacturing is one third of the EU average. Therefore, he draws attention to the fact that the productivity in the industry is much lower than that of the EU countries, and that the industrial 4.0 revolution could further deepen this gap if the necessary priorities are not taken (Özlü, 2017). Medium and high-tech products constitutes the 30% of Turkey’s manufacturing and 37% of exports, it is 63% of EU’s exports. Therefore, since digitalization could affect the high-tech sectors more than others it is critical to adopt new technologies to increase our high-tech products and exports (Özlü, 2017). According to the former Minister (2017), to reveal the digital transformation of Turkish manufacturing industry, capacity for generating technology should be supported and a sectoral perspective in industry 4.0 must be formed.

Bulut (2017) states that in order to increase the strength of Turkey's ability to compete on a global scale, the development of new technology products and increasing exports of technology has a vital importance. Priority measure that can be done within the industry 4.0 for Turkey's economy is to create a commission for the fourth industrial revolution as well as Germany and the United States have done. The primary objective of this commission should be to determine exactly the measures to

be taken in Turkey for Industry 4.0, the direction of R&D expenditures and innovation (Bulut, 2017).

Koca (2018) states that in order to prevent Turkey from missing the train in this new industrial revolution, techno parks should be established; in particular companies should establish industry 4.0 departments and employ 4.0 industrial engineers in these departments. Compared to neighboring countries Turkey has a comparative advantage in many areas that it is possible to increase the speed of growth of the economy with the industry's 4.0 (Koca, 2017).

Sayar and Yüksel (2018) suggest that with the Industry 4.0 transformation in the public sector; error rates, wastes, waiting times and paper usage will be reduced and processes will be simplified, quality level of public services will be increased and government spending will be greatly reduced. He also states that all units, processes and operations of the government will be monitored in real time, most processes will be automated thanks to artificial intelligence applications, resources will be managed in an optimum level and real-time reports will be obtained for investments.

The literature review on Turkey's position to industry 4.0 indicates that Turkey is at the beginning of the technological transformation journey yet. It is understood that each sector needs to be examined separately in this journey; however, it is necessary to have a total work throughout the country in order to realize the transformation with the participation of all actors like public and private sector and universities.

2.3. Pharma 4.0

With usually used name Industry 4.0, fourth industrial revolution has started to affect pharmaceutical sector’s nature of work as well as many other industries. International Society for Pharmaceutical Engineering (ISPE) introduced the concept of “Pharma 4.0” to apply Industry 4.0 concepts to pharmaceutical manufacturing in 2017. Therefore, pharma 4.0 is being used as a term for describing Industry 4.0’s pharmaceutical applications. In other words, pharma 4.0 is the convergence of

patient, physical systems, and data analysis in an industrial process to increase quality of life and productivity (Markarian, 2018).

Actually, Pharma 4.0 is called an industrial revolution; however, its applications are expected to more likely represent an evolution that digitalization and automation encounter very complicated products with long life cycles. Thus, achieving a common understanding of readiness and maturity is crucial (ISPE, 2019).

Main goal of Pharma 4.0 movement is to bring pharmaceutical processes to perfection with more efficient and faster way. By using new technologies; productivity and increase in profits is expected while human mistakes, physical pharmacovigilance problems and communication problems decrease in manufacturing phase. Digitization will enable faster decision-making by connecting whole systems, provide real time control over business and create new transparency modes by safer way. As a big development, personalized treatment is possible in this new age. Hence, these innovations will ensure the excellence in operation and process quality (Gilchrist, 2016).

We are on our way to a digital world as fast and unpredictable as ever. It is expected that there will be more knowledgeable patients who can monitor themselves in this digital world. Body sensors will change the physical structure of the people; will bring the discomfort to the health center immediately and the clinical findings obtained quickly. According to the patient's genetic structure, physical values and medications used 3D printers prepared by the patient can be presented to the patient very quickly. Surgical operations can be performed fast and flawlessly with robots, and medical problems can be improved very quickly with wearable technological products. Thanks to Artificial Intelligence, we will be able to manage Pharmacy management, inventory counting and determination ordering strategies, patient information and interpretation (Ener, 2018).

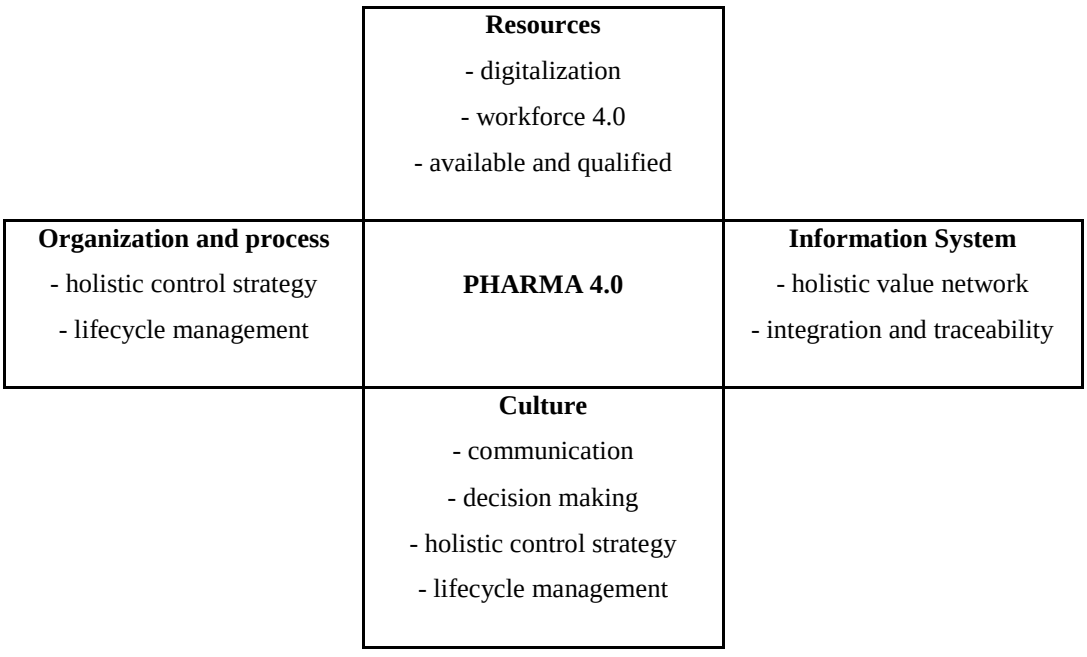
Modern information and communication technologies such as cyber-physical systems, big data analytics and cloud computing can provide early detection of production errors. Thus, steps can be taken to prevent errors in advance. On the other hand, when more databases are integrated with cloud technology, security issues can

be seen as an obstacle to adopting the new technology. Therefore, it is important to ensure that all databases are adequately protected with industry 4.0 technologies too (Guilfoyle, 2018).

The pharmaceutical industry is one of the sectors where regulation is very high. Therefore, it offers many opportunities for digitalization. Since the development, testing, production, packaging, marketing, storage, distribution and use of a pharmaceutical is subject to review, it is very important to collect, analyze and report data at each stage (Guilfoyle, 2018).

ISPE's Pharma 4.0 Special Interest Group (SIG) has developed an operating model for moving from Industry 4.0 to Pharma 4.0, which is shown in the image below. According to Pharma 4.0 Operating Model (Figure 4) for the factories and the supply chains of the future created by ISPE initiative driven by the Special Interest Group, there are four main components of the model introducing the process from Industry 4.0 to Pharma 4.0. The model is specific to pharma industry that provides a maturity model. It suggest an integration of resources, organization and processes, information systems and culture in the pharmaceutical company.

Figure 4. From Industry 4.0 to Pharma 4.0 Operating Model



Source: ISPE, 2019

2.3.1. New Technologies of Pharma 4.0 and Applications

With the introduction of Industry 4.0 technologies in various areas of the pharmaceutical sector, some technologies specific to the pharmaceutical industry have also been developed. Thanks to basic industry 4.0 technologies, more specific and individualized systems have started to be developed. There are many technologies that can be applied to all the processes the pharmaceutical goes through from the production process to the pharmacy's shelf. Some of them are listed below.

- **Robotic Process Automation (RPA)**

In other words, Automated Process Control (APC) or Smart Manufacturing means advanced production technique, which comprises IoT, machine learning, high-level data analytics by artificial intelligence, cognitive computing, cloud technologies etc. This development is able to complete complex tasks much more efficiently, profitable and safer by comparison traditional automation methods.

Leader global pharmaceutical companies have already started to change their production site within new concept. For instance, Pfizer is moving towards "connected manufacturing plants" that make data visible and available on demand. Merck seeks to connect "smart factories" for responsive and adaptive manufacturing. Finally, Sanofi is using collaborative robots, augmented reality, and paperless operations in their manufacturing site (Markarian, 2018).

- **Digital Twins**

The digital twin of a product is a virtual replica of the product that exhibits its behavior in the real physical world. Digital twins help us identify problems, test new settings, simulate all kinds of scenarios, analyze what we need to analyze, and do virtually everything we need to do in the physical world on the virtual product.

The creation of digital twins of patients for the healthcare industry can be used in many fields from drug interactions to predicting the consequences of possible treatments. As one of the leader life science industry managers, Docherty suggest that digital twins technology could be a "game changer" (Markarian, 2019). This

technology has the potential to create radical transformation in many areas of the pharmaceutical industry from patient care to production. As a pioneer company, Sanofi has already started employing “digital twins” to simulate biopharma production processes (Markarian, 2018).

- **Data Analytics, Drug Development & Discovery**

Data analytics is a process which using the “Big Data” collected. Senior partner at McKinsey stresses that the pharmaceutical sector is based on scientific knowledge and produce more data than other sectors as a result of R & D and clinical studies. Appropriate use and filtering of this data ensure optimization and control of the work. Actions can be performed much faster to correct potential errors or improve the situation. Data and analytics advisor from Lilly company states that their company’s digital plant called smart manufacturing is largely driven by analysis of data and the communication of what adjustments need to be made based on the results of the data analysis (Markarian, 2019).

From another perspective, pharma 4.0 can also be used effectively in diagnosis, treatment and follow-up. Health data of individuals of various diseases with embedded algorithms and system bases predicting risk situations; disease-related measures can be obtained. Health personnel through artificial intelligence and algorithms redirected; misdiagnosis and treatment will be prevented. Thus, errors that may occur during diagnostic processes will be minimized.

- **Omnichanel Communications**

This is an opportunity for marketing and medical communication activities of pharmaceutical sector that involves real time connections, public survey or alarm systems from patient to physician with a smart device (phone, watch, etc.) application.

- **Wearable Technology**

Patients can provide a continuous data stream to help drug companies and providers better understand medical conditions, responses to treatment and potentially improve medical outcomes with wearable technologies.

People with wearable devices or smart phones are instantly monitored by health care facilities; early interventions can be made without increasing risk levels. While individuals' life expectancy and quality of life increase, government expenditures will decrease (Sayar and Yüksel, 2018).

- **Personalized Care**

The route of administration and amount of the pharmaceutical will be optimally regulated taking into account all the individual characteristics of each patient. Thus both wrong and overdose pharmaceutical use will be avoided; in addition, pharmaceutical import expenditures of Turkey will be reduced by preventing pharmaceutical waste. (Sayar and Yüksel, 2018)

3D printers will make progress in personalized treatment with customized pharmaceutical production. In March 2016, the US Drug and Food Administration approved the first pharmaceutical produced with a 3D printer. Spritamlevetiracetam, which reduces seizures in epilepsy patients, was produced using 3D printers. All the active and non-active components of this drug produced by the American pharmaceutical company Aprecia were combined with a tablet machine with a layer-by-layer 3D printer. With this development, Aprecia became the first pharmaceutical company to produce with printers.

2.3.2. Barriers to Transformation of Pharma 4.0

It is clear to say that industry 4.0 technologies are expected to have numerous advantages on pharmaceutical industry. However, it can be predicted that there will be some barriers in the process from industry 4.0 to pharma 4.0.

For instance, the equipment cost of manufacturing area which is equipped with Pharma 4.0 technologies could be accepted as a barrier, but that cost will be balanced if increased productivity and reduction of waste time and labor are considered.

Gilchrist (2016) who is an executive about digital transformation and writer speaks of 'the power of 1%', which includes the idea that an industry only needs to decrease operational costs / inefficiency by just 1% by using Industry 4.0 principles to realize significant savings. He explains this claim with an example: "*If the aviation industry could save 1% of fuel costs per year, it would save $30 billion. If a gas-fired power station could save 1% on gas per year, it would save $66 billion. If the oil and gas industry could reduce capital spending on equipment by 1% per year, it would save $90 billion*." (Gilchrist,2016)

Finding enough skilled labor seems to be difficult, as universities endeavor to predict which skills will be required in the future and start adding appropriate programs or courses.

Internal culture of organization is important on the way of technological transformation. Since culture involves the company's vision, all decision-making processes and manner of work for each employee are directly associated with adoption to new approach. Making digitalization a new reality, there needs to be complete awareness – from the board and executive team through the whole organization- and tenacity. If companies change their internal culture, in time, all barriers will be fall and Pharma 4.0 technologies will be new standard.

2.3.3. Pharma 4.0 in Turkey

In recent years, Turkish pharmaceutical sector is in uptrend both multinational and local companies level (TEPAV, 2015). Supported public health policies such as localization, new reimbursement regulations and incentive system for local manufacturers not only triggered sector but also revealed sector oriented technological needs.

On the other hand, the study driven by TÜSİAD in 2016 and 2017 shows that the technological transformation process in Turkish industry is still in its planning stage and Turkey has many areas that need improvements related to this issue.

In this context, as described in the previous sections, considering the Status of Turkish pharmaceutical industry and Turkey's competence in industry 4.0, pharma 4.0 is not expected to be on the top places of the agenda of Turkish pharmaceutical industry. Thus, in the literature search any significant data or study cannot be found about pharma 4.0 transformation in Turkey.

In this chapter, the pharmaceutical industry has been examined in detail and put forward the state of the pharmaceutical industry in Turkey. Then, the historical process of the industry 4.0 and its main components, possible opportunities and potential threats of new industry 4.0 technologies and the effects on Turkey were analyzed. Finally, industry 4.0 applications in the pharmaceutical industry were examined under the name of the pharma 4.0.

Industry 4.0 technologies are thought to have significant effects on the pharmaceutical industry as in all other industries. Along with the rapidly developing technologies, there are important steps to be taken to achieve technological transformation in the pharmaceutical sector. In the next section, the study will be carried out in order to determine whether the Turkish pharmaceutical industry has sufficient preparation in order to realize technological transformation within the scope of industry 4.0 and to adapt to radical changes. In the light of the information obtained in the literature review, the results of the study conducted on the companies and policies to be developed will be emphasized in the next chapter.

CHAPTER 3

METHODOLOGY AND FINDINGS

3.1. Methodology

As stated in the introduction, the aim of this thesis is to measure the readiness of Turkish pharmaceutical companies for technological transformation within the scope of industry 4.0. In this context, the qualitative method followed to measure the preparation will be mentioned in this section.

As the methodology of the paper, survey and semi-structured interview methods are used. In order to measure the technological readiness of Turkish pharmaceutical companies for technological transformation, the information is collected from questionnaires shared with companies, which are the members of Association of Research-Based Pharmaceutical Companies (AİFD) and Pharmaceutical Manufacturers Association of Turkey (İEİS).

AİFD, was founded in 2003 by the research-based pharmaceutical companies operating in Turkey in order to ensure Turkish people to access to new and original pharmaceuticals and contribute to the presence of human and effective solutions to health problems in Turkey. AİFD is one of the most important non-governmental organizations in the sector with its 34 members in the pharmaceutical sector.

İEİS was established in 1964 with the aim of improving the working conditions of its members and contributing to the development of health policy in Turkey. İEİS has 55 members including national and multinational companies, whose main field of activity is pharmaceutical production and it is another important non-governmental organization in pharmaceutical sector.

Since these two non-governmental organizations, which bring together the most important manufacturers and importers of the sector, represent almost the entire Turkish pharmaceutical sector, the questionnaire and interview questions prepared for this study have been transmitted to 89 companies that are members of these organizations.

Therefore, this study aimed to cover almost all representatives of pharmaceutical sector related to production and import aspects. For the purpose of the study that focused mainly on the manufacturing, other important actors in the pharmaceutical sector which are pharmaceutical warehouses and pharmacies are not included in the study as they do not have a role in the production stage.

3.1.1. Data Collection and Sampling

In order to measure whether Turkish pharmaceutical companies are ready for technological transformation within the scope of industry 4.0, the questionnaire prepared firstly was sent to 89 companies through AİFD and İEİS.

The questionnaire asks general information about the company; production and import business models; market and customer access; value chains and distribution / procurement processes; IT architecture; digital compliance, legal processes, risk management and security; industry 4.0; and finally, open-ended questions on general evaluation.

In the first part of the survey, it is aimed to define the company in general and its field of activity (manufacturer, importer, etc.), target markets (domestic, overseas, etc.), partnership structure and its employee's structure.

Then, in the section where the business models are analyzed in terms of production and import dimensions, the level of in-house digitalization, the importance of digitalization in the life cycle of the pharmaceutical, data collection and analysis in terms of the business models of the company are questioned and the responses in these issues are expected to be evaluated in two separate frames: current status and target.

In the third part, questions were asked about the use of multiple integrated distribution channels and digital tools in marketing and customer access processes, the extent to which cooperation with other companies on R & D, production, training, marketing, and in which areas the company benefited from information-based services. It is expected that the answers given to the questions will be graded to measure the current situation and the targeted situation.

In the value chains and distribution / procurement processes section of the survey, it is aimed to get information about the extent to which the value chain is digitized in the process ranging from product development to production / import, the real-time follow-up of its processes, the digitalization of the processes that the pharmaceutical goes through until it reaches the final consumer and how the data tracking can be performed.

In the IT architecture section, which constitutes the fifth section, it is aimed to measure the extent to which the company's IT architecture is digitized and the extent to which IT integration with the customers, suppliers and partners of the company is improved.

In the section titled Digital Compliance, Legal Processes, Risk Management and Security; questions were posed about the company's assessments on digital compliance, risk management and information security. It is aimed to measure the current status and target of the company on these issues.

In the seventh section where questions related to Industry 4.0 are asked: the company's knowledge of industry 4.0 and its readiness for technological transformation, its relevance to industry 4.0 technologies, expectations about industry 4.0 technologies, and the extent to which these technologies will change processes. The situation of the company in the context of industry 4.0, the level of usage of technologies and expectations about the issue, the level of awareness within the scope of industry 4.0, the obstacles in front of digital transformation and the areas in which the state intervention is required are examined.

In the last section, open-ended questions are asked about the issues that are thought to contribute to the development of the company in terms of technological transformation, the issues that restrict the company in terms of technological transformation, how to overcome potential problems and what kind of policies can be applied to the pharmaceutical sector in the context of industry 4.0 if they are policy makers.

It was stated in the questionnaire that the study has the ethical approval, the survey was on a voluntary basis, that the answers would only be evaluated by the researchers and used for the determinations to be determined by the sector in general, that the information to be obtained from the participants would be used only in scientific publications and that the data provided would not be matched with the information collected by the surveys / interviews.

However, no return has been provided from the companies. Afterwards, the survey was revised and the company name was not requested and the questionnaire was sent back to 89 companies. However, only 3 firms completed the survey in approximately 6 months and no return from the other firms was provided. It was understood from the interviews with the representatives of the sector that pricing and reimbursement was the most important issue for pharmaceutical companies, which represents the possible non-response.

Therefore, the semi-structured interviews planned to be conducted in addition to the questionnaire formed the basis of the study, since the survey, which is expected to be the basis of this study, did not reach its aim as intended.

3.1.2. Interviews

Since there was no return to the questionnaire, the companies who wanted to contribute to the study were contacted through AİFD and İEİS. In this context, interview questions were shared with 25 companies in total and 11 representatives from 10 companies answered. As will be explained in detail in the Findings section, 8 of the 10 companies participating in the interview consisted of both domestic and

international manufacturers. Therefore, the selected sample is balanced in terms of origin and field of activity and can provide information about the sector in general. Following the general information about the company, 9 different questions were asked to the companies. In this context, the awareness of pharmaceutical companies about industry 4.0, the stage of the technology level in the pharmaceutical sector, which of the technologies within the scope of industry 4.0 are most needed for the technological transformation and to what extent industry 4.0 technologies can be applied to production, import, in-house storage, pharmaceutical warehouse, pharmacy, post-market process areas, the reduction can be achieved in costs with industry 4.0 applications, how it may affect pricing and reimbursement process in Turkey, which technology of the industry 4.0 can bring solutions to the problems, issues that should be developed by the private sector, whether the current public policies are sufficient to provide the technological transformation are examined.

3.2. Findings

The data structure emerging from the data gathered from interviews, provide five aggregate dimensions, which are awareness, technological situation, effects on pricing and reimbursement processes, changes on the private sector side and expectation from the public sector. In this chapter, these theoretical aggregate dimensions determined by the question heading in the interview will be introduced.

3.2.1. General Information about Companies

In the first part, information was requested under three main headings: the field of activity of the company, the shareholding structure and size of the company. The Table 2 shows the information about the companies.

8 of the 10 participating companies are manufacturers and 3 of these 8 companies are both exporters and importers. 3 of them are only producing, 1 of them is manufacturer-exporter and 1 of them is manufacturer importer. While one of the two

companies that do not produce is a sales and marketing company who outsource production in Turkey, the other is only an importer.

Table 2. General Information about Companies

Intervewees (Firms)	Fields of activity				Origin		Scale		
	Producer	Importer	Exporter	Other	Local	International	Small-scale	Medium-scale	Large-scale
1	X		X		X				X
2				X		X	X		
3	X	X			X			X	
4	X	X	X		X				X
5		X				X			X
6	X	X	X			X			X
7	X	X	X		X			X	
8	X					X			X
9	X				X				X
10	X				X				X

6 of the 10 participating companies are local and 4 of them are multinational companies. All of the local companies are manufacturing in Turkey. While 2 out of 4 multinational companies are manufacturing in Turkey, one of them is an importer at the same time. The other is both exporter and importer with its manufacturing activity. One of the multinational companies is a sales and marketing company who outsource production in Turkey.

According to company declarations, one of them is small, two of them are medium-sized companies and seven of them are large-scale firms. Six of the large-scale companies have manufacturing operations in Turkey.

3.2.2. Awareness

All of the 10 companies that participated in the interview stated that the companies operating in the Turkish pharmaceutical sector are aware of the industry 4.0.

On the other hand, three of them stated that the level of awareness was advanced and two of them stated that the level of awareness of manufacturing firms was higher than the others. The other two companies state that the level of awareness of international pharmaceutical companies is more advanced than that of local companies.

Three of the firms report that there is awareness of industry 4.0 in pharmaceutical companies, but that the level is not sufficient / there are delays in the formation of awareness. In general, it is stated that budget and information constraints in practice cause this delays.

As stated in the previous section, only three firms completed the questionnaire submitted to 89 firms and no results were obtained from the questionnaire. Thereupon, two separate unofficial interviews were held with AİFDand İEİS officials to identify the firms that could be interviewed, to understand the pharmaceutical industry's overview of industry 4.0, to find out the reasons behind the failure of companies to fill out the questionnaire and to exchange ideas about the study. From these unofficial interviews; it is understood that industry 4.0 is a new but important topic for pharmaceutical companies. However, the low interest of pharmaceutical companies in the survey is thought to be due to sector’s main focus on the pricing and reimbursement processes.

In this context, although it is stated in the interviews that all companies have awareness about industry 4.0, it is thought that the interest and contribution to this issue is quite limited.

3.2.3. Technological Situation

Companies participating in the interview generally state that high technology are used in the pharmaceutical sector in terms of the nature of the industry, all of the industry 4.0 technologies can be used in different stages of the process from the production process to the end user, and that each of the 4.0 technologies is important in different processes.

Pharmaceutical industry is a sector that uses computer-based, network-controlled and automatic recording systems that continuously monitor all parameters directly affecting product quality. Considering the unique structure of the sector and its importance arising from its direct impact on health, it is of utmost importance to use the latest technologies in all processes such as production, supply and storage.

The majority of the respondents emphasized the importance of the situation mentioned above. Eight of them stated that different systems for the production, supply and storage processes are applied in the pharmaceutical sector, some of these technologies are sufficient, but some need to be developed.

It is understood from the data that the Drug Tracking System which enables the drug to determine its position in the procurement and distribution processes, and to monitor the processes that drugs go through in the supply chain, and to store records in a real-time database has been used by the companies. In addition, it is seen that the systems used by companies such as Manufacturing Execution System (MES) which enables to follow all the movement in production from raw material to finished product with the help of information tools and Warehouse Management System (WMS) which makes it possible to manage supply chain and order management operations from distribution center to store shelf are important for the companies..

On the other hand, it can be said that many of the similar systems are used by large-scale companies since they can bear the high costs, of software procured from abroad. It can be stated from the data that the transition to industry 4.0 is delayed due to the failure of these systems to be used by all companies in the sector.

In general, as a result of the interview data, although it is stated that the level of technology is advanced compared to other sectors, this level is not sufficient. It can be said that only large-scale firms can use important technologies at high costs and that high technology comes into prominence especially in the R & D stage.

On the other hand, according to the answers to the question of which of the industry 4.0 technologies are needed, the majority of firms think that all 4.0 technologies in the pharmaceutical sector are needed. It can be stated that big data analysis, robotic automation, sensors and cloud technologies are the most needed technologies in the sector.

Furthermore, two separate participating firms stated that the technological transformation could be achieved by using all of the 4.0 technologies together. They emphasized the need to invest in varying levels for each field.

The fact that only two participants made references to the production of personalized medicines, which can be said to require the most advanced level of technology at present, can be considered as an indication that the technology need is not yet at high level.

On the other hand, according to the data obtained, it is understood that almost all of the hardware and software are costly due to being supplied from abroad and therefore not all companies can use the systems that require advanced technology. Therefore, it is thought that there is a critical need for local suppliers in terms of software.

According to the data obtained from the answers to the question of which areas Industry 4.0 technologies can be used, it can be stated that industry 4.0 technologies can be applied to all areas of production, R & D, marketing, procurement and storage.

Since it is directly related to health, production without touch is a necessity in the pharmaceutical sector. Therefore, the error rate is expected to be very low. In addition, storage and access to the right pharmacy is critical for the industry. For these reasons, the need for industry 4.0 technologies in the pharmaceutical sector is evident. According to the data obtained; robotic automation, sensors and augmented

reality in R & D and production processes; big data analysis and cloud technologies in production and marketing processes; cyber security, big data analysis and cloud systems in storage and marketing processes come into prominence.

3.2.4. Effects on Pricing and Reimbursement Processes

One of the interview questions explores the impact of the reduction in costs with industry 4.0 on pricing and reimbursement processes, one of the most important issues in the Turkish pharmaceutical sector, and its implications for the private and public sectors. Thanks to Industry 4.0 technologies, R & D, production, logistics, marketing etc. costs are expected to decline, and declining costs will lead to changes in the firm's price strategy in the long run.

All of the firms stated that industrial 4.0 applications would have a positive effect on costs. However, there are different views as to which areas this cost reduction will affect. It is stated by three separate participants that cost reduction provided by the widespread application of industry 4.0 technologies will has a positive impact on the pricing and reimbursement process in Turkey. With the idea that costs can be minimized in the long term since pharmaceutical industry requires high-cost investments in general, it is understood that there will be limited effect on pricing in the short term, and that the low prices of pharmaceuticals that produced at high costs can be compensated in the long run for pharmaceutical companies with industry 4.0 applications.

According to the data from interviews, it can be said that the decrease in the costs experienced with industry 4.0 technologies will lead to the formation of companies that are structurally stronger and can be directed to investment, thus domestic production is expected to increase. As the costs will decrease with mass production, the reimbursement times can be expected to be shortened. According to these data, it can be said that industry 4.0 applications will indirectly contribute to the pricing process in the pharmaceutical sector.

However, two of the participants stated that the industry 4.0 applications could not have an effect on pricing and reimbursement process in Turkey. Their main argument is that there will be no significant change in pricing as a result of investments to be made as technology transformation requires serious and high-cost investments.

3.2.5. Changes on the Private Sector Side

Since the pharmaceutical sector is directly related to the patient, minimizing the problems that may occur in the processes in production, supply and so on is vital. It is thought that industry 4.0 applications should be used much more in the sector in order to eliminate the errors such as fracture of the ampoule inside the medicine box, empty blister, degradation of products such as syrup or cream in liquid form, insoluble effervescent in water, damage to the product by deteriorating the cold chain, reverse boxing and not reading the data matrix.

The answers to the question of which problems can be solved by industry 4.0 technologies in the pharmaceutical sector support the above-mentioned idea. The vast majority of companies agree that industry 4.0 technologies are particularly important for efficient and quality production. Data gathered from interviews show that with the help of big data analysis access to more information can be provided; the quality risks associated with working with the transition to robotic automation systems in production can be reduced; again with the help of robotic-automation and intelligent sensors failure of production machines can be detected before the failure occurs; information can be protected by cloud and cyber security systems. In this context, it is envisaged that the applications of industry 4.0 will bring solutions to the quality problem in the first place, and secondly, the entire process from production to pharmacy will be monitored and contribute to the elimination of possible errors. With these solutions, many problems can be solved and many radical changes can be seen on the private sector side by industry 4.0 applications.

On the other hand, the answers to the question of what are the issues need to be developed by the private sector can be grouped under four headings: training, employment of qualified personnel, investment and follow-up of developments. The

two companies argue that the private sector should educate itself within the scope of technological transformation. According to these two companies, the pharmaceutical sector needs awareness trainings in the industry, although it is not being far from the subject of industry 4.0 and consultancy trainings should be taken. On the other hand, another two firms stated that more information technology specialists should be employed, and that the need for qualified personnel should be met, especially during the R & D phase. Otherwise, three companies emphasize the importance of investments. They state that industry 4.0 should be included in the priority investment plans, and the culture of R & D and innovation and technology investments should be increased.

According to the data, closely following and internalizing the existing public resources and policies in order to be able to adapt rapidly to the changes and transformations, following the developments in the world are another issues to be developed by the private sector on industry 4.0.

3.2.6. Expectations from the Public Sector

According to the answer to the question of whether public policies are sufficient to ensure technological transformation, more than half of the firms do not find public policies sufficient.

Suggestions such as the establishment of special incentive mechanisms to ensure technological transformation, continuous cooperation of the public sector with the private sector and re-determination of public policies were made by the firms. It is stated that the public sector should lead the sector with pioneering and binding decisions and ensure the continuity of the legislation, and that incentives should be given within the framework of the technological transformation policy targets of the country, not according to the investment size. In addition, monitoring public awareness policies and raising awareness about incentives that may be related to industry 4.0 by the public are also mentioned by the companies.

In the answers to the question "What kind of policies would you apply to the pharmaceutical sector in the context of industry 4.0 if you were a policy maker?" the reference to incentives is remarkable. The majority of firms state that the government should support firms in certain areas. While some firms argue that financial support is necessary directly to R & D and production aspects, one of the companies suggest that pharmaceutical companies that develop e-transformation systems based on industry 4.0 should benefit from processes similar to those used by techno parks or R & D centers. Another interviewee thinks that companies should be encouraged to develop projects that will ensure data protection.

In this chapter, the methodology of the study and main findings from the data gathered from the interviews were introduced. Data provided different aggregate dimensions that summarize the answers from interviews. To sum up, while all companies suggest that they have awareness about industry 4.0, it is not sufficient for technological transformation. On the other hand, due to the nature of the industry high technology is used in the pharmaceutical sector it can be said that all of the industry 4.0 technologies can be used in different stages of the process of pharmaceuticals. According to the data obtained; robotic automation, sensors and augmented reality in R&D and production processes; big data analysis and cloud technologies in production and marketing processes; cyber security, big data analysis and cloud systems in storage and marketing processes come into prominence. However, it is thought that level of technology is not sufficient again for the transformation. Furthermore, there are two different opinions in terms of the effect of industry 4.0 on pricing and reimbursement processes according to the data. While one side states that industry 4.0 technologies will affect directly the pricing and reimbursement, the other side claims that the industry 4.0 applications cannot have an effect on pricing and reimbursement process in Turkey. Finally, it is stated nearly by all companies that the public sector should lead the sector and support firms in certain areas.

In the next chapter, the concluding part and the policy recommendations will be presented in the light of the main findings mentioned above.

CHAPTER 4

CONCLUSION AND POLICY RECOMMENDATIONS

We are in an economic system where technological change is felt and needed in every field much more than before. Industry and service sectors are looking for ways to exist in an economic environment where competition is at the highest level by making use of the knowledge provided by new technologies in order to make the processes more efficient, requiring less labor, and lowering costs of quality product production. In this environment, it is industry 4.0 that the whole world has started to think about in some way and that many of the developed countries have taken serious steps about it.

Industry 4.0 technologies are expected to trigger and pioneer of technological transformation in many areas of the economy, especially in the industry. Developed to make many processes from production to supply, from marketing to data analysis more efficient and quality, industry 4.0 technologies have become a very important issue at both micro and macro levels.

In the pharmaceutical sector, which is one of the most competitive sectors in the industry, technological transformation has started to be felt in every field together with the use of industry 4.0 technologies. The pharmaceutical industry can be defined as a sector in which high value-added products are produced as a result of long and costly research and development studies, and the products that are subject to serious regulations in almost every stage. Factors such as the increase of the world population and average life expectancy, the emergence of new diseases and new treatment methods, demographic changes and the phenomenon of social state constantly increase the need for health care and medicine.

At this point, it is more important than ever to achieve technological transformation in order to exist in the industry, which has a market size of over US $ 1 trillion. Referring to the developments related to industry 4.0, it is seen that Turkey is lagging behind the development of the pharmaceutical industry in the world. While there is no local firm that can produce an original pharmaceutical in Turkey yet, personalized pharmaceutical production is realized with 3D printer in the world. As can be understood from this example, Turkey's pharmaceutical industry has to improve many areas related to technology level and the sector is not yet ready for technological transformation.

In addition to this, the research carried out within the scope of this study suggest that the necessary investment climate in Turkey's pharmaceutical industry and R & D ecosystem was not created at enough level, international standards cannot be achieved completely and educational standards required by the industry and skilled labor is relatively fall behind the international level.

In this respect, it is essential to determine where the Turkish pharmaceutical sector is in the stage of the transformation process and to determine the steps to be taken in order to achieve the transformation in order to be able to take place in the competitive environment of the pharmaceutical sector which has developed seriously in the world.

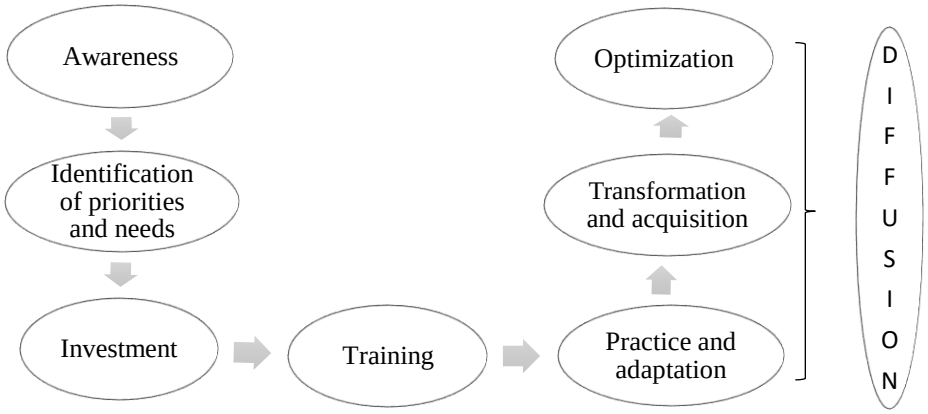
The main purpose of this study is to measure the technological readiness of Turkish pharmaceutical companies for the technological transformation within the scope of industry 4.0 and identify the policy tools to be needed. To the best of our knowledge, there is no other study in this area. The method followed and the results obtained in the study are given in the previous section. When the number of returns to the survey is taken into consideration, it is seen that the interest of the Turkish pharmaceutical sector to industrial 4.0 is very low and therefore the sector is not ready for technological transformation as expected.

In the following part of this section, policy recommendations regarding the stages of transformation and steps that can be taken in the pharmaceutical sector which is considered to be at the initial levels for technological transformation will be included.

4.1. Stages of Technological Transformation in the Context of Industry 4.0 in Turkish Pharmaceutical Sector

Before determining the policies that can be developed to ensure the technological transformation of the Turkish pharmaceutical sector in the context of industry 4.0; it will be appropriate to determine the stages of this transformation (Figure 5), the stage in where the pharmaceuticals firms are and the steps to be taken.

Figure 5. Technological Transformation Process



The stages mentioned in Figure 5 are summarized under 7 main headings as a result of literature research and interview studies. According to Figure 5, for technological transformation:

1. First, awareness of industry 4.0 at both the micro level (firm level) and the national level (public level) needs to be raised / increased. The first step of the transformation process can be taken by all actors, especially firms, by understanding the importance of industry 4.0 and to focus on this issue.

2. Then, together with the awareness, the public and the private sector (firms and non-governmental organizations) should determine their own priorities and needs. At this stage, the issues such as the cost of the investments to be made and the areas in which industrial 4.0 technologies are needed (production, procurement, marketing,

etc.) should be analyzed by the private and the public sector and strategic plans for the future should be developed.

3. In the next stage, within the framework of the strategic plans to be established, investment decisions to the technical equipment and the qualified labor force required by the new technologies should be made and appropriate investments should be realized together with the incentives of the state where necessary.

4. Simultaneously with the investments made, the organization of in-company training programs to ensure the development of qualified labor force through the use of systems, machines and software offered by new technologies should be done, as well as it will be necessary to provide training to the private sector by government, educate the personnel who will be able to lead the sector to the appropriate areas.

5. Assuming that all necessary infrastructures are provided, the next stage is the implementation of industry 4.0 technologies in production, procurement, marketing, pharmacy and adaptation to this process. This process constitutes the stage where the most feedback will be received on the way of technological transformation and the requirements of new technologies will be fully understood.

6. At the point where the investments are put into practice, the implementation becomes continuous and the adaptation process is completed, the optimization process enters the circuit. In this phase, which is intertwined with the adaptation process, the fields to be developed and the processes to be changed can be determined according to the data obtained through industry 4.0 technologies. In this way, all processes can be optimized.

7. As a result, when the aforementioned stages are completed, technological transformation can be achieved in the pharmaceutical sector and the magnitude of the profit to be obtained can be revealed at this point.

Actually, the stages 5, 6 and 7 in the figure, constitutes the technological diffusion process since these stages represent the spreading of new technologies to the use and application.

It can be said in general that the Turkish pharmaceutical sector is at the beginning of the stages summarized in Figure 5 in order to achieve technological transformation. According to the results of the interviews, it is seen that there is awareness in companies but not at desired levels. Judging by the advent of the global pharmaceutical industry, the international firms are expected to be more advanced than domestic firms are, however the proportion of those firms is not known. On the other hand, the information obtained from 4 international companies participating in the interview shows that they are still in the early stages of industry 4.0.

Since the pharmaceutical sector requires advanced technology, it is thought that some companies may take part in the first 5 stages of transformation on the basis of specific technologies. Considering that technological transformation is a process that needs to be handled altogether and includes all processes and Technologies related to industry 4.0, it is considered that there is a long way ahead for the Turkish pharmaceutical sector.

Considering that there is no plan for industry 4.0 in the pharmaceutical sector at the public level, it can be said that the Turkish pharmaceutical sector is still in the first phase of the transformation process at the macro level. In this context, the policies that can be developed in order to achieve technological transformation in the pharmaceutical sector in the context of industry 4.0 technologies are given below.

4.2. Policy Recommendations

The policies that can be developed within the framework of the technological transformation stages described above are summarized in Table 3. Accordingly, within the framework of the research, policy recommendations are presented as to where the Turkish pharmaceutical sector is located in the field of industry 4.0. In these policies, which can be developed at micro (firm level), meso (sectoral level) and macro (national level) levels, each actor has separate duties. The private sector and the academy should play a very important role in the process which is thought to be progressed under the leadership of the public sector. As a matter of fact, the private

sector is the basis of technological transformation in the pharmaceutical sector. The issues intended by the said policies are as follows:

- Increasing awareness level,
- Identification of priorities and needs,
- Increasing the investment required for transformation,
- Providing the necessary labor force for transformation,
- Increasing domestic technology suppliers according to need.

Table 3. Policies

Policy Aim	Increasing awareness level	Identification of priorities and needs	Increasing the investment required for transformation	Providing the necessary labor force for transformation	Increasing domestic technology suppliers according to need
PR1	Giving more importance to academic studies	Constitution of actions aimed at Pharma 4.0 technological transformation on "Turkish Pharmaceutical Industry Strategy Document and Action Plan"	Making the necessary arrangements by the state and the state being the guide	Making strategic labor force plan	Establishing the supply-demand balance
PR2	Encouraging participation in workshops, seminars and international congresses on Industry 4.0	Determining the private sector's own strategic plan and needs	Establishing new support mechanisms and providing tax advantage	Giving scholarships to graduate and doctorate students	Government support of domestic technology suppliers
PR3	-	-	Encourage investments via PPP model	Promotion of technical high schools	Meeting of pharmaceutical companies and technology suppliers in domestic fairs
PR4	-	-	-	Adding courses to undergraduate, graduate and doctoral programs	-

4.2.1. Increasing Awareness Level

The first stage of technological transformation is the creation of awareness. Considering that the Turkish pharmaceutical sector has a long way to go at this stage, some policies can be implemented to increase this awareness.

- **Giving more importance to academic studies**

Scientific studies are the starting point for many subjects. Therefore, one of the starting points of the Pharma 4.0 transformation will be the academy. With the studies to be carried out in this field, interest and scientific knowledge will be increased and thus, an academy-based awareness will be formed about industry 4.0 in the pharmaceutical sector. The findings of the academy on many issues such as cost, opportunities/threats and steps to be taken will provide accumulation of knowledge.

- **Encouraging participation in workshops, seminars and international congresses on Industry 4.0**

With the help of workshops and seminars organized by public and academy, also organized within the private sector itself on the importance, necessity and advantages of Industry 4.0, all actors' awareness level will be contributed. Public and private sectors must join together to Pharma 4.0 congresses held abroad, as well as in Turkey, steps should be taken to organize congresses on this issue.

4.2.2. Identification of Priorities and Needs

One of the prerequisites for achieving technological transformation in the context of Industry 4.0 is to identify priorities and needs. To this end, both the public and the private sector have responsibilities.

- **Constitution of actions aimed at Pharma 4.0 technological transformation on "Turkish Pharmaceutical Industry Strategy Document and Action Plan"**

Turkish Pharmaceutical Industry Strategy Document and Action Plan with the aim of "To make the Turkish pharmaceutical industry a global player with international competitiveness and a greater share of world exports" is a strategic plan prepared by the government (it is a plan prepared by the cooperation of all relevant stakeholders under the coordination of the Ministry of Industry and Technology) that determines steps to be taken for the sectoral development with the overall objectives and action plans. One of the most important steps is to put action plans in place to identify the areas of priorities and needs of Pharma 4.0 using the regulatory and steering authority of the government. It is of great importance for the public and private sector that the plan, which was prepared to cover the latest 2015-2018 years, will be updated to include Pharma 4.0 as one of its main focuses for the coming years.

- **Determining the private sector's own strategic plan and needs**

With the guidance of the public sector, the private sector will need to identify its areas of need for Pharma 4.0 and formulate its long-term strategic plans. In fact, the Turkish pharmaceutical sector, which requires advanced technology, high-cost investments and a large part of which is composed of medium and large-scale and institutional firms, is expected to formulate these plans in line with their own needs, but the inadequate level of awareness of industry 4.0 makes the role of the public more important. Therefore, together with the consultancy and support of the public, strategic plans that will cover the basic issues such as analyzing the returns, costs and necessities of industry 4.0 technologies, determining the area in which the investments will be made, and the need for skilled labor will be a road map for the companies in the way of technological transformation. First, key areas to be improved, such as flexibility, speed, efficiency and quality should be identified. At this point, instead of focusing on small improvements, ways to make fundamental changes should be sought. In this process, business partnerships can be established if necessary. In addition, testing the technologies to be invested by applying pilot projects will enable companies to make benefit / cost analyzes for the applications.

4.2.3. Increasing the Investment Required for Transformation

One of the most important steps to achieve technological transformation is the investments to be made for technical equipment and qualified labor force. Public regulation, guidance and incentives to increase these investments are one of the most critical elements of the transformation process.

- **Making the necessary arrangements by the state and the state being the guide**

The public should identify the missing areas in the transformation process by using its regulatory authority and establish / update the necessary legislation for these deficiencies. The public should in particular define the education, infrastructure and investment framework. One of the major tasks of the public sector is to identify the technologies that should be focused on for the Turkish pharmaceutical sector and to create the necessary incentive mechanisms to direct companies and investments to these areas. In addition, the public should provide the companies with the guidance and consultancy services they need in order to realize the digital transformation.

- **Establishing new support mechanisms and providing tax advantage**

In order to realize the technological transformation, an incentive mechanism should be developed for companies that will support the companies invest in pharmaceutical production and high-tech products in this field and that will provide support for consulting services companies will need to accelerate the transformation.

On the other hand, under the Investment Incentives Legislation, there are some tax advantages in Turkey. This incentive system, which aims to support high and medium-high technology investments that will ensure technological transformation; provides many tax advantages like VAT exemption for investment goods to be procured, customs tax exemption for investment goods to be purchased from abroad, tax reduction in income or corporate tax, insurance premium employer share support in employment dimension, insurance premium support, income tax withholding support.

At this point, although there is an adequate and advantageous incentive system for the investments to be made in the dimension of pharmaceutical production, investments in the field of technology and software that the pharmaceutical sector will need and support only for the personnel to be employed within the scope of industry 4.0 are not the subject of this system. In addition, considering the integration of pharmaceutical actors not only manufacturers but also importers, pharmaceutical warehouses and pharmacies, it is important to encourage investments and employment for all actors for industry 4.0 technologies that will be required at every stage.

- **Encourage investments via Public Private Partnership (PPP) model**

PPP can be briefly referred to cooperation agreements between the state and the private sector for the provision of public services. Public administration in PPP projects primarily responsible for determining the objectives to be achieved in relation to the public interest, the quality of public services provided and the price policy, and to check the appropriateness of the works. At this point, investments required for transformation made by PPP models can provide more use of private sector's know how and expertise and solutions that overcome the budget constraints. Moreover, with PPP models, the coordination of the investments will be made by the state, so that areas such as auditing and policy making can be under control.

As a result, it is thought that higher quality and sustainable services can be provided and access to experience and technology can be ensured more easily. The City Hospitals in Turkey is one of the most important examples of this model.

4.2.4. Providing the Necessary Labor Force for Transformation

Skilled labor force is one of the most important actors in the process of technological transformation. Planned employment, training and orientation of this workforce is one of the key points of the process.

- **Making strategic labor force plan**

With the new technologies or machines planned to be used, the new workforce to be employed should be handled in a planned manner, short and long-term impact analysis on the workforce should be conducted, and vocational training should be determined according to the competencies that the labor force will need.

Companies need to have a more competent workforce in order to manage the systems that will realize the technological transformation effectively. On the other hand, since the process of training newly recruited people will take time, it will be very important for the public to make a strategic and long-term plan on the labor force.

Since the pharmaceutical sector cannot be limited only by the production size, it will be important to make the personnel competent in the processes such as marketing, logistics and R & D. In addition, companies' transfer of experts from abroad as well as technology investments will accelerate the development of human resources within the company.

- **Giving scholarships to graduate and doctorate students**

The private sector, with the support of the state, can provide scholarships to students who will enroll in graduate and doctoral programs in the fields they need. The scholarship may be a precondition for future employment. In this way, the required personnel at the company level can be trained with the guarantee of hiring.

As an example, biotechnology company Amgen Turkey provides scholarship to PhD students from Ankara University Faculty of Pharmacy in order to raise required skilled labor for industry with PhD level with the help of university-industry cooperation and to encourage doctorate researcher employed in industry within the "TÜBİTAK 2244 Industrial PhD Program". After graduation, scholars will be able to employ within the company with the support of TÜBİTAK.

- **Promotion of technical high schools**

The data of the Ministry of National Education shows that although the quota of vocational and technical high schools increased in 2019, the occupancy rate increased compared to previous years. Increasing interest in these high schools will bring the qualified labor force needed by the industry. There are some projects carried out in order to solve the lack of qualified labor, which is one of the most important problems of all branches of industry.

For instance, ASELSAN Vocational and Technical Anatolian High School, established within the scope of the protocol signed between the Ministry of National Education and ASELSAN in order to train qualified personnel for the defense industry, is one of the important tool for the training of qualified personnel in need of the defense industry.

The initiation of a similar project between the pharmaceutical sector and the Ministry of National Education, especially for technical high school level, will be a big step for the development of the personnel required for technological transformation.

- **Adding courses to undergraduate, graduate and doctoral programs**

Adding pharma 4.0-related courses to undergraduate, graduate and doctorate level in the departments of pharmacy, medicine, biology, biotechnology, molecular biology and genetics etc. will be important for the development of the people needed by sector. Adapting the curricula to increase the competence of the labor force in connection with industry 4.0 technologies will be a strategic step to direct future generations to the appropriate areas.

4.2.5. Increasing Domestic Technology Suppliers According to Need

Currently, the need for a local solution provider for the integration of industry 4.0 technologies across supply chains is mostly met from international markets (TÜSİAD, 2016). One of the companies participating in the interview importantly emphasizes this situation for the pharmaceutical sector.

- **Establishing the supply-demand balance**

The study made by TÜSİAD (2016) related to Turkish industrial sector suggests that while technology users think there are no domestic suppliers, technology suppliers show the decrease in demand while the company as a major problem. Therefore, according to the study, this situation indicates a gap between supply and demand of technology. It is thought that this situation is also valid for the pharmaceutical sector. Therefore, it is important to provide the supply-demand balance between the technology user pharmaceutical sector and domestic technology suppliers by the public sector.

- **Government support of domestic technology suppliers**

In order to enable local technology suppliers and solution partners to participate more in the digital transformation journey in the industry, the government should give incentives as well as the support of these suppliers to pharmaceutical companies. In addition to financial support, the consultancy of these firms should be provided by the government.

- **Meeting of pharmaceutical companies and technology suppliers in domestic fairs**

Considering the fact that a significant portion (70%) of the revenues of domestic suppliers is obtained from the domestic market, however it is understood that the technology user companies prefer foreign technology supplier companies instead of domestic suppliers, the importance of a mechanism where domestic technology supplier companies and technology user companies will come together is better understood (TÜSİAD, 2016). In this context, the method that can be developed for the pharmaceutical sector may be to bring together pharmaceutical companies and domestic technology suppliers in domestic fairs. In this way, the parties will be able to communicate with each other in a more healthy way and determine the needs mutually.

4.3 Limitations of the Study and Suggestions for Further Research

The scope of the questionnaire planned to be used in the study was quite wide. The questionnaire includes questions that must be answered jointly by the different departments of a firm or by a senior executive. Therefore, one of the most important constraints is the lack of direct access to relevant persons in pharmaceutical companies. For this reason, the questionnaires were sent to the firms by means of AİFD and İEİS both because they were in direct contact with the interested parties in the companies and they could contribute to the study.

However, very limited feedback on the questionnaire created a constraint on the course of the study. As mentioned in the previous chapters, the interest and focus of the firms is considered to be in the pricing and reimbursement processes and therefore the contribution of the questionnaire to the study has been limited.

On the other hand, while determining the firms for the interview, the expected demands and interests of the firms and NGOs could not be seen. As a result, interviews with the desired number of companies could not be achieved.

However, despite the limitations, this study will be a resource for future researches. Furthermore, to the best of our knowledge there is no study measuring the readiness of the Turkish pharmaceutical sector for technological transformation in the context of industry 4.0 in Turkey. In this context, it is thought that more support can be obtained from government agencies and NGOs, and different methods can be followed in order to get companies' contribution to the work with a joint study. For instance, the support of Ministry of Health and Ministry of Industry and Science in the process of survey collection and of determination of the firms that will be interviewed would be very beneficial.

It is inevitable that Industry 4.0 will be on the agenda of the pharmaceutical sector and become one of the most important focal points of the sector. For this reason, it would be beneficial to increase the academic studies on these issues and to carry out studies on distribution, marketing, pharmaceutical warehouses and pharmacies in

addition to the production process in the pharmaceutical industry. Since the import processes and distribution stage of the pharmaceutical value chain are very significant for the Turkish pharmaceutical industry, specific researches on new industry 4.0 technologies that can affect the way of doing business and facilitate the processes will be helpful. Moreover, since it will be one of the first studies in its field, this study discussed the production in general terms. However, further researches may be focus only either on the R&D and the production of original pharmaceuticals side or the production of the generic pharmaceuticals side.

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APPENDICIES

A. INTERVIEW QUESTIONS

Sayın Yetkili,

Bu araştırma, ODTÜ Bilim ve Teknoloji Politikası Çalışmaları Bölümü öğrencilerinden Ömer İLHAN tarafından Prof. Dr. Erkan ERDİL danışmanlığında yürütülmektedir. Bu form sizi araştırma koşulları hakkında bilgilendirmek için hazırlanmıştır.

Araştırmanın amacı Türk ilaç firmalarının sanayi 4.0/teknolojik dönüşüm alanındaki teknolojik hazırlıklarının ölçümlenmesidir. Araştırmaya katılmayı kabul ederseniz, sizden beklenen, mülakat sorularını eksiksiz bir şekilde doldurmaktır.

Araştırmaya katılımınız gönüllülük temelinde olmalıdır. Cevaplar sadece araştırmacılar tarafından değerlendirilerek sektör geneli itibariyle belirlenecek tespitler için kullanılacaktır. Katılımcılardan elde edilecek bilgiler toplu halde değerlendirilecek ve bilimsel yayımlarda kullanılacaktır.

Bu çalışmaya katıldığınız için şimdiden teşekkür ederiz. Araştırma hakkında daha fazla bilgi almak için ODTÜ Bilim ve Teknoloji Politikası Çalışmaları Bölümü öğrencisi ve aynı zamanda Ticaret Bakanlığı Dış Ticaret Uzmanı Ömer İLHAN (E-posta: omer.ilhan@metu.edu.tr) ile iletişim kurabilirsiniz.

Çalışmayla ilgili Etik Kurul Onayı bulunmakta olup, talep edilmesi halinde iletilebilecektir.

A. ŞİRKETE İLİŞKİN BİLGİLER

1. Şirket Unvanı:

2. Şirket Faaliyeti: ( ) Üretici ( )İthalatçı ( )İhracatçı ( )Diğer (açıklayınız) *Birden fazla işaretleyebilirsiniz.

3. Şirketin Ortaklık Yapısı:

( ) Yerli ( ) Çokuluslu ( ) Önemli Yabancı Ortaklar ( ) Diğer (açıklayınız)

4. Şirket Büyüklüğü: ( ) Küçük Ölçekli ( ) Orta Ölçekli ( ) Büyük Ölçekli

B. MÜLAKAT SORULARI

1. İlaç firmalarının endüstri 4.0 konusundaki farkındalığı nedir?

2. İlaç sektöründeki teknoloji seviyesi hangi aşamasındadır?

3. Endüstri 4.0 kapsamındaki teknolojiler düşünüldüğünde (yapay zeka ve akıllı sistemler, 3D yazıcı,sensörler, artırılmış gerçeklik, robot ve otomasyon, büyük veri ve analizleri, siber güvenlik, bulut, simülasyon vs.) ilaç sektörünün teknolojik dönüşümünün gerçekleşebilmesi için en çok hangi teknolojiye/teknolojilere ihtiyacı olduğunu düşünüyorsunuz?

4. Endüstri 4.0 teknolojilerinin; üretim, ithalat, şirket içi depolama, ecza deposu, eczane, pazar sonrası süreç alanlarından hangileri için ve ne ölçüde uygulanabileceğini düşünüyorsunuz?

5. Endüstri 4.0 uygulamaları ile birlikte ilaç sektöründeki ar-ge, üretim, lojistik, pazarlama vb. maliyetlerinde sağlanabilecek azalmaların, Türkiye'deki fiyatlandırma ve geri ödeme süreçlerini nasıl etkileyebileceğini düşünüyorsunuz? Hem kamu hem de özel sektör açısından olası etkilerini değerlendirebilir misiniz?

6. Endüstri 4.0 teknolojilerinin ilaç sektöründeki hangi sorunlara çözüm getirebileceğini düşünüyorsunuz?

7. Türkiye ilaç sektöründeki teknolojik dönüşümün sağlanabilmesi yolunda özel sektör tarafında geliştirilmesi gereken konular nelerdir?

8. Güncel kamu politikaları ilaç sektörünün teknolojik dönüşümünün sağlanması için yeterli midir?

9. Politika yapıcı olsaydınız endüstri 4.0 bağlamında ilaç sektörü için ne tür politikalar uygulardınız?

B. APPROVAL OF METU HUMAN SUBJECTS ETHICS COMMITTEE

UYGULAMALI ETİK ARAŞTIRMA MERKEZİ
APPLIED ETHICS RESEARCH CENTER

ORTA DOĞU TEKNİK ÜNİVERSİTESİ
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06 Haziran 2018

Konu: Değerlendirme Sonucu

Gönderen: ODTÜ İnsan Araştırmaları Etik Kurulu (İAEK)

İlgi: İnsan Araştırmaları Etik Kurulu Başvurusu

Sayın Prof.Dr. Erkan ERDİL

Danışmanlığını yaptığınız yüksek lisans öğrencisi Ömer İLHAN'ın **"Türk İlaç Firmaları Sanayi 4.0 Bağlamında Teknolojik Dönüşüme Hazır Mı?"** başlıklı araştırması İnsan Araştırmaları Etik Kurulu tarafından uygun görülerek gerekli onay **2018-SOS-114** protokol numarası ile **18.06.2018 - 30.12.2019** tarihleri arasında geçerli olmak üzere verilmiştir.

Bilgilerinize saygılarımla sunarım.

Prof. Dr. Ş. Halil TURAN
Başkan V

Prof. Dr. Ayhan SOL
Üye

Prof. Dr. Ayhan Gürbüz DEMİR
Üye

Doç. Dr. Yaşar KONDAKÇI
Üye

Doç. Dr. Zana ÇITAK
Üye

Doç. Dr. Emre SELÇUK
Üye

Dr. Öğr. Üyesi Pınar KAYGAN
Üye

C. TURKISH SUMMARY/TÜRKÇE ÖZET

Son yıllarda, yeni teknolojilerin toplum üzerindeki etkisi her zamankinden daha fazla hissedilmektedir. Dolayısıyla, bu hızlı değişime ayak uydurmak kaçınılmaz hale gelmiştir. Tüm sektörlerin, özellikle üretim sektörünün teknolojik dönüşümünün tamamlanması, rekabetin hızla arttığı ve yeni teknolojilerin takibinin zor bir şekilde geliştiği günümüz dünyasında firmaların hayatta kalabilmesi için en önemli konulardan biri haline gelmiştir.

Bu noktada, ilk akla gelen konulardan birisi endüstri 4.0'dır. Endüstri 4.0 son zamanlarda çok fazla gündeme gelen ve konuyu araştıran kişi sayısının her geçen gün arttığı bir fenomen haline gelmiştir. Farkına varılması gereken önemli noktalardan bir tanesi, endüstri 4.0 ile hayatımıza giren teknolojileri içselleştirmeden ekonomik hayatın birçok noktasında ilerlemenin mümkün olmamasıdır. Akıllı robotlar, büyük veri, nesnelerin interneti, üç boyutlu baskı ve bulut gibi toplamda dokuz ana teknoloji bu devrimi tetikleyen teknolojilerdir. Bu devrimle ortaya çıkan endüstri 4.0 kavramı, değer zincirlerinin her bir parçasının kendi otomasyonlarının ötesinde birbirleriyle entegrasyonu olarak tanımlanmaktadır. Schwab (2017), devrimlerin hem ekonomik hem de sosyal yapılarda önemli değişikliklere yol açan yeni teknolojilerle birlikte gerçekleştiğini belirtmektedir. Bu nedenle, endüstri 4.0'ı sosyal gelişmeler açısından temel bir fenomen olarak algılamak doğru olacaktır.

Boston Consulting Group (BCG) tarafından 2015 yılında yapılan ayrıntılı bir araştırmaya göre, endüstri 4.0'ın yaygın bir şekilde uygulanmasının önümüzdeki 10-15 yıl içinde Alman ekonomisi üzerinde önemli etkilerinin olması beklenmektedir. Üretim dönüşüm maliyetlerinin %15-25'ine karşılık gelen endüstriyel verimlilik artışının bir sonucu olarak 90-150 Milyar Euro'luk bir maliyet düşürücü etkiden söz edilmektedir (BCG, 2015).

Öte yandan, teknolojik dönüşümün önemi göz önüne alındığında, dünyanın stratejik endüstrilerinden biri olan ilaç sektörünün (İEİS, 2018) bu dönüşüme ayak uydurması elzem görünmektedir. İlaç sektörü büyük bir sosyal öneme sahip olup, kendine özgü

sektörel özellikleri nedeniyle bir ülkenin ekonomik kalkınmasına önemli katkı yapma potansiyeline sahiptir. Bilgi ve teknoloji yoğun bir sektör olan ilaç endüstrisinde (Gambardella et al, 2001) teknolojik değişiklikler son zamanlarda oldukça hızlanmıştır.

Bu çerçevede, teknolojik gelişmeleri küresel düzeyde takip etmek ve son derece rekabetçi olan küresel ekonominin içinde yer almak için Türk ilaç sektörünün teknolojik dönüşümünü sağlaması adına adımlar atılması gerekmektedir. Zira endüstri 4.0 teknolojileri kapsamında gerçekleştirilecek teknolojik dönüşümün, Türk ilaç sanayinin rekabet edebilirliğinin gelişmesinde ve artmasında en önemli faktörlerden biri olabileceği düşünülmektedir.

Dünyanın en büyük 17. ilaç pazarı olan Türk ilaç sanayisi, ilaç üreticileri ve ithalatçıları ile ilaç depoları ve eczaneleri kapsamaktadır (İEİS, 2019). Uzun ve maliyetli ürün geliştirme süreçleri de dahil olmak üzere, araştırma ve geliştirmenin en yoğun olduğu yüksek teknoloji gerektiren bir sektör olması, temel araştırma safhasından ilacın tüketiciye sunumuna kadar geçen süreç içerisinde birçok düzenlemeye tabi olması ilaç endüstrisini diğer sektörlerden oldukça farklı kılmaktadır.

Bu bağlamda, Türk ilaç firmalarının teknolojik pozisyonlarını ortaya koymak ve endüstri 4.0 kapsamında teknolojik dönüşüme hazırlıklarını ölçmek önem arz etmektedir. Bu tezin temel amacı, Türk ilaç firmalarının endüstri 4.0 kapsamındaki teknolojik dönüşüme hazırlıklarını ölçmek ve dönüşümün sağlanabilmesi adına politika önerilerinde bulunmaktır. İlaç sektörü Ar-Ge, dağıtım, pazarlama vb. pek çok başka süreci de içinde barındırmakla birlikte tezdeki temel odak noktası ilaç sektöründeki üretim safhasıdır. Tezde, aşağıda yer alan araştırma sorularına cevap bulabilmek için nitel bir metodoloji benimsenmiş ve anket ve yarı yapılandırılmış mülakatlar kullanılmıştır:

- Türk ilaç endüstrisi, endüstri 4.0 kapsamında teknolojik dönüşüme hazır mı?

- Dönüşümün sağlanması için hangi politikalar uygulanmalıdır?

Bu soruların cevapları bulunduğunda, bu tez alandaki ilk çalışma olacaktır. Bilindiği kadarıyla, Türkiye'de endüstri 4.0 kapsamında teknolojik dönüşüm için ilaç sektörünün hazır olup olmadığını ölçen bir çalışma bulunmamaktadır.

Tez dört ana bölümden oluşmaktadır. 2. Bölüm'de ilaç endüstrisi ana hatlarıyla anlatılmakta ve endüstri 4.0 kavramı ve bileşenleri hakkında bilgi verilmektedir. Devamında, endüstri 4.0 ile ilaç sanayi arasındaki ilişkiyi açıklayan Pharma 4.0'dan bahsedilmektedir. 3. Bölüm'de ise araştırmanın kapsamı, veri toplama ve analizi sürecinde izlenen metodoloji açıklanmaktadır. Ayrıca, yarı yapılandırılmış mülakatlar yoluyla elde edilen verilerin analizi bu bölümde yapılmaktadır. Son olarak, 4. Bölüm'de varılan sonuçlar ile olası politika önerileri sunulmaktadır.

İlk olarak ilaç sanayinden bahsetmek gerekirse, ilaç endüstrisi, farmasötik teknolojiye uygun olarak tedavi edici, önleyici ve teşhis amaçlı kullanılan sentetik, bitkisel, hayvansal ve biyolojik kimyasal maddeler üreterek terapötik tedavi sağlayan endüstriyel bir alandır. Günümüz devletlerinin en büyük sosyal sorumluluklarından biri, halk sağlığını korumak ve sürdürmek için vatandaşlarına kaliteli ve etkin bir şekilde sağlık hizmetleri sunmaktır. Bu sorumluluğun yerine getirilmesi ancak güçlü ve etkili bir ilaç sektörü ile mümkündür. Ekonomik gelişme açısından önemli katkılar sağlamasının yanı sıra, savaş, salgın hastalıklar ve olası ambargo gibi faktörler karşısında ülkenin ihtiyaçlarını karşılayan ilaç üretebilecek bir ilaç endüstrisine sahip olmak da gereklidir. (MIT, 2016)

Buna ek olarak sektör, yoğun Ar-Ge faaliyetleri gerektirmesi nedeniyle katma değeri yüksek ürünler sunmaktadır. Dünyada Ar-Ge'ye en fazla kaynak ayıran sektör olan ilaç sektöründe Ar-Ge çalışmaları sürdürülebilir ekonomik büyüme için son derece önemlidir (TEPAV, 2015). Farmasötik ürünler, uzun ve maliyetli araştırma ve geliştirme faaliyetlerinin bir sonucu olarak geliştirilen katma değeri yüksek ürünlerdir.

Teknolojik değişimlerin çok hızlı olduğu ilaç endüstrisinde üretilen ürünler patent koruması altındadır. Üretim teknolojisi, aktivite veya tedavi şekli nedeniyle fark yaratan ilaçlar, kısa sürede patent sahiplerine ciddi pazar payı sağlayabilmektedir. Bu nedenle, etkin ve güçlü bir ilaç sektörüne sahip olmak, katma değerli ve ileri teknoloji

ürünleri yaratarak Ar-Ge faaliyetlerinin artmasına, ihracata ve ekonomik gelişmeye katkıda bulunacaktır.

Sektörün bir diğer özelliği de hemen hemen her alanda birçok ciddi düzenlemeye tabi olmasıdır. Klinik öncesi ve klinik sonrası çalışmalar, üretim aşaması, fiyatlandırma ve satış süreçleri; uluslararası kuruluşlar tarafından belirlenen standartlar, ülkelerin yasal düzenlemeleri ve sosyal güvenlik politikaları çerçevesinde ciddi düzenlemelere tabidir. Yoğun Ar-Ge faaliyetlerine ek olarak, bu düzenlemeler ilaç geliştirme maliyetlerini artıran ve yatırım süreçlerini uzatan nedenlerdendir.

İlaç endüstrisinde kabaca iki ürün sınıfı bulunmaktadır. Geliştirilen ve piyasaya ilk kez giren yeni ürünler referans veya orijinal ilaçlar olarak adlandırılmaktadır. Referans ilaçlar 20 yıllık koruma süresine sahiptir. Orijinal ilacın patent koruması sona erdikten sonra pazara giren, orijinal ilaçlar ile aynı özelliklere sahip ve bilimsel olarak kanıtlanmış ilaçlar ise jenerik ilaçlar olarak adlandırılmaktadır. Jenerik ilaçlar, referans ilaç ile aynı aktif maddeyi içeren aynı formülasyon ve ilaç formuna sahip olmalıdır. Orijinal ilacın patenti sona erdikten sonra piyasaya giren ilaçlar, kısa sürede piyasa paylarını artırabilir, zira maliyetler çok daha düşüktür.

Information Medical Statistics (IMS) verilerine göre, küresel ilaç pazarı 2005'ten bu yana ortalama % 6 oranında büyümüş, 2015 yılında 1.08 trilyon ABD dolarına yakın pazar hacmine ulaşmıştır. Pazar hacmi, 2018'de 1,2 trilyon ABD Dolarına ulaşmıştır (İEİS, 2019). ABD, 2018 yılı itibarıyla 485 milyar ABD doları pazar büyüklüğü ile dünyadaki en büyük ilaç pazarına sahiptir. ABD'yi sırasıyla Çin ve Japonya izlemektedir.

Sektördeki gelişmelere bakıldığında, son zamanlarda, konvansiyonel ilaçlar yerini biyoteknolojik ilaçlara bıraktığı görülmektedir. Küresel biyoteknolojik ilaç pazarı son yıllarda hızla büyümektedir. 2002 yılında 46 milyar ABD doları değerinde olan biyoteknolojik ilaç pazarı, 2012 yılında 163 milyar ABD doları pazar değerine ulaşmıştır (Statista, 2019). Öte yandan, 2002 yılında dünyadaki biyoteknolojik ilaçların toplam ilaç harcaması içindeki payı % 11 iken, 2012'de bu oran % 18'dir. (Statista, 2019). Geleneksel ilaçlardan daha karmaşık, pahalı ve büyük moleküllü ürünler olan biyoteknolojik ilaçlar, daha etkili ve güvenli tedavi seçenekleri

sunmakta ve daha önce tedavi edilmemiş hastalıkların tedavisinde öenmli rol oynamaktadır. Bu nedenle, yenilikçi ilaç üreticileri ürünlerini yüksek fiyatlarla pazarlayabilmekte ve yüksek taleple önemli kazanımlar elde edebilmektedir. Global ilaç pazarındaki lider şirketler Ar-Ge faaliyetlerini ve kaynaklarını biyoteknolojik ürünlere kaydırıyor gibi görünmektedir.

Türkiye'de sektörün durumuna bakıldığında, ilaç sektöründe ithalata bağımlı yapı karşımıza çıkmaktadır. Türkiye'de genel olarak, jenerik ilaç üretimi ve ilaç doldurma işlemleri yapılmakta iken, hala Türkiye'de üretilen orijinal veya biyoteknolojik bir ilaç bulunmamaktadır.

Türkiye, dünyadaki 17. en büyük ilaç pazarıdır (İEİS, 2019). Türkiye ilaç pazarı 2018'de 30.9 milyar Dolarlık katma değer ve 2.3 milyar kutu ilaç hacmine ulaşmıştır (İEİS, 2019). Türkiye'de ilaç endüstrisinin 2010-2018 dönemindeki büyüme oranları göz önüne alındığında, pazardaki değer artışı yaklaşık % 131; kutu bazındaki artış ise % 42,3 civarındadır.

Türkiye ilaç sektörü piyasaya dahil olan ekonomik aktörler açısından incelendiğinde, Sağlık Bakanlığı verilerine göre Türkiye'de 2015 yılında 71 ilaç üreticisi (56 yerli), 77 ilaç fabrikası (60 yerel) ve 12 hammadde tesisi (6 yerel) bulunmaktadır.

Tezin temel taşlarında bir tanesi de endüstri 4.0 konusudur. Hala çok yeni olan dördüncü sanayi devrimi, endüstriyel üretimde yer alan tüm aktörlerin birbirleriyle iletişim kurmaları, tüm verilere aynı anda ulaşmaları ve bu veriler üzerinden yüksek katma değer yaratmalarının temelini oluşturmaktadır. Bilgi teknolojilerinin yayılması ve otomasyonla birlikte siber fiziksel sistemler, dinamik veri işleme ve değer zincirlerinin birbirine bağlandığı yeni bir aşamaya gelinmiştir. Sensörlerin, üretim araçlarının ve bilgi teknolojilerinin entegrasyonu ile endüstriyel zincirler oluşmuştur (Özsoylu, 2017).

Dördüncü sanayi devrimi, diğer sanayi devrimlerinden çok daha hızlı gelişmektedir. Bu devrimin öncekilerden farkı, teknolojideki gelişmelerin birbiriyle iç içe geçmiş olması, koordineli bir şekilde hareket etmesi ve tüm alanların birlikte etkilenmesidir (Schwab, 2017).

Endüstri 4.0, makineler arasında veri toplama ve analizini sağlayarak düşük maliyetle daha kaliteli ürünler üretmek için daha hızlı, daha esnek ve verimli süreçler sağlamaktadır. Bu katkı ile üretim verimliliğini ve ekonomisini değiştirecek, endüstriyel büyümeyi teşvik edecek ve işgücünün profilini değiştirecektir (Rüßmann ve ark., 2015).

Öte yandan, endüstri 4.0 devriminin olumsuz etkileri hakkında çok fazla tartışma da bulunmaktadır. Yeni teknolojilerin istihdam, büyüme vb. üzerine olumsuz etkileri de ele alınması gereken önemli konulardır.

Dünya ekonomisinin küreselleşmesi, sermaye hareketlerinin serbestleşmesine ve üretimin yer değiştirmesine imkân sağlamıştır (Özkan ve diğerleri, 2018). Gelişmiş ülkeler, üretimlerini, ucuz emek ve vergi avantajları nedeniyle, emeğin ucuz olduğu ülkelere kaydırmaktadırlar (Eğilmez, 2017). Küreselleşme sayesinde gelişmiş ülkelerdeki yatırımcılar, maliyetlerini ucuz işgücünden yararlanarak düşürmüş, gelişmekte olan ülkeler ise ekonomik potansiyellerini büyüme ve istihdam gibi konularda kullanabilmişlerdir. Bununla birlikte, üretimde otomasyonun gelişmesi, gelişmekte olan ülkelerde ucuz işgücünün önemini azaltmıştır. Bu durum; gelişmekte olan ülkelerin bu avantajı kaybedebileceği ve istihdam ve büyüme oranlarında ciddi sorunlar yaşayabileceği anlamına gelmektedir (Özkan et al, 2018).

Ayrıca, gelişmiş ülkelerdeki dördüncü sanayi devrimi ile bağlantılı olarak ortaya çıkabilecek verimlilik artışları, gelişmekte olan ülkelerin küresel anlamda rekabet edebilirliğinin azalmasına yol açabilir (TÜSİAD, 2016). Büyük ölçekli yüksek teknoloji şirketlerini kullanan, yüksek üretim maliyetlerine sahip ülkeler; üretim maliyetleri düşük olan ülkelere kıyasla yeni teknolojilere daha kolay erişerek, küresel arenadaki rekabet pozisyonlarını güçlendirecektir (TÜSİAD, 2016).

2016 yılında TÜSİAD ve BCG tarafından yapılan bir çalışmada; otomotiv, beyaz eşya, tekstil, kimya, gıda ve makine sanayilerinde endüstri 4.0 uygulamaları incelenmiştir. Çalışmaya göre; bilgi ve malzeme akışı, tedarikçilerle entegrasyon, tasarım aşamasında ürün ve üretim sürecinin simülasyonu, üretim ve üretim hatlarında esnekliği ve öngörülebilirliği artıran akıllı ürünler önemli fırsatlar olarak ön plana çıkmaktadır. Sektör temsilcileri ile yapılan görüşmelerde; fırsatlar

konusunda yüksek düzeyde bir farkındalığın olduğu göze çarpmaktadır ve pek çok sanayi kuruluşu endüstri 4.0 uygulamalarında farklı olgunluk seviyelerinde ilerlemeye başlamıştır. Ortak sonuç, dönüşüm sürecinin ancak tüm paydaşların katkısı ve bütünsel politikaların oluşturulması ile sağlanabileceğine inanılmasıdır (TÜSİAD, 2016).

Öte yandan, TÜSİAD tarafından 2017 yılında yayınlanan bir rapora göre, Türkiye'de teknolojiyi kullanan şirketlerin dijital dönüşüm için yeterlilik düzeyini ölçmek, teknoloji tedarikçisi firmaların yetkinlik alanlarını belirlemek üzere 108 teknoloji kullanıcısı ve 110 teknoloji tedarikçisi firma ile kapsamlı bir araştırma yapılmıştır. Çalışmanın sonuçlarına göre; şirketlerin dijital dönüşümüne ilişkin yüksek düzeyde bilgi ve ilgisi bulunmaktadır. Ayrıca, sanayi şirketleri dijital dönüşüm alanında pilot projeler geliştirme sürecindedir ve şirketler stratejik yol haritalarını belirleme konusunda düşük bir yeterliliğe sahiptir. Araştırma, büyük ölçekli şirketlerin dijital dönüşüm yetkinlik seviyelerinin küçük şirketlerden daha yüksek olduğunu ve dijital dönüşümün önündeki en büyük engellerin yüksek yatırım maliyetleri ve yatırımların getirisinin belirsizliği olduğunu göstermektedir.

Türkiye'nin endüstri 4.0 konusundaki durumuna ilişkin literatür taraması, Türkiye'nin henüz teknolojik dönüşüm yolculuğunun başında olduğunu göstermektedir. Bu yolculukta her bir sektörün ayrı ayrı incelenmesi gerektiği, ancak kamu ve özel sektör ile üniversiteler gibi tüm aktörlerin katılımıyla dönüşümü gerçekleştirmek için ülke genelinde topyekûn bir çalışma yapılması gerektiği anlaşılmaktadır.

2017 yılında ISPE tarafından endüstri 4.0 teknolojilerinin ilaç üretimine uygulanmasını temsil eden “Pharma 4.0” kavramı ortaya koyulmuştur. Pharma 4.0, endüstri 4.0’ın farmasötik uygulamalarını tanımlamak için kullanılan bir terimdir.

Pharma 4.0 uygulamalarının temel amacı, farmasötik süreçlerinin daha verimli ve daha hızlı bir şekilde geliştirilmesidir. Pharma 4.0 ile birlikte yeni teknolojiler kullanarak üretkenlik ve karlarda artış beklenirken, insan hataları, fiziksel farmakovijilans sorunları ve iletişim problemlerinin imalat aşamasında azaltılması beklşenmektedir. Dijitalleştirme, tüm sistemleri birbirine bağlayarak daha hızlı karar

vermeyi mümkün kılmakta ve işletmeler üzerinde gerçek zamanlı kontrol sağlamaktadır.

Son yıllarda, Türk ilaç sektörü hem çokuluslu hem de yerel şirketler düzeyinde yükselme eğilimindedir (TEPAV, 2015). Yerelleştirme, yeni geri ödeme düzenlemeleri ve yerel üreticilere yönelik teşvik sistemi gibi halk sağlığı politikaları yalnızca sektörü tetiklememekle kalmayıp aynı zamanda sektöre yönelik teknolojik ihtiyaçları da ortaya koymaktadır.

Öte yandan, 2016 ve 2017 yıllarında TÜSİAD'ın yürüttüğü çalışma, Türk endüstrisindeki teknolojik dönüşüm sürecinin hala planlama aşamasında olduğunu ve Türkiye'nin bu konuda iyileştirilmesi gereken birçok alanı olduğunu göstermektedir.

Bu bağlamda, Türk ilaç endüstrisinin durumu ve Türkiye'nin endüstri 4.0'daki yeterlilik seviyesi göz önüne alındığında, pharma 4.0'ın Türk ilaç endüstrisi henüz gündeminin en üst sıralarında olması beklenmemektedir. Bu nedenle, literatür araştırmasında Türkiye ilaç sektöründe teknolojik dönüşüm ile ilgili herhangi bir veri veya çalışma bulunamamıştır.

Literatür taramasında elde edilen bilgiler ışığında, Türk ilaç sanayinin, endüstri 4.0 kapsamında teknolojik dönüşümünü gerçekleştirmesi ve değişikliklere uyum sağlaması için yeterli hazırlığa sahip olup olmadığını belirlemek amacıyla yapılan bu çalışmada, metodoloji olarak anket ve yarı yapılandırılmış görüşme yöntemleri kullanılmıştır. Türk ilaç firmalarının teknolojik dönüşüm için teknolojik hazırlığını ölçmek amacıyla, Araştırma Bazlı İlaç Firmaları Derneği (AİFD) ve Türkiye İlaç Üreticileri Birliği (İEİS) üyesi olan şirketlerle paylaşılan anketlerden bilgi toplanması amaçlanmıştır.

Sektörün en önemli üreticilerini ve ithalatçılarını bir araya getiren bu iki sivil toplum kuruluşu neredeyse tüm Türkiye ilaç sektörünü temsil etmektedir. Bu kapsamda, Türk ilaç firmalarının endüstri 4.0 kapsamında teknolojik dönüşüme hazır olup olmadıklarını ölçmek için hazırlanan anket AİFD ve İEİS aracılığıyla 89 şirkete gönderilmiştir.

Anket, şirket hakkında genel bilgi; üretim ve ithalat iş modelleri; pazar ve müşteri erişimi; değer zincirleri ve dağıtım / tedarik süreçleri; BT mimarisi; dijital uyum, yasal süreçler, risk yönetimi ve güvenlik; endüstri 4.0; ve son olarak, genel değerlendirme hakkında açık uçlu sorular içermektedir.

Ancak, şirketlerden söz konusu ankete hiçbir geri dönüş sağlanmamıştır. Daha sonra anket revize edilerek şirket ismi istenmeden 89 şirkete tekrar gönderilmiştir. Bununla birlikte, anket 6 ayda sadece 3 firma tarafından tamamlanmış olup, diğer firmalardan hiçbir geri dönüş sağlanmamıştır.

Ankete geri dönüş olmadığından, araştırmaya katkıda bulunmak isteyen şirketler ile AİFD ve İEİS aracılığıyla iletişime geçilmiştir. Bu kapsamda, mülakat soruları toplam 25 şirket ile paylaşılmış ve toplamda 10 şirketten 11 temsilci yanıt vermiştir. Görüşmeye katılan 10 şirketin 8'i hem yerli hem de uluslararası üreticilerden oluşmaktadır. Bu nedenle, seçilen firma grubu, menşei ve faaliyet alanı bakımından dengeli ve genel olarak sektör hakkında yeterli bilgiyi sağlayabilecek düzeydedir.

Görüşmelerden toplanan verilerden çıkan veriler; farkındalık, teknolojik durum, fiyatlandırma ve geri ödeme süreçleri üzerindeki etkiler, özel sektör tarafındaki değişiklikler ve kamu kesiminden beklenenler olarak beş toplam başlık altında incelenmektedir.

Bu çerçevede, görüşmelerde tüm şirketlerin endüstri 4.0 konusunda farkındalıklarının olduğu belirtilmiş olmasına rağmen, bu konuya olan ilginin ve katkının oldukça sınırlı olduğu düşünülmektedir. Mülakatta yer alan firmalar, genel olarak ilaç sektöründe sektörün doğası bakımından yüksek teknolojinin kullanıldığını, sektörün tüm endüstri 4.0 teknolojilerinin, üretim sürecinden son kullanıcıya kadar sürecin farklı aşamalarında kullanılabileceğini ve 4.0 teknolojisinin her birinin farklı süreçlerde önemli olduğunu belirtmişlerdir.

Endüstri 4.0 ile maliyetlerdeki düşüşün fiyatlandırma ve geri ödeme süreçlerine etkisine dair sorulan soruya verilen yanıtlardan, fiyatlandırma ve geri ödeme süreçlerinin Türkiye ilaç sektöründeki en önemli konulardan biri olduğu ve endüstri

4.0 teknolojileri sayesinde maliyetlerde yaşanabilecek düşüşün hem dolaylı hem de doğrudan etkilerinin olacağı anlaşılmaktadır.

İlaç sektörü doğrudan hasta ile ilgili olduğu için üretim, tedarik ve benzeri süreçlerde ortaya çıkabilecek sorunları en aza indirmek hayati önem taşımaktadır. Endüstri 4.0 uygulamalarının, ilaç kutusunun içindeki ampulün kırılması, boş blisterlerin çıkması, sıvı şurup veya krema gibi ürünlerin formunu kaybetmesi, çözünmeyen efervesanlar gibi sorunların bertarafında büyük rol oynayabileceği düşünülmektedir.

Son olarak, neredeyse tüm şirketler tarafından kamu sektörünün sektöre öncülük etmesi ve firmaları belirli alanlarda desteklemesi gerektiği mülakat verilerinden anlaşılmaktadır.

Sonuç olarak, bu çalışmanın temel amacı, Türk ilaç firmalarının, endüstri 4.0 kapsamındaki teknolojik dönüşüm için hazır olup olmadıklarını ölçmek ve dönüşüm için ihtiyaç duyulacak politika araçlarını belirlemektir. Bilindiği kadarıyla, bu alanda başka bir çalışma bulunmamaktadır. İzlenen yöntem ve çalışmada elde edilen sonuçlar önceki bölümde verilmiştir. Ankete geri dönüşlerin sayısı göz önüne alındığında, Türk ilaç sektörünün endüstri 4.0'a olan ilgisinin çok düşük olduğu ve bu nedenle sektörün beklendiği düzeyde gibi teknolojik dönüşüme hazır olmadığı görülmektedir.

Türk ilaç sektörünün endüstri 4.0 bağlamında teknolojik dönüşümünü sağlamak için geliştirilebilecek politikaları belirlemeden önce, bu dönüşümün aşamalarından bahsetmek uygun olacaktır.

7 ana aşamadan oluşan dönüşüm sürecinin ilk adımı farkındalığın oluşmasıdır. Yeterli farkındalığın oluşması ile birlikte önceliklerin ve ihtiyaçların belirlenmesi safhası gelmektedir. Stratejik planların oluşturulmasının ardından, gerekli yatırımların hayat geçirilmesi ardından da her alanda bir eğitim planının oluşturtulması aşamaları gelmektedir. Daha sonra uygulamaların hayata geçirilmesi ve adaptasyon süreci yaşanmakta ve bununla birlikte dönüşümün son aşamalarına gelinerek, dönüşümün getirileri elde edilmeye başlanmaktadır. Son olarak dönüşüm sonucunda her alanda bir opitimizasyon süreci yaşanmakta olup, uygulamaların

hayata geçirilmesiyle başlayan ve optimizasyonla son bulan süreçte yeni teknolojilerin difüzyonu olarak karşımıza çıkmaktadır.

Bulgular ışığında, Türk ilaç sektörünün hala makro düzeyde dönüşüm sürecinin ilk aşamasında olduğu söylenebilir. Bu bağlamda, ilaç sektöründe endüstri 4.0 teknolojileri bağlamında teknolojik dönüşümü sağlamak için geliştirilebilecek politikalar oldukça önemlidir.

Yukarıda bahsedilen teknolojik dönüşümün aşamaları çerçevesinde geliştirilebilecek politika önerilerine mikro (firma düzeyinde), meso (sektörel seviye) ve makro (ulusal düzeyde) düzeyde yer verilmiştir. Kamu sektörünün önderliğinde ilaç sektöründeki teknolojik dönüşümün temellerini oluşturacağı düşünülen beş ana hedef bu hedefler doğrultusunda belirlenen 14 farklı politika önerisine aşağıda yer verilmiştir:

- Farkındalık seviyesinin arttırılması,

  - Akademik çalışmaların artırılması,
  - Konuya ilişkin çalıştay, seminer ve uluslararası kongrelerin teşvik edilmesi,

- Önceliklerin ve ihtiyaçların belirlenmesi,

  - "Türkiye İlaç Sektörü Strateji Belgesi ve Eylem Planı"nında Pharma 4.0 konusuna yönelik eylemlerin hazırlanması
  - Özel sektörün kendi stratejik planının ve ihtiyaçlarını belirlemesi,

- Dönüşüm için gereken yatırımın arttırılması,

  - Devletin gerekli düzenlemeleri yapması ve rehberlik etmesi,
  - Vergi avantajı sağlayan yeni teşvik mekanizmalarının geliştirilmesi,
  - Kamu Özel Sektör İşbirliği ile yatırımların özendirilmesi

- Dönüşüm için gerekli işgücünü sağlamak,

  - Stratejik işgücü planı oluşturulması
  - Yüksek lisans ve doktora öğrencilerine burs verilmesi
  - Teknik liselerin özendirilmesi

- Lisans, yüksek lisans ve doktora düzeyinde ders verilmesi

- İhtiyaca göre yerli teknoloji tedarikçilerinin arttırılması

- Arz-talep dengesinin sağlanması
- Yerel teknoloji tedarikçilerinin desteklenmesi
- Teknoloji kullanıcıları ile tedarikçilerinin yurtiçi fuarlarda bir araya getirilmesi

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