A SURVEY ON THE IRANIAN PHARMACEUTICAL SECTOR





February 2020

Customer Base in Iranian Pharmaceutical Sector

According to the World Bank, Iran is a country with upper middle range income and the total expenditure on the pharmaceutical products is 1.16 % Of GDP. The following figure shows more data about the Iranian pharmaceutical customers.

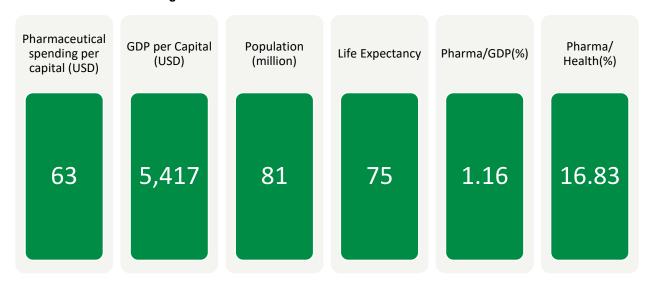


Figure 1. Customer base in Iranian Pharmaceutical Sector

Customer Demographics

Population of Iran as a Middle Eastern country with the growth rate of about 1.24% has passed 81 million. Iran has a young population and according to the national statistics center, in 2019, 47% of the population is between the ages of 15-20. However, due to a substantial decrease in population growth rate and increase in life expectancy, Iran will face an aging population in the coming decades. This represents a growing customer base for pharmaceutical products, with baby-boomers of the 1980s now entering the workforce and fueling out-of-pocket spending. In addition, the proportionally high urban population enjoys good access to basic healthcare. In rural areas, the access is growing due to government reforms, further boosting potential. More than 90% of the population is covered by one of the four government-run health insurers.

Therefore, Iran is a potentially lucrative market of about 83 million consumers, ready to be tapped by pharmaceutical manufacturers. In addition, Iran's well-educated labor force would likely lure global pharmaceutical firms interested in setting up research facilities or manufacturing plants. Meanwhile, Iran under sanctions draw well on its domestic resources and become somehow self-sufficient in generic drugs, and has one of the largest capacity of production of generic medicines in the Middle East and MENA region.

The country is an attractive target for the companies seeking to sell new medicines to its large and growing population, but going to the ground and securing effective relations with authorities seems critical.

Purchasing Power in the Pharmaceutical Market

Regarding the Iran's constitutional law, the government is responsible for providing the highest attainable level of the health care services for Iran citizens. Therefore, currently almost all Iranian have access to one sort of state supported health insurance services and national insurance schemes are responsible for reimbursement of medicine costs.

However, due to lack of sufficient resources in public health sectors and national health insurance schemes, in past years and up to 2014 out of pocket (OOP) payments of patients have substantially increased up to 50%¹, well above the developed countries rate (15-20%).

In 2014 a "Health Evolution Plan" was initiated to overcome some of the main challenges of Iran's health system. However, the focus of the plan is to lower OOP payments for inpatients, mainly those in hospitals belonging to the Ministry of Health and Medical Education (MOHME). Nevertheless, pharmaceutical costs still impose a heavy burden on households.

According to the latest report of the Statistical Centre of Iran, the OOP payment has reached 35.6% in 2018, and the MOHME reported that around 30% of this cost is for medicine and medical necessities. Regarding the drastic devaluation of the national currency (Rial) in past years, the consumer cost of the pharmaceutical products, which heavily depends on international currencies, has increased dramatically. However, most of the imported medicines are including bio-therapeutics, recombinants, oncology medicines, and active pharmaceutical ingredients (APIs) are still in high demand in the territory.

Iran's Pharmaceutical Market Map

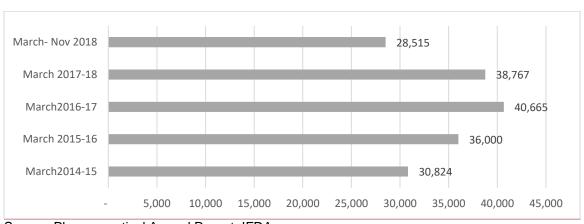
Within this part, we are going look at Iranian pharmaceutical market from the valid national organizations. The IFDA valued the Iranian pharmaceuticals market 3.7 billion USD from March-November 2018 including domestic, import and licensed products. Moreover, according to the president of the CBI the importation value of pharmaceutical and medical necessities is around 4 billion in the same period in 2019. As depicted in the charts below, Iran pharmaceutical sectors experienced a steady growing market in the last 3 years.

¹ https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0214783&type=printable

March- Nov 2018 March 2017-18 4.5 March2016-17 March 2015-16 4.06 March2014-15 3.5 0.5 1 1.5 2 2.5 3 3.5 4.5 5

Graph 1. Pharmaceutical Products Market Size -Sales in billion USD

Source: Pharmaceutical Annual Report, IFDA

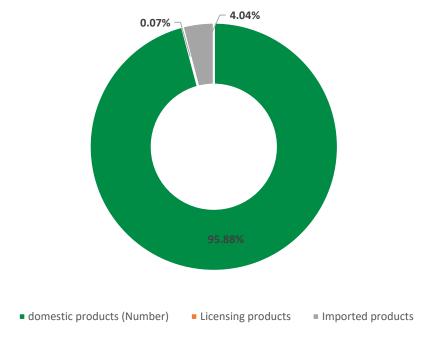


Graph 2. Pharmaceutical Products Market Size- Units in Million

Source: Pharmaceutical Annual Report, IFDA

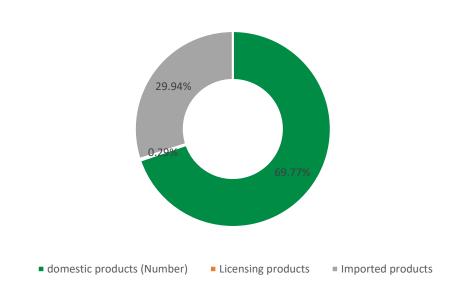
The following pie charts shows that Iranian pharmaceutical plants produce almost 40 billion drug units each year, meeting 96% of domestic demand that is 70% of the market value. Iran's pharma-production capacity is high. Different factories with an impressively high production capacity are at work but mostly Iran's domestic manufacturing is more basic than that of many Western companies. Some of Iranian pharmaceutical factories make up to 200 types of medicine, some of produced under foreign license in Iran.

Graph 3. Pharmaceutical Products Segmentation in Numbers, from March- Nov 2018



Source: Pharmaceutical Annual Report, IFDA

Graph 4. Pharmaceutical Products Segmentation Value in USD from March- Nov 2018 (USD)



Source: Pharmaceutical Annual Report, IFDA

In presence of a large domestic market, lack of efficient innovation activities and marketing strategies are also main weakness of Iran pharmaceutical market. Marketing strategies of productionpharmaceutical companies are poorly developed and mostly focused on price war by providing discount offers to the pharmacy outlets.

Key Market Players of the Iranian Pharmaceutical Products

Iranian Food and Drug administration (IFDA), which is a sub-branch of MOHME, is responsible for the management and regulation of the Iranian pharmaceutical sector, including biological and herbal products. The national regulatory system of Iran is composed of two main sectors; pharmaceutical affairs and the national control laboratory. The former is responsible for supervision of manufacturing, distribution, and importation of medicines. The latter checks the quality, origin, etc. of the medicines.

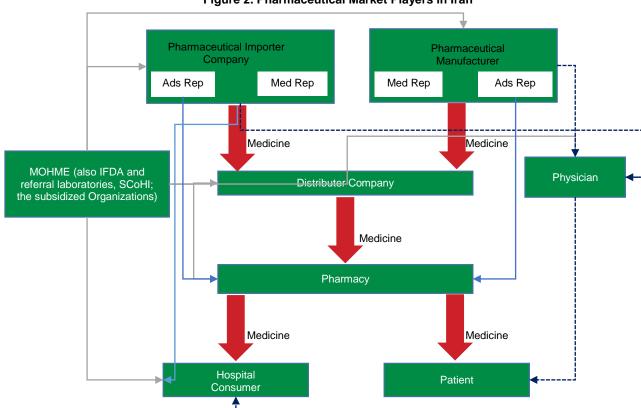


Figure 2. Pharmaceutical Market Players in Iran

Registration is the main and the most important requirement for marketing of medicines in Iran. First, Iran's Drug Selection Committee evaluates the new medicines for inclusion in the Iran Drug List (IDL)² based on their safety, efficacy, and cost-effectiveness. The registration process may take up to one year and even longer. Nonetheless, the process is not always clear and based on the announced guidelines. Since the Iranian system exhibits unique features that present both opportunities and hurdles for new entrants. Thorough preparation, including acquiring a deep knowledge of structure, decision makers and key stakeholders, is therefore essential, as is fostering good relationships with market players. The import of generic drugs listed on the IDL but with a locally produced equivalent is not officially allowed. Pharmaceutical exemptions are rarely granted, for example during a drug shortage. Currently, 70% of the APIs of the world's top-selling

² Under article 93 of the 4th development plan, physicians are urged not to prescribe items which are not in the IDL

drugs are listed on the IDL. Nevertheless, there are notable exceptions, including Insulin lispro (off-patent), used in type-1 diabetes, and Aflibercept (patented), used in the treatment of macular degeneration and metastatic colorectal cancer. Second, the Supreme Council of Health Insurance (SCoHI) evaluates the medicines included in the Iran IDL and if approved, they would be included in the national health system. This Council decides which drugs can have their costs reimbursed and at what level. The costs of most drugs in Iran are reimbursable, so securing this status ensures a strong competitive advantage. About 400 currently qualify for reimbursement, including some over-the-counter products. Insurers pay either 70% or 90% of costs. The prescribing physician is usually the key decision maker in the buying process. Most physicians split their time between public and private practice. Healthcare facilities include 954 hospitals, 4423 clinics, 6625 medical laboratories, 17857 health stations and 10937 pharmacies. The four health insurers own or contract these services, covering the full cost of treatment for their members.

As in most Pharmaceutical markets, patients are consumers of prescription medicines rather than the selectors. This is completely true in Iran, with its high proportion of prescription pharmaceutical products' sales. However, as with pharmacists, they have a growing decision making power in the Over-the-Counter (OTC) market due to the fall in medicines with reimbursable status.

About 185 domestic pharma manufacturers, 232 pharma import companies and 50 pharma distributor companies are active in Iran and can serve as accelerators for multinationals entering the market. Most of them are affiliated with government-backed investment companies because of the fact that the government through the national insurances is the biggest pharma consumer in Iran. New and infrequently prescribed medicines are separately imported or manufactured and offered through special stores affiliated with the Red Crescent Society, private sector and/ or voluntary associations formed to support people suffering from specific disorders.

Iranian Pharmaceutical Companies Morphology

Iranian pharmaceutical companies are neither completely private nor fully governmental. The government supports some seemingly private Iranian pharmaceutical companies. In other words, the government is the main competitor of the private sector, and this has created a kind of governmental monopoly.

After the revolution, almost the major pharmaceutical companies were taken over by the government. As they had been mostly run with the international owners, the takeover led to imposition of restrictions on the import of many products. To deal with this limitation, as well as foreign exchange shortages, the government developed a list of basic drugs to be produced locally.

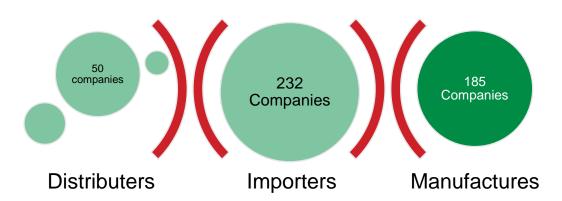
In fact, the modern pharmaceutical industry in Iran started its activity by licensing the products and process from multinational pharmaceutical companies and importing API and formulating them locally. The first modern Iranian pharmaceutical company by private sector established about 70 years ago.

In the recent decades, the pharmaceutical industry has started joint projects with international companies for production of new drugs. The government has however maintained overall control in the area of pricing and quality assurance. The distribution system, which has traditionally consisted of individually owned facilities, has remained intact over the years.

Despite implementation of national scheme for privatization of the industry, still majority of the local pharmaceutical market is managed by the semi-governmental organizations. According to Tehran Securities Exchange Technology Management (TSETMC), the three below companies hold more than 50% of the Iran local pharmaceutical market.

- Tamin Pharmaceutical Investment Co (TIPICO, was set up in 2003, manages 30 pharmaceutical companies in Iran with a workforce of nearly 8,000. It holds 70% of the active pharmaceutical ingredients market, 30% of finished pharmaceuticals and 40% of distribution networks in the country),
- Barkat Pharmaceutical Corporation (affiliated to office of supreme leader of Iran was set up in 2010, manages 25 pharmaceutical companies in Iran. It supplies 14 percent of all the country's essential drugs and produces 700 kinds of products) and
- Shafadaru Corporation (affiliated to Bank of Melli, a state owned bank)

Therefore, despite the fact that private pharmaceutical companies gained more market share in Iran in recent years, their share in Iran pharmaceutical market is still less than 50%.



Graph 5. Morphology of Iranian Pharmaceutical Companies

Source: Pharmaceutical Annual Report, IFDA

Manufacturing: The government is planning to expand Iran's already considerable drug-making capacity. It wants to build on its mostly generics-producing base by branching out into the manufacture of patented medicines as part of its post-sanctions strategy. Nevertheless, whether carried out at self-owned facilities or those of partners, manufacturing in Iran must abide by certain cultural rules. Selected medicines and dosage advice must be halal compliant, for example, and patient information must be provided in English and Farsi.

Importing companies, which are often subsidiaries of large local pharmaceutical groups. These offer significant opportunities to tap into local expertise. Import taxes and custom tariffs range between 0 and 65% depending on whether the product has a locally produced equivalent.

Distribution: Six government-owned companies primarily distribute the pharmaceutical products. Nevertheless, smaller private operators are increasing entering the market, with about 20 currently active. The state-backed Darou Pakhsh Distribution, which deals in both local and imported products, is the market leader with a 25% share. Overall, the 10 largest distributors have

a 75% market share. This level of consolidation makes the leveraging of existing local networks an attractive option.

Iranian Pharmaceutical Syndicates

سندیکای صاحبان صنایع داروهای انسانی ایران
Iranian Pharmaceutical Industries Syndicate "Iranian Pharmaceutical Industries Syndicate3" was established in 2005. This syndicate has around 150 members including 101 pharmaceutical manufacturers, 22 affiliated companies, 14 exporters and 8 distributors. It plays the executive role of the Food and Drug Administration with the aim of

- organizing human pharmaceutical production,
- improving the quality of the products
- promoting export
- continuous marketing by providing information on supply, demand, prices, consumer
- protecting the interests of pharmaceutical manufacturers,
- assisting their access to the global markets
- providing appropriate investment opportunities,
- participating in developing the related standards for the medicines production and supervising them

The Iranian Pharmaceutical Industries Syndicate has been organizing IRANPHARMA EXPO4 from 2014. IRANPHARMA EXPO is a well-known name in the pharmaceutical industry. This EXPO aims to introduce the capabilities and potentials of the Iranian pharmaceutical industry, present the latest changes and achievements in pharmaceutical industries, get to know new markets and prepare the required platform for technology transfer.

Syndicate of "Iranian Pharmaceutical Importers⁵" established in 2006 to organize timely pharmaceutical import, promote and strengthen communications between pharmaceutical and treatment activists, establish integrated relationships with the Ministry of Health and Medical Education and other relevant agencies and organizations, supply pharmaceutical requirements for patients, also initiate joint ventures and utilize the scientific and practical experiences of stakeholders. This syndicate is established in accordance with Clause (k) of Article 5 of the Iran Chamber of Commerce and Industries and Mines, and now has more than 70 members.



Iran's API, Chemical and Pharmaceutical Packaging Syndicate⁶ established in 2016 to make a network for following up its members' interest. APIs manufacturers, chemicals manufacturers, manufactures of pharmaceutical packaging materials and manufacturers of equipment and related industries are the member of this. The syndicate organizes Pharmex⁷

³ http://svndipharma.org/index.php

⁴ http://www.iranpharmaexpo.com/index.php/en/

⁵ http://siphi.org/

⁶ http://cppsynd.com/

⁷ http://www.pharmex.me/index.php/en/

exhibition annually for 2 years. This event is held in three main sectors, including PharmaPack, APIs, PharmaTech.

Iran's Pharmaceutical Import and Export

According to Tehran Chamber of Commerce, Industries, Mines and Agriculture (TCCIM), the total import value of pharmaceuticals in the previous Iranian year (March 2018-19) is around 1.6 billion USD, that Italy has a share of around 4%. Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses (3004) is the most demanded category in case of Importing to Iran with the value of 1.1 billion USD. In addition, the Pharmaceutical chapter is the fifth in comparison to others in case of importing to Iran.

Chapter 84
Nuclear reactors, boiler, machinery and mechanical appliances; parts thereof

Cereals

Chapter 10
Cereals

Chapter 10
Cereals

Chapter 30
Chapter 30
Pharmaceutical Products

Chapter 30
Pharmaceutical Products

1
2
3
4
5

Figure 3. Import Value Ranking of Pharmaceutical Products in comparison to other chapters

The country is trying to grow its pharmaceutical exports and attract investment in the industry. However, an increase in output could potentially have a detrimental effect on the price and availability of certain medicines.

Iran is aiming for expanding export markets, but it is too few in comparison to the export. The following graph shows the balance trade in pharmaceutical sectors from March 2013-2018 according to the statistical center of Iran.

1,868,328.12 2.000.000.00 1.670.569.15 1,650,677.05 1,629,971.12 1.573.544.76 1,498,811.95 1,500,000.00 1,000,000.00 500,000.00 188,476.10 159.056.10 121.048.91 133,638.03 110,524.14 105,051.70 2013 2014 2015 2016 2017 2018 (500,000.00)(1,000,000.00)(1,500,000.00)(1,388,287.81)(1,414,488.66)(1,462,200.95)(1,536,931.12) (1,524,919.42) (2,000,000.00)(1,747,279.21)**Export Tausand USD** Import Thausand USD Balance of Trade

Graph 6. Iran's Pharmaceutical Products Import/Export from March 2013-18 (Thousand USD)

Source: Statistical Center of Iran

It would appear that importation of medicines are not only due to shortage of that production but also to the reason of the better quality. Even though, producing the same imported generic drugs can be considered as a potential profitability of pharmaceutical companies. In most cases, only one-step of the eight stages of pharmaceutical synthesis operates in Iran; sometimes the share of domestic production is only in its packaging.

Eurostat⁸, the EU statistical office based in Luxembourg, collects and publishes import and export data⁹ based on reporting by the Union's 28 member states. Iran's €320 million of pharmaceutical imports during the first half of 2019 is about 2.5 percent higher than the amount imported during the first half of 2018. Tehran imported €480 million of pharmaceutical products from EU countries in the second half of 2019, an increase of 13 percent compared to the second six months of 2018.

Despite sanctions, Iran's imports of European pharmaceuticals increased in 2019 compared to the year prior. This trend suggests the exemption of humanitarian goods from U.S. sanctions has enabled Iran to meet its needs.

The top five exporters of pharmaceutical products to Iran in 2019 were Germany, France, the Netherlands, Belgium, and Italy. Germany and Belgium maintained a stable level of exports over the last five years, while exports from other nations showed greater volatility. It is difficult to determine whether these fluctuations relate to sanctions, since French exports began to fall substantially in 2018 before sanctions returned, while Dutch and Italy exports continued growing in 2019.

⁸ https://ec.europa.eu/eurostat/about/overview

⁹ https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=DS-575274&lang=en

Figure 4. Top Five EU Pharmaceutical Exporters to Iran in 2019



Source: Eurostat, last visited on February 2020

Eurostat data also covers EU imports of pharmaceuticals from Tehran, whose value is less than 5 percent of EU exports. Iran's government is keen to promote the export of medicines to help chip away at its negative trade balance. By 2025 it hopes to have balanced exports and imports of medicines; as such, drug export income is tax exempt, and initiatives are underway to improve manufacturing practices. Pharmaceutical companies in Iran mostly export their products to some neighboring countries including Tajikistan, Afghanistan, Pakistan, Iraq and Azerbaijan. According to the national pharmaceutical annual report, the value of imported medicines accounts for about 30% of the value of the whole market.

Italy in Iran's Pharmaceutical Import Market

Table 1. Italy export value of Pharmaceutical products to Iran

Year	2016	2017	2018	2019 (without Dec)
Export Value 1000 €	30,393.42	39,793.04	38,257.97	42,319.51

Source: Eurostat, last visited in February 2020

According to the TCCIM, Italy export around 34 million-euro medicaments to Iran. The below table provide more information about Italy role in Iran's import pharmaceutical market.

HS		Import to Iran March 2018-19					
SUBH EADI NG	Description	Market Volume thousand	Italy Export to Iran Market Market Volume		Market leader in This Category		
		(USD)	share (%)			Category	
30	Pharmaceutical Product	1,577,328	3.8	60,000	Country	Market Share (%)	
3001	Glands and other organs for organo- therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo- therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or	1,754	26.43	464	Germany	67.78	
3002	Obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products. Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera other blood fractions an	374,420	6.50	24,337	Germany	25.40	
3003	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.	16,470	1.17	193	UAE	42.87	
3004	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packing	1,115,232	3.00	33,457	Swiss	18.70	
3005	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.	16,491	2.01	331	China	27.56	
3006	Pharmaceutical goods specified in Note 4 to this Chapter.	52,960	1.90	1,006	UAE	25.29	

Pharmaceutical Innovation in Iran

Most of the companies around the world spend almost more than 4% of their income on R&D. However, this sector is not the first priority for Iranian pharmaceutical companies.

A reason for this lies in the relative stability of Iranian pharmaceutical firms as well as the low competition between these firms. Since we do not have strong competition between Iranian companies to win the market shares and each of them has its own certain market share, they feel no need to invest in their R&D department. On the other hand, the participants in our study stated that R&D requires a long-term investment, but managerial and financial instability of companies along with not having suitable legislation to make companies invest in R&D are the main barriers to achieving this goal.

Private companies cannot properly invest in R&D activities due to the high costs of raw materials' production, low marginal profit for pharmaceutical products, and weak governmental supporting polices; so, they are a lot far from innovation and creativity within pharmaceutical sector.

Having a super-concentrated planning system for both national and imported pharmaceutical products within the government, applying ineffective and inflexible pricing system, which reduces companies' motivation to be innovative, and presence of some very strong semi-public companies are the most challenging issues for this sector. On the other hand, not including R&D expenditures in pharmaceutical pricing, and not paying attention to intellectual property rights have motivated national companies to only think about making their products domestic or produce the generic forms of available foreign drugs.

Due to lack of efficient R&D projects in local pharmaceutical companies, it is unlikely to produce new break-through products for years to come. Therefore, the overall technological capacity of national pharmaceutical industry still mostly limited to manufacturing and formulation of generic medicines.

Apart from generic medicines such as anti-biotics and over-the-counter painkillers, Iran has managed to enter the realm of complex medicine such as radiopharmaceuticals and biologic drugs for special illnesses. In addition, the country is queuing among the world's leading nation as for stem-cell research and has a considerable infrastructure of related facilities, e.g. for plasmapheresis (blood plasma treatment). The biggest biopharmaceutical company, CinnaGen, produces Biosimilars of leading immunology and cancer drugs, among others, and invests 20% of revenues in R&D.

In a nod to the global trend of establishing biotechnology hubs, Iran is also building a government-backed 2 billion USD "Industrial Pharmaceutical City" near Tehran. It will house incubators and startups under the same roof as research labs and biotech producers. Foreign investors are exempted from taxes and it is hoped the venture will attract international experts

Sanctions in Pharmaceutical Sectors

Section 1245¹⁰ of the National Defense Authorization Act of 2012 imposed broad sanctions on Iran's financial sector but prohibited the president from imposing sanctions on "agricultural commodities, food, medicine, or medical devices." The Treasury Department in 2013 issued detailed guidance¹¹ affirming these exceptions.

Yet the greater problem is a lack of legitimate partners in Tehran because the regime has corrupted the financial system so thoroughly. In response to concerns about the alleged chilling effect, the Departments of State and Treasury has announced¹² a new mechanism to facilitate and bring greater transparency to permitted trade with Iran. Foreign governments and financial institutions that choose to participate will commit¹³ to detailed reporting about their transactions with Iranian partners and can seek "written confirmation from Treasury that the proposed financial channel will not be exposed to U.S. sanctions."

As the EU data show, sanctions have not disrupted pharmaceutical imports, so corruption may once again be contributing to shortages.

Because of these sanctions and restrictions Iran industrial sector, including local pharmaceutical industry faced a complex procedure for acceptable procurement of machinery, technology and even finished products and API. This happened mainly due to difficulties to access lines of international credits for Iran pharmaceutical companies in procurement and shipping. Because of the fear of falling afoul of Washington has made many banks wary of processing any financial transactions - including humanitarian ones - with the Islamic Republic.

Recently, the Swiss Humanitarian Trade Arrangement (SHTA) has helped the Swiss-based exporters and trading companies in the food, pharmaceutical and medical sectors to sell their products to Iran without landing in the crosshairs of the US Treasury. Three shipments of cancer and transplant drugs were sent to Iran through this and the transaction was processed in January.

Apart from the international actions, Iran has mobilized financial resources to subsidize prices for essential products and has planned for procurement and distribution of the medicines in response to the new round of sanctions and this has resulted in 4 billion USD¹⁴ import of pharmaceutical products and medical necessities from March to December 2019.

Registration Process of New Pharmaceutical Products

New entrants to the pharmaceutical market will select whether to operate here as a joint venture company or to export. In the case of generic drugs that domestically manufactured, local production has advantages because of the prohibited imported equivalents, or heavy taxes. According to the IFDA rules and regulations, the importation costs the 5% customs tariff, and in selected cases this is even subsidized; means zero. Local production may also be cost efficient,

¹⁰ https://www.treasury.gov/resource-center/sanctions/Programs/Documents/ndaa publaw.pdf

¹¹ https://www.treasury.gov/resource-center/sanctions/Programs/Documents/hum exp iran.pdf

¹² https://home.treasury.gov/news/press-releases/sm804

¹³ https://www.treasury.gov/resource-

center/sanctions/Programs/Documents/iran_humanitarian 20191025.pdf

¹⁴ https://cbi.ir/showitem/19849.aspx

either at owned facilities or via cooperation with in-country partners. It also affords rudimentary IP protection. The following figure shows the process of new pharmaceutical products registration.

Graph 7. Pharmaceutical products registration Process

Approval

•FDA authorization is a prerequisite for the sale of drugs in Iran, whether the product is imported or produced locally. The application process to introduce new drugs is not dissimilar to those in developed markets, but may be less transparent and more time consuming. The first step involves registering the product by submitting drug data, import-export and authorization documents. Once certified by an Iranian consulate, these documents are passed to legal commissions for consideration. If successful, the drug is added to the IDL. The process usually takes about a year. If approval is being sought for a drug already listed on the IDL, the imported version need only be approved by an IFDA-accredited laboratory.

IP Rights

•There is little patent protection for drugs in Iran. Under current legislation, pharmaceutical formulae and compounds are not patentable, leading to extensive unauthorized production of generic medicines. However, with Iran currently seeking World Trade Organization membership, this is likely to change as the country will have to adopt the WTO's patent protection terms.In Fact, lack of intellectual property rights (IPR) protection law is also a concern for international Pharma companies. So far, international pharmaceutical companies mostly operate in Iran through providing dealership to Iranian companies to sell their products. Interestingly some Iranian companies represent more than one foreign company and simultaneously their competitors.

<u>Prici</u>ng

Drug prices are determined by the FDA's Pricing Commission. It decides on the expenses incurred
by producers and importers for each drug, and then fixes a price under the top-mark system, taking
into account the upper range of cost.

Reimbursement

•Health insurers pay 70% (outpatient dispensed) or 90% (inpatient dispensed) of the cost of drugs with reimbursement status. The remaining amount is paid by users. Most drugs, for example cancer medicines, have this status, but numerous drugs commonly used in the West do not, including pantoprazole, a treatment for excess stomach acid.

Because of Iran's bureaucracy and risky legal environment instead of establishing a direct manufacturing presence, it seems reasonable to ally with domestic companies.





