

PHARMACEUTICAL INDUSTRY IN IRAN

October 2020

TABLE OF CONTENTS

- FACTS ABOUT THE IRANIAN PHARMACEUTICAL INDUSTRY
- EUROPEAN PRESENCE
- MARKET SIZE
- IRANIAN PHARMACEUTICAL MARKET PLAYERS
- KEY STAKEHOLDERS
- GENERAL INFORMATION ABOUT THE MARKET
- REGULATORS AND FUNDING BODIES
- INTELLECTUAL PROPERTY ISSUES
- PRICING
- DISTRIBUTION
- NEW DEVELOPMENTS IN TRADE IN PHARMACEUTICALS BETWEEN EUROPE & IRAN
- OPPORTUNITIES
- CHALLENGES
- TRADE OPPORTUNITIES IN THE PHARMACEUTICAL INDUSTRY
- 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 50 years supplying the market with all types of medicine.

Sanofi Aventis has been in Iran since 2006, and supplies vaccines, branded and generic medicine.

Novo Nordisk is considered an investment pioneer in the Iranian pharmaceutical industry by establishing an insulin plant in 2016.

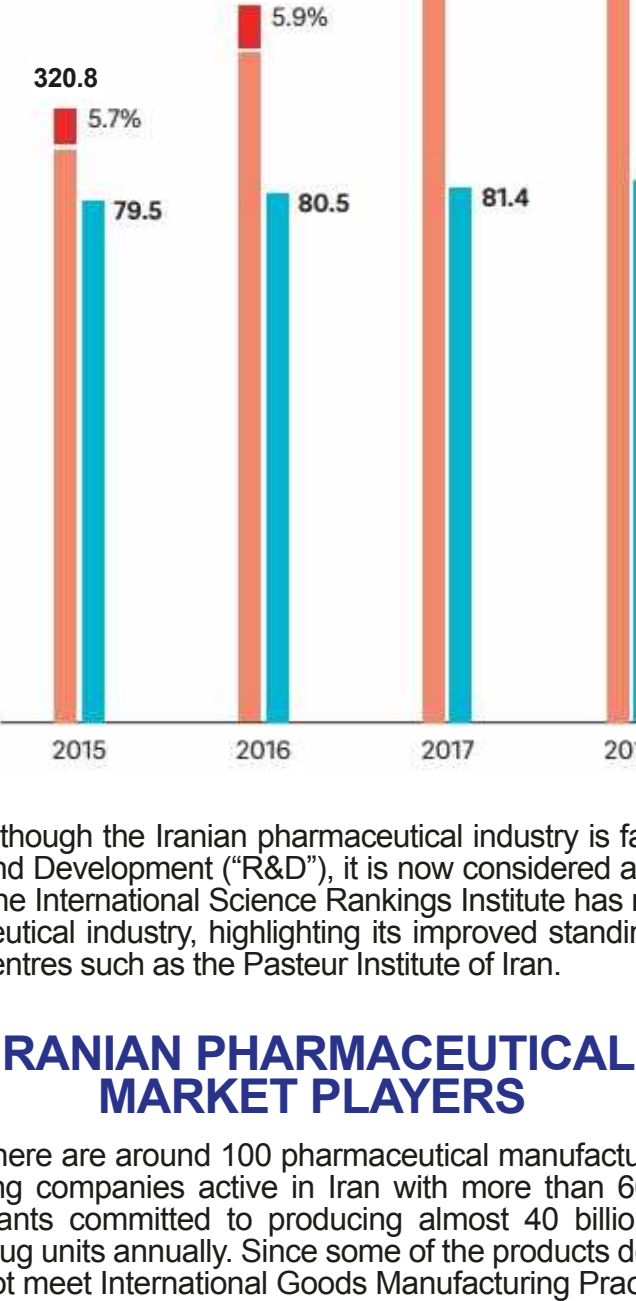
FACTS ABOUT THE IRANIAN PHARMACEUTICAL INDUSTRY

Historically, Iran has been very important to the world of medicine. In ancient times, the Mesopotamians carved prescriptions and diagnosis into stone tablets. Avicenna, considered as the father of early modern medicine by developing the Canon of Medicine, and Muhammad ibn Zakariya al-Razi who discovered medicinal alcohol (ethanol), both hail from Iran.

Today, Iran's domestic pharmaceutical industry is one of the most developed in the Middle East and North Africa region ("MENA"). While initially, Iranian pharmaceutical manufacturers only produced Over the Counter ("OTC") and generic medicine, they have since evolved towards producing more sophisticated medicine used in the treatment of different types of cancers, diabetes and multiple sclerosis. For example, CinnaGen, the largest biopharmaceutical company in Iran manufactures biosimilars of leading immunology and cancer medicine.

International sanctions have obliged Iran to evolve from importing almost 100% of its pharmaceutical needs to manufacturing more than 60% locally. As a result, while still not self-sufficient in the pharmaceutical industry, Iran has pursued international pharmaceutical companies to increase imports to ensure supply of vital medicine. Health insurance coverage is one of the most important market drivers in the pharmaceutical industry. Since 2019, the Iranian government has introduced a comprehensive health insurance plan to all Iranians to cover basic medical costs. This plan covers 70% of the cost of medicine with an additional coverage for those with rare diseases. According to the World Health Organization (WHO), all the medicine incorporated into the latest version of the WHO Model List of Essential Medicines are available in Iran; with 100% insurance coverage available with two exceptions.

Fig. 1- Symbol originates from Persia

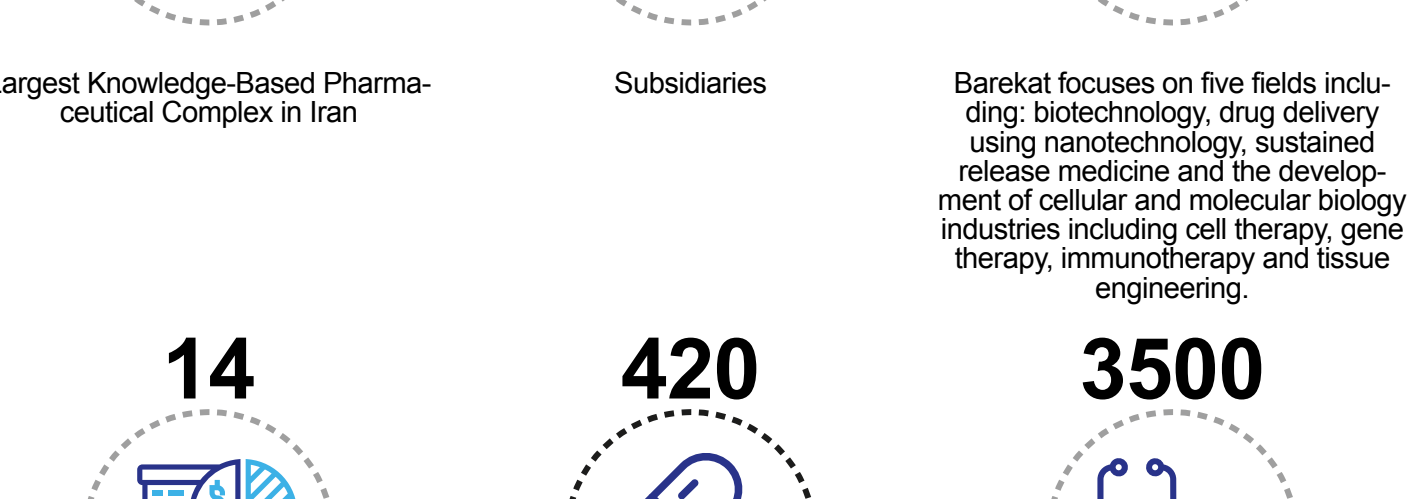


MARKET SIZE

At the end of 2019, Iran's pharmaceutical industry was valued at € 2.5 billion annually and is expected to grow € 3.1 billion by 2024. Since Iran currently manufactures 90% of the medicine for its population, 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 over the counter, with some patented prescription medicine, while imported medicine consists mainly of more expensive branded specialised medicine. As a result, the 10% of imported medicine outweighs the local products in terms of value. In 2020, Iran's pharmaceutical exports stood at €90 million, mostly destined 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. 2- 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 is becoming a future research hub. The International Science Rankings Institute has ranked Iran as 15th 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 100 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

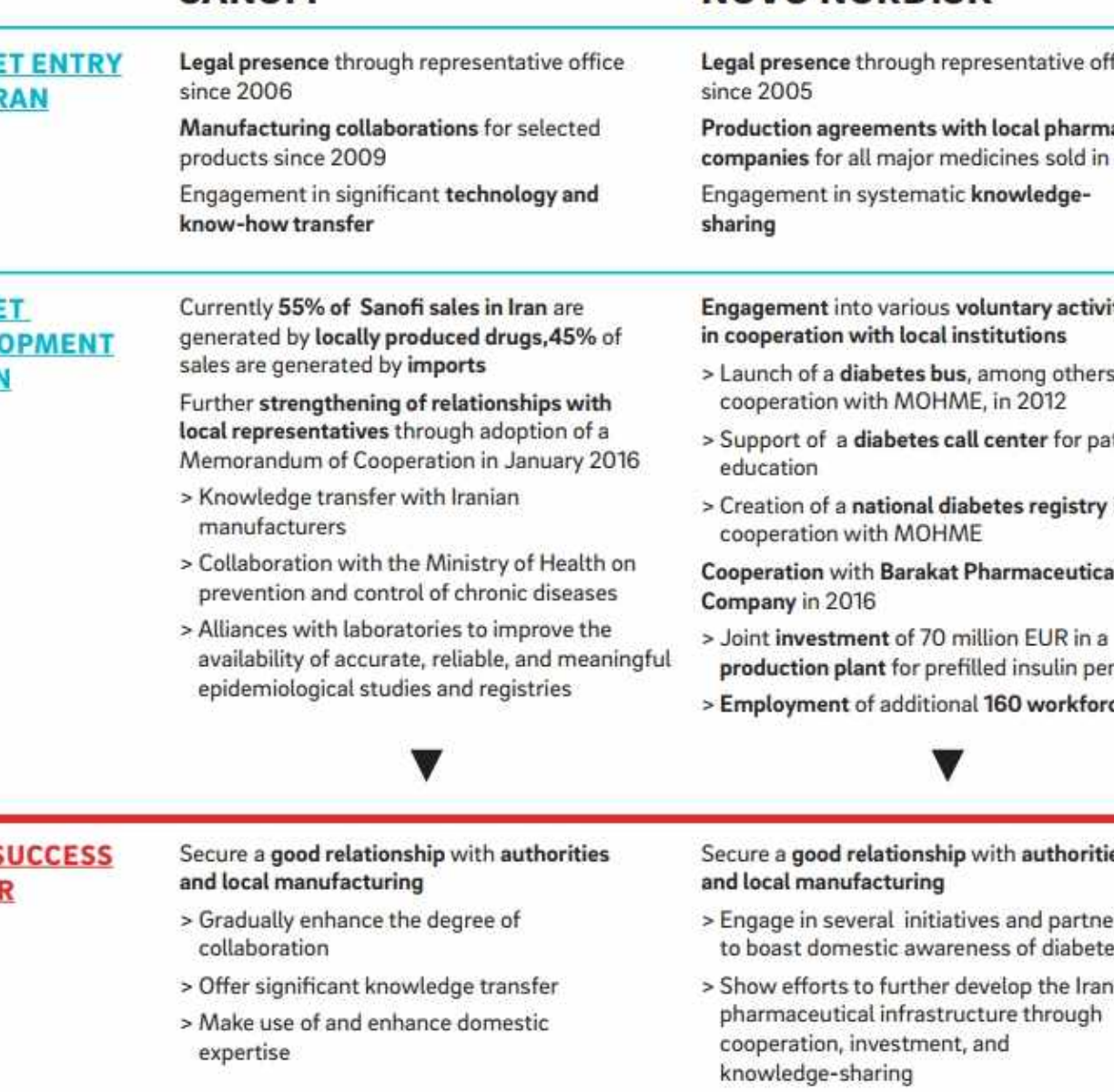
plasma treatment) and infertility. Even during the COVID-19 pandemic Iran was one of the first countries to use plasmapheresis as a possible treatment to fight the virus.

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 specialized 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. 3- A comparison between the key market players (Barekat & TPICO)

Barekat at a Glance



TPICO At a Glance



Even though Barekat and TPICO manage the majority of Iran's pharmaceutical industry, there are a few privately held 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 following figure describes the successful experience of two European pharmaceutical companies in Iran:

Fig. 4- Market Entry Strategies by two European Pharmaceutical Companies:

SANOFI	NOVO NORDISK
MARKET ENTRY INTO IRAN Legal presence through representative office since 2006 Manufacturing collaborations for selected products since 2009 Engagement in significant technology and know-how transfer	MARKET ENTRY INTO IRAN Legal presence through representative office since 2005 Production agreements with local pharmaceutical companies for all major medicines sold in Iran Engagement in systematic knowledge-sharing
MARKET DEVELOPMENT IN IRAN Currently 55% of Sanofi sales in Iran are generated by locally produced drugs, 45% of sales are generated by imports Further strengthening of relationships with local representatives through adoption of a Memorandum of Cooperation in January 2016 > Knowledge transfer with Iranian manufacturers > Collaboration with the Ministry of Health on prevention and control of chronic diseases > Alliances with laboratories to improve the availability of accurate, reliable, and meaningful epidemiological studies and registries	MARKET DEVELOPMENT IN IRAN Engagement into various voluntary activities in cooperation with local institutions > Launch of a diabetes bus, among others in cooperation with MOHME, in 2012 > Support of a diabetes call center for patient education > Creation of a national diabetes registry in cooperation with MOHME Cooperation with Barekat Pharmaceutical Company in 2016 > Joint investment of 70 million EUR in a production plant for prefilled insulin pens > Employment of additional 160 workforces
MAIN SUCCESS FACTOR Secure a good relationship with authorities and local manufacturing > Gradually enhance the degree of collaboration > Offer significant knowledge transfer > Make use of and enhance domestic expertise	MAIN SUCCESS FACTOR Secure a good relationship with authorities and local manufacturing > Engage in several initiatives and partnerships to boost domestic awareness of diabetes > Show efforts to further develop the Iranian pharmaceutical infrastructure through cooperation, investment, and knowledge-sharing

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 ("IFDA"), 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 IFDA 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 IFDA 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.

Intellectual Property Issues

Given the relatively basic nature of the Iranian market, limited patent legislation exists, which deters overseas market entrants. According to Article 28 of the Law of Registration of Marks and Patents in Iran, pharmaceutical formulae and compounds are not patentable, but a patent may be filed for processes related to pharmaceuticals manufacturing. However, according to specially devised legislation, pharmaceutical products - whether produced in Iran or imported - are required to have a registered trademark. Iran is presently seeking WTO membership, which would improve its intellectual property (IP) protection, as well as require further economic liberalisation.

Pricing

Drug prices are determined by the IFDA's Pricing Commission. Decisions are based on the expenses incurred by producers and importers for each drug, and then prices are fixed, considering the upper range of the cost.

Distribution

Medicine is primarily distributed by six government-owned companies, however smaller private distributors are increasingly entering the market, with about 20 currently active. Overall, the 10 largest distributors have a 75% market share, showing a high level of consolidation, which makes the leveraging of existing local networks an attractive option.

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 AnyoGen Pharmed, an Iranian biopharmaceutical company advancing a bevacizumab biosimilar candidate, BE1040V, 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.

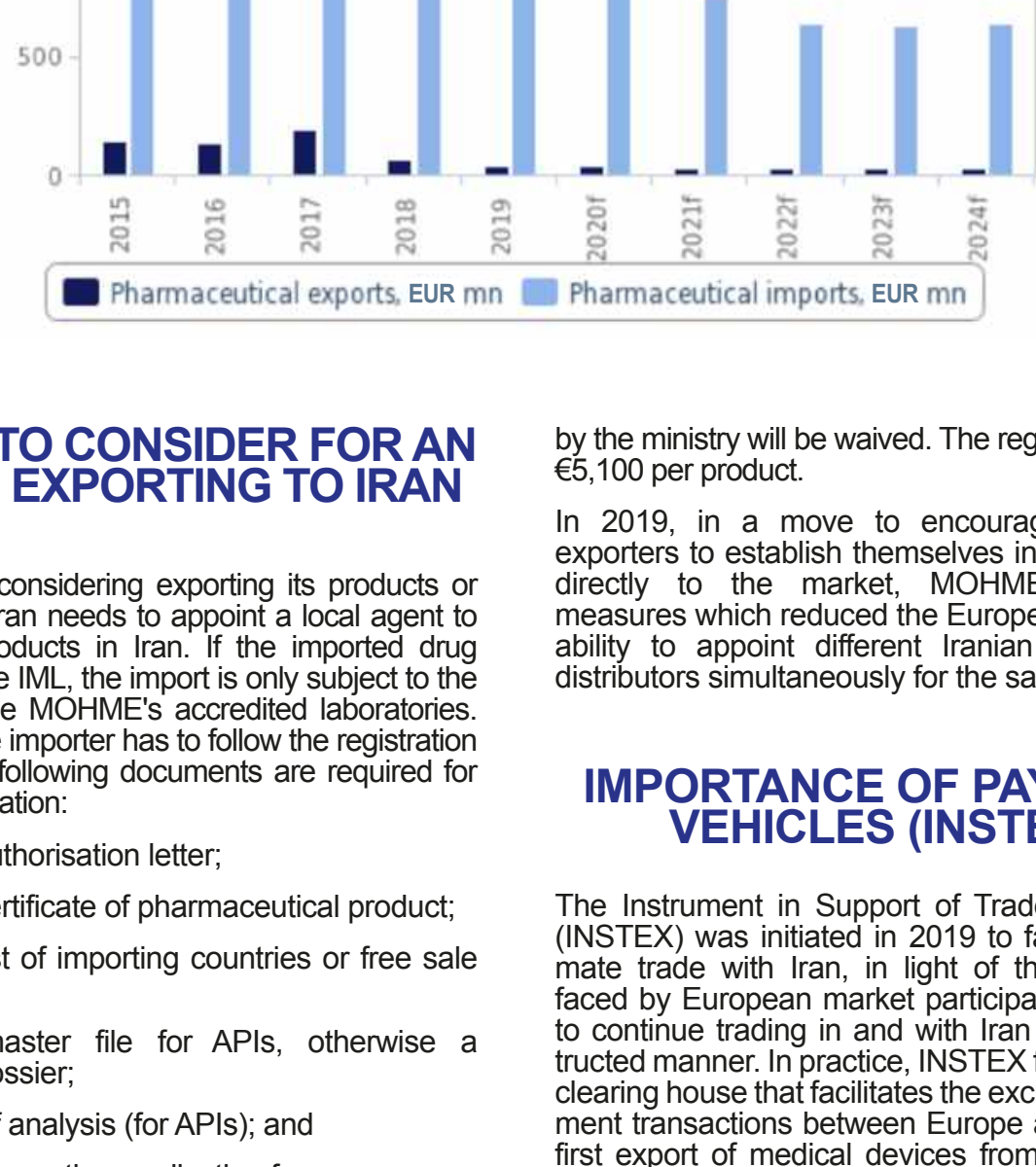
Opportunities

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.

TRADE OPPORTUNITIES IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical imports reached €819.31 million in 2019 with estimates at €538.56 million in 2024 due to a hard currency crunch.

Fig. 6- Iran's Pharmaceutical Trade Forecasts



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 letter;
- 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.

The Consulate of Iran must certify all these documents, which are then forwarded together with the quality control certificate from the manufacturer to the MOHME. Imports are subject to a 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 €5,100 per product.

In 2019, in a move to encourage European exporters 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.

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-europe.com>

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.

Fig. 7- Iran's Pharmaceutical Market Forecast



IMPACT OF COVID-19 ON THE IRANIAN PHARMACEUTICAL INDUSTRY

The global pandemic has prioritized spending on fighting COVID-19, reducing allocations for other essential medicine to treat other diseases. However, this is considered a temporary shift, while the pandemic has strengthened international cooperation both to combat COVID-19 and within the pharmaceutical sector in General. In Iran the pandemic is responsible for Fast Track Approvals for Covid-19-Related Treatments by the IML And Medicine Registration Process.

Fig. 8- Short term & Long term Impact of COVID-19 on the Pharmaceutical Industry in Iran

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

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

For further information, please contact us at:

info@sanctions-helpdesk.eu
www.sanctions-helpdesk.eu

