

# PHARMACEUTICAL INDUSTRY IN IRAN

August 2022

## TABLE OF CONTENTS

- FACTS ABOUT THE IRANIAN PHARMACEUTICAL INDUSTRY
- EUROPEAN PRESENCE
- GENERAL INFORMATION ABOUT THE MARKET
- REGULATORS AND FUNDING BODIES
- INTELLECTUAL PROPERTY ISSUES
- PRICING
- DISTRIBUTION
- MARKET SIZE
- IRANIAN PHARMACEUTICAL MARKET PLAYERS
- KEY STAKEHOLDERS
- TRADE OPPORTUNITIES IN THE PHARMACEUTICAL INDUSTRY
- NEW DEVELOPMENTS IN TRADE IN PHARMACEUTICALS BETWEEN EUROPE & IRAN
- CHALLENGES
- POINTS TO CONSIDER FOR AN EU SME EXPORTING TO IRAN
- IMPORTANCE OF PAYMENT VEHICLES (INSTEX)
- OUTLOOK
- IDENTIFYING GROWTH SEGMENTS FOR EUROPEAN SMEs



## EUROPEAN PRESENCE

Bayer AG has been operating in Iran for more than 60 years supplying the market with all types of medicine.  
Sanofi Aventis has been in Iran since 2006, and supplies vaccines, branded and generic medicines.  
Novo Nordisk is considered an investment pioneer in the Iranian pharma industry by establishing an insulin plant in 2016.

## GENERAL INFORMATION ABOUT THE MARKET

Prior to entering the Iranian market, EU SMEs should consider the following:

### Regulators and Funding Bodies

In addition to complying with trade regulations, new product registration and authorization is granted by the Food and Drug Administration of Iran (FDA); an agency operating under Iran's Ministry of Health and Medical Education (MOHME), responsible for regulating the pharmaceutical industry including manufacturing, distribution and imports. The FDA issues both import and manufacturing licenses for all medicine and publishes the Iran Medicine List (IML). The Iran Drug Selection Committee has the responsibility to maintain and revise the IML on an annual basis. However, there are systematic mechanisms for the FDA to allow for import or manufacturing of new medicine in case of an emergency.

Another key agency is the Supreme Council of Health Insurance (SCOHI), which determines which drugs can be covered by insurance and to what extent. The higher the rate of inclusion by the medical insurance companies, will have a more positive impact for consumers.

## MARKET SIZE

At the end of 2021, Iran's pharmaceutical industry was valued at €3.01 billion and is expected to grow to €3.8 billion by 2031.

Since Iran currently manufactures 96% of the medicine for its population in numbers and 69.7% in terms of value, Iranian manufacturers are now prioritizing the development of partnerships with foreign pharmaceutical companies in order to improve industry and quality standards. Locally produced medicine is mainly generic and for less expensive branded specialised medicine. As a result, the 10% of imported medicine mostly destined the local products in terms of value. In 2021, Iran's pharmaceutical exports stood at €52.28 million, outwards for Central Asia.

In recent years, the use of herbal and traditional medicine has increased in Western countries, presenting an opportunity for Iran to export these products to European markets, in particular Germany. In 2019, pharmaceutical imports from Iran into Germany stood at €26.95 million.

Fig. 1 - Development of Pharmaceutical sales, GDP, healthcare spending, and population



Although the Iranian pharmaceutical industry is far behind its European counterparts in terms of Research and Development (R&D), it is now considered as a strategic sector and aims to become a future regional research hub. The International Science Rankings Institute has ranked Iran as 14th worldwide for research in the pharmaceutical industry highlighting its improved standing as evidenced by internationally recognized biomedical centres such as the Pasteur Institute of Iran.

## IRANIAN PHARMACEUTICAL MARKET PLAYERS

There are around 92 pharmaceutical manufacturing companies active in Iran with more than 60 plants committed to producing almost 40 billion drug units annually. Since some of the products do not meet International Goods Manufacturing Practice Standards, the Iranian Government has introduced key policy initiatives.

Initiatives include promoting R&D and investing in new products, with Iranian pharmaceutical companies developing more than 12 new treatments for diseases including cancer and diabetes. With investment in start-ups active in biotechnology and stem cell research, Iran has achieved a recognized international status and is ranked among the world's leading stem cell research countries. It has also invested heavily in relevant facilities and requisite infrastructure for plasmapheresis (blood plasma treatment) and

infertility. Even during the COVID-19 pandemic Iran was one of the first countries to use plasmapheresis as a possible treatment to fight the virus.

Following international trends, Iran is constructing a €1.85 billion government-backed 'Industrial Pharmaceutical City' near Tehran, as a hub for incubators, research laboratories, biotechnology manufacturers and start-ups active in the Pharmaceutical sector. This hub provides tax exemptions to foreign investors.

Despite the large number of companies active in the market, the pharmaceutical industry is highly consolidated in Government-owned controlled holdings including Barekat Pharmed Co. ("Barekat") and Tamin Pharmaceutical Investment Company ("TPICO"), as demonstrated by the following figures. TPICO is a subsidiary of the Social Security Organization of Iran, the Government pension fund.

Fig. 2 - A comparison between the key market players (Barekat & TPICO)

### Barekat at a Glance

- 1 Largest Knowledge-Based Pharmaceutical Complex in Iran
- 20 Subsidiaries
- 5 Barekat focuses on five fields including: biotechnology, drug delivery using nanotechnology, sustained release medicine and the development of cellular and molecular biology industries including cell therapy, gene therapy, immunotherapy and tissue engineering.
- 14 Holds 14% of Iran's market share.
- 420 In charge of producing 420 types of medicine.
- 3500 Barekat employs more than 3500 pharmaceutical experts to meet the domestic healthcare requirements.

### TPICO At a Glance

- 1 The largest exporter of pharmaceutical products in Iran
- 10000+ More than 10,000 people working in 25 subsidiary companies
- 50+ Export of raw materials and final products to over 50 countries
- 70%+ Production of more than 70% of the country's pharmaceutical raw materials.
- 35%+ Distributing more than 35% of the pharmaceutical products in Iran
- 30%+ 30% of final domestic pharmaceutical products

Even though Barekat and TPICO manage the majority of Iran's pharmaceutical industry, there are a few private held pharmaceutical companies in Iran, such as Akbarieh, Cobel and Pharma Chini, with a long working history with European companies such as DSM, Bayer Schering Pharmaceuticals and Boehringer Ingelheim.

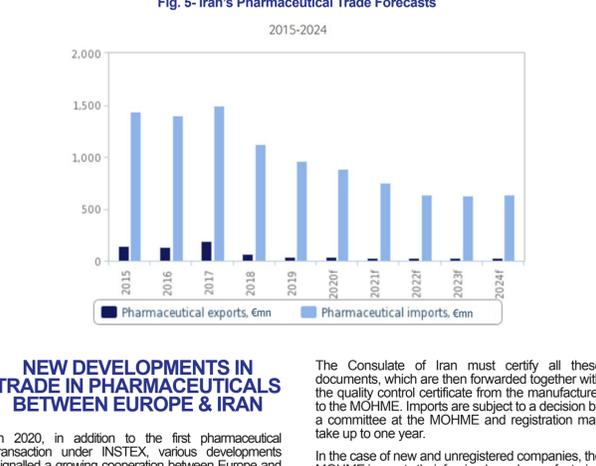
## KEY STAKEHOLDERS

The Iranian pharmaceutical industry presents different opportunities to European companies and SMEs. However, market entry requires deep knowledge of the structure of the industry, the decision-making process and how to develop key partnerships with the right market players. The following figure describes the successful experience of two European pharmaceutical companies in Iran:

Fig. 3 - Market Entry Strategies by two European Pharmaceutical Companies:

SANOFI	NOVO NORDISK
<p><b>MARKET ENTRY</b></p> <p>Legal presence through RP Iran Initially imported RTX drugs.</p> <p>Since 2012, after the grant of the import license for Magne B6, Sanofi initiated imported OTC drugs.</p> <p>Technology and know-how transfer and training with respect to gene therapy.</p> <p>It has been involved in manufacturing collaborations for certain products since 2009.</p> <p>Engagement in significant technology and know-how transfer</p>	<p>Legal presence through representative office since 2005.</p> <p>Its purpose was to provide access to insulin and haemophilia products to the Iranian public.</p> <p>In 2015, it provided a small number of diabetes products free of charge to Iranian pharmaceuticals companies.</p> <p>Established Novo Nordisk Pars (NN Pars), a wholly-owned subsidiary.</p> <p>Executed five contracts with local State-owned enterprises as distributors.</p> <p>Promotes knowledge sharing and sponsors programs with universities and the Iranian Government about diabetes awareness.</p> <p>In 2016 NN started a manufacturing plant which to date uses for assembly and packaging of insulin pens in Iran.</p>
<p><b>MARKET DEVELOPMENT IN IRAN</b></p> <p>Currently most of Sanofi sales are from local production and the rest from imports (imports are for specialized drugs).</p> <p>In 2016 Sanofi entered a memorandum of cooperation (MOC) with Iran Food and Drug Administration (FDA) to:</p> <ol style="list-style-type: none"> <li>1. reinforce future projects to pursue ongoing partnerships to enhance manufacturing quality standards; initiate collaborations with Ministry of Health re: prevention and control of certain chronic and non-communicable diseases (diabetes), and conduct research on epidemiology.</li> <li>2. General IVD Demands</li> <li>3. Supply Shortages (API and Finished Products)</li> </ol> <p>Following the MOC, Sanofi entered an LOI with Barekat Pharmed to evaluate the possibility of a joint venture to manufacture and distribute pharmaceuticals in Iran.</p> <p>The LOI expired and did not lead to any new business for Sanofi.</p>	<p>Sponsored education programs and congresses with medical universities.</p> <p>An MOU for contract manufacturing with a local company in 2018 was signed.</p> <p>It sold products into the Iranian market thru its German subsidiary for production of dialysis filters and leucocyte filters and syringes.</p> <p>In 2013 executed an agreement with a blood fractionation company.</p> <p>Novo Nordisk made an investment of approximately DKK 520 million from 2015 to build a manufacturing facility in Iran together with Barekat Pharmed.</p>
<p><b>MAIN SUCCESS FACTORS</b></p> <p>Initiated from bilateral governmental dialogue</p> <p>Offered significant knowledge transfer</p> <p>By local manufacturing, it also capitalized on local expertise.</p>	<p>Good relationship with SOEs engaged in pharmaceuticals.</p> <p>Awareness campaigns about diabetes and towns.</p> <p>Demonstrate a high sense of commitment to the market by its level of employment, investment, engagement and collaboration with local market players.</p>
<p><b>CURRENT STATUS</b></p> <p>In 2021 business activities with hospitals and distributors (General IVD Demands, pharmaceuticals and vaccines) generated more than €14.5 million gross revenue with more than €3 million in net profits. More than €22.8 million in gross revenues were generated by other Sanofi affiliates.</p>	<p>In 2021, it conducts limited business relating to pharmaceutical products and devices within the diabetes care and biopharma segments in Iran.</p> <p>It reports that its direct and indirect sales with the Ministry will be around €53 billion.</p>

Fig. 4 - Iranian Pharmaceutical Industry at a Glance



## CHALLENGES

Iran's pharmaceutical industry requires modern production technologies and ways of increasing economies of scale. Years of underdevelopment, economic slowdown and a subsequent lack of financing has severely impeded the industry's path to growth. Public and private funds remain scarce, which reduces investment in new product research and development. Innovative financing, such as through investment banks and specialized investment companies is a new growth area. Share flotation on domestic stock exchanges by pharmaceutical companies also has an untapped potential to help further develop new products. Mergers and acquisitions have to some extent helped to consolidate the sector and establish major pharmaceutical holdings and more comprehensive production chains.

## TRADE OPPORTUNITIES IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical imports reached €538.83 million in 2021 with estimates at €445.58 million in 2026 due to a hard currency crunch.

Fig. 5 - Iran's Pharmaceutical Trade Forecasts



## NEW DEVELOPMENTS IN TRADE IN PHARMACEUTICALS BETWEEN EUROPE & IRAN

In 2020, in addition to the first pharmaceutical transaction under INSTEX, various developments signalled a growing cooperation between Europe and Iran. For example, in April 2020 the European Medicines Agency (EMA) issued a good manufacturing practice (GMP) certificate to AyoGen Pharmed, an Iranian biopharmaceutical company advancing a bevacizumab biosimilar candidate, BE104OV, currently in a Phase III study as a potential treatment for metastatic colorectal cancer. In May 2020, Iran and Germany signed an agreement to boost trade in pharmaceuticals.

### Opportunities

The Iranian government unveiled plans in September 2019 to initiate domestic production of 135 medical products. This coupled with Iran's large population and high burden of chronic diseases, provides impetus for the growth of the local pharmaceutical market, with innovative international manufacturers able to participate in domestic investments.

The Consulate of Iran must certify all these documents, which are then forwarded together with the quality control certificate to the manufacturer to the MOHME. Imports are subject to decision by a committee at the MOHME and registration may take up to one year.

In the case of new and unregistered companies, the MOHME inspects their foreign-based manufacturing facilities in order to evaluate its suitability in terms of Good Manufacturing Practices (GMP). However, if the manufacturing facility holds accreditation from the European Medicines Agency or the US Food and Drug Administration (FDA), then the GMP audit by the Ministry will be waived. The registration fee is €5880 per product.

In 2019, in a move to encourage European exports to establish themselves in Iran and sell directly to the market, MOHME introduced measures which reduced the European exporters' ability to appoint different Iranian agents and distributors simultaneously for the same products.

## POINTS TO CONSIDER FOR AN EU SME EXPORTING TO IRAN

An EU SME considering exporting its products or services into Iran needs to appoint a local agent to register its products in Iran. If the imported drug appears on the IML, the import is only subject to the approval of the MOHME's accredited laboratories. Otherwise, the importer has to follow the registration process. The following documents are required for product registration:

- Legalised authorisation;
- Legalised certificate of pharmaceutical product;
- Legalised list of importing countries or free sale certificate;
- Medicine master file for APIs, otherwise a registration dossier;
- Certificate of analysis (for APIs); and
- A medicine importing application form.

## IMPORTANCE OF PAYMENT VEHICLES (INSTEX)

The Instrument in Support of Trade Exchanges (INSTEX) was initiated in 2019 to facilitate legitimate trade with Iran, in light of the challenges faced by European market participants who wish to continue trading in and with Iran in an unobstructed manner. In practice, INSTEX functions as a clearing house that facilitates the exchange of payment transactions between Europe and Iran. The first export of medical devices from Germany to Iran using INSTEX was completed in March 2020.

More details are available at: <https://instex.europa.eu/>

## IDENTIFYING GROWTH SEGMENTS FOR EUROPEAN SMEs

- Use of AI & Machine Learning in Biotechnology
- Tele Medicine & Tele Drug Delivery
- Medicine tracking (Identification of counterfeit medicine)
- Sophisticated production lines
- Packaging of raw materials
- Consumer education
- Vitamins & supplements
- Development of local APIs
- R&D methodology
- Quality control & standardization

## OUTLOOK

Given the planned prioritisation on R&D, Iran's demographic outlook, and a rise in Government initiatives with a view to international cooperation, the sector looks very promising.

« Medicine is the restoration of discordant elements; sickness is the discord of the elements infused into the living body »  
Leonardo da Vinci

## References

<https://store.fticonsolutions.com/all-products/iran-pharmaceuticals-healthcare-report>  
[https://www.novonordisk.com/content/dam/novonordisk/global/en/investors/material/annual\\_report/2022/novo-nordisk-form-20-f-20-21.pdf](https://www.novonordisk.com/content/dam/novonordisk/global/en/investors/material/annual_report/2022/novo-nordisk-form-20-f-20-21.pdf)  
<https://www.sanofi.com/iran/fr/fr/01e8793-2e68-402f-9090-9e665c4215f6/Form-20-F-2021.pdf>  
[http://ifeh.com/wp-content/uploads/2017/05/ILARB\\_Pharmaceutical\\_Regulatory\\_Report2020.pdf](http://ifeh.com/wp-content/uploads/2017/05/ILARB_Pharmaceutical_Regulatory_Report2020.pdf)  
[https://pharmexcel.com/uploads/country-reports/iran\\_Market\\_Regulatory\\_Report2020.pdf](https://pharmexcel.com/uploads/country-reports/iran_Market_Regulatory_Report2020.pdf)  
<https://www.aesofibarcia.it/serveizi/internazionalizzazione/documenti/la-survey-on-the-iranian-pharmaceutical-report>  
<https://tradingeconomics.com/germany/imports/iran/pharmaceutical-products>  
<https://www.scimgoijr.com/country/iran.php?area=3000&category=3003>  
<https://www.imf.org/en/Countries/IRN>  
<https://country.eiu.com/Industry.aspx?Country=Iran&Topic=Industry&Subtopic=Healthcare>  
<https://www.ceidatata.com/en/indicator/iran/imports-medical-and-pharmaceutical-product>  
<https://www.ceidatata.com/en/indicator/iran/imports-medical-and-pharmaceutical-product>

Avati, N., Sayar, A. B., & Nikfar, S. (2020). Short and long term impacts of COVID-19 on the pharmaceutical sector. DARU Journal of Pharmaceutical Sciences, 28(2), 799-805.

For further information, please contact us at: [info@sanctions-helpdesk.eu](mailto:info@sanctions-helpdesk.eu) or [www.sanctions-helpdesk.eu](http://www.sanctions-helpdesk.eu)