Health and Science Projects in Iran

Dentons Europe

Overview

The Iranian pharmaceutical and healthcare products market has had steady growth during the last decade. There have been significant improvements in living standards in Iran, in particular adequate access to healthcare facilities in urban areas and developing access in rural regions due to government policies. These obviously have entailed a remarkable growth in the demand for consumer health products. Moreover, Iran's population status promises a wide range of opportunities to investors who seek to do business in this market. Currently, Iran has a population of approximately 80 million people, and it is forecasted to reach 84.2 million by 2020. This is also an indication of a growing customer base for pharmaceutical products.

The population growth rate however is in decline. The Iranian government is now faced with the prospective of an aging population in future decades. Accordingly, the Iranian Supreme Leader has approved guidelines in 2014 stipulating that adequate infrastructure must be established for the production of pharmaceutical raw materials, vaccines, bio products and medical equipment, all in conformity with international standards.

The World Health Organization classifies the Iranian health system as one of the strongest in the world, with a first line service fair and efficient. Iran spends approx. six percent of its GDP (Gross Domestic Product) in the health sector which represents approx. US$826 per inhabitant. The Iranian government has increased healthcare budget on an annually basis and the healthcare spending is projected to grow at a similar rate to GDP (12 percent) reaching nearly $40 billion (six percent of overall spending) in 2020, driven by rising Health Ministry expenditure.

With the release of sanctions since the JCPOA (Joint Comprehensive Plan of Action) Implementation Day in 2016, imports will pick up again to reach US$1.16 billion in 2019. The market has been forecasted to become the fourth largest pharmaceutical market in the Middle East and North Africa region by 2024, in terms of market size. Iran has a lively pharmaceuticals market. The sector is made up of approx. 100 companies, with most focused on drug manufacturing. Some also carry out R&D (Research and Development), import non-locally produced drugs or provide distribution, offering ample potential for cooperation.

Body in charge

Ministry of Health and Medical Education (MOH) is the main body that regulates and implements import, registration, and customs release of any sort of pharmaceutical products.[1] The Ministry has the legal authority to supervise, license and manage the activities of the private health sector in the country.

The MOH in accordance with its objectives and for enhancement of use and rational consumption of pharmaceutical products and development of a dynamic competition for manufacture and import of these products announced its rules and regulations of importation of these products. MOH has engaged a department which is responsible specifically for medicines.

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[1] Article 14 of Medical Affairs, Pharmaceuticals and Foodstuff.

The main laws and regulations which govern pharmaceutical products can be listed as follows:

All the activities with respect to pharmaceutical products including manufacturing, distribution and importation are managed and supervised by the Office of Pharmaceutical Affairs of MOH.

Any legal entity that holds an exclusive agency from the Product License Holder (PLH) or Marketing Authorization Holder (MAH), can apply for registration and import of the related pharmaceuticals at the Division of Pharmaceutical and Narcotic Affairs (DPNA) (a division of Food and Drug Administration (FDA)). Import of pharmaceuticals shall be according to Iran's List of Drugs provided by the Iranian Drug Evaluation Committee Secretariat. The Ministry of Health and Medical Education (MOH) is the main body that, as the Iranian National Drug Regulatory Authority, regulates and implements the imports, registration and customs release of any sort of pharmaceutical products. As stated in article 20 of the Law on Medical Affairs, Pharmaceuticals and Foodstuff, the MOH enforces standards and authorizes the manufactures and imports of pharmaceuticals and biological products. Imports of pharmaceuticals that are listed by the Iranian Drug Evaluation Committee Secretariat are subject to the Guidelines on Registration of Pharmaceutical Products for Imports.

The list is available at (www.FDA.ir)

Based on the law of medical, pharmaceutical, edibles and potables, all pharmaceutical products must be registered in the national drug list (NDL) to be authorized to be distributed in the market. However, some products might be available in certain circumstances to specific patients with special conditions without being on the national drug list. According to the Act of Emergency Pharmaceutical Centres (EPCs) (2008), the pharmaceutical products that are not registered in the NDL could be imported by institutions called EPCs, whenever a shortage or crisis happens or an alternative is not available for a specific patient.

According to Article 12 of the Act on production and importation of pharmaceuticals, the establishment of a pharmaceutical manufacturing company must be licensed by both the ministry of industry and the MOH. Moreover, all pharmaceutical companies are obligated to introduce a responsible officer (qualified pharmacist with an experience in the industry). According to this Act, the first batch of each new pharmaceutical or biological product (domestically manufactured or imported) must be analyzed in MOH laboratories; they can be distributed in the market only after being approved. Furthermore, the marketed products should be randomly sampled regularly and sent to the laboratories for post marketing quality evaluation. According to this Act, the importation of the active pharmaceutical ingredient (APIs) by domestic manufacturers must be also under the supervision and approval of the MOH.

Registration of application

Any legal entity that holds an exclusive agency letter of the PLH or MAH, can apply for the registration and import of related pharmaceuticals at the DPNA. The applicant has to provide the following documents for registration:

- The application form for registration and import
- A copy of exclusive agency letter certified by Iranian embassy in the country of origin
- An agency registration certificate issued by the Iranian Ministry of Mining, Trade and Industry

In case the application is approved by the expert committee, the applicant has to introduce a qualified pharmacist as a technical supervisor to the DPNA to follow up the registration and relevant issues. DPNA then decides on the qualifications of the nominated technical supervisor and whether to approve or refuse him.

The law on Medical, Pharmaceutical, Edibles and Potables is among the oldest integrated laws related to pharmaceutical products in Iran.

The law on conditions of production and import of drugs and biologic and laboratory products was ratified on 1955/06/19 and modified on 1988/04/12. According to this law, importation of any natural drug into Iran is conditioned to regulations of pharmaceutical registration and importation, and its discharge from customs and distribution requires

prior approval from the “pharmaceutical and narcotic affairs division.” The legal committee of production and importation is responsible for issuance of authorization of importation of natural drugs.

It is mandatory to mention IRC on imported drug labeling alongside introduction of brochure and labeling in Persian and English.

According to the law of medical, pharmaceutical, edibles and potables (1995), importing, exporting, selling and purchasing medicines without acquiring a license from the Ministry of Health (MOH) is considered to be a crime.

Pricing

Agent shall provide the related pricing documents to the Pricing Committee of the DPNA.

According to the Pharmaceutical Pricing Act, the price of original medicines in their patent protection period would be calculated by considering their prices in either exporter or reference countries; moreover, the price of a particular medicine in Iran's market must be lower than its price in all those countries. The price setting for patent-expired original medicines would be calculated based on either reference countries’ prices or at least via calculating 20 percent reduction from their under-patent prices, whichever is lower.

It is worth mentioning that the “cost-plus” method is still used only for the generic medicines without any trade mark or brand name, which means that it is based on the cost of the ingredients, and manufacturing costs, plus marginal profits. This is done after scrutinizing the questionnaires of prices of products and the purchase proforma delivered by the manufacturing companies for raw materials.

There is no specific regulation with respect to pricing of imported raw materials, and it is usually concluded by the agreement between the importer and the manufacturer.

However, in practice for the products manufactured in Iran locally with imported raw materials, the price is determined by the FDA’s Pricing Committee. The FDA’s Pricing Committee is required to consider all the factors which affect the prices of products and decide on the price of products to the distributor, drug store and the end user. The commission’s decisions depend on the expenses incurred by the manufacturer when delivering the products to the distributor, delivering the products to the drug stores by the distributor and bringing it to the end user’s hands. It should also be noted that prices for each product may vary. The manufacturers are required to fill out specific forms and indicate the name of the products in order for the committee to decide on the price.

The price of products after being reviewed by experts and approved by the Commission is fixed for the duration of at least one year in Iranian Rials. If the components of cost of production or import are changed, the prices can be reviewed after six months.

IP in pharmaceutical products

Iran has enacted various IP laws and has acceded to some conventions that form the regulatory framework of Iran’s Intellectual Property laws.

The Act on Patent, Industrial Designs and Trademarks Registration is currently the main local law governing IP rights (patent, trademarks industrial designs) which have been passed in 2007. The Industrial Property Office at the Organization for Registration of Deeds and Estates of the Judiciary is in charge of industrial property affairs, which is also affiliated to the Judiciary.

Iran has also acceded to a number of international conventions in this regard, such as the Paris Convention, Lisbon Act of 1958 in 1959 and its revisions in 1967 and 1979 in 1998. Iran has also acceded to the Convention Establishing the World Intellectual Property Organization (WIPO), the Madrid Agreement Concerning the International Registration of Marks and the Protocol relating to that Agreement, the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods.

In 2005, for reinforcing the supporting system for intellectual property rights, Iran joined the Lisbon Agreement for Protection of Appellations of Origin and their International Registration and also in 2007 ratified the Cooperation Treaty for registration of patents. Currently, applications for joining two agreements, namely Nis (International Classification of Trademarks) and Locarno (Classification of Industrial Designs) have been submitted to the competent authorities for approval.

1.1 Patent

According to the mentioned Act, a patent can be registered which includes a new innovation and is industrially applicable.[2] In case the subject of a patent is a product, its owner shall enjoy the exclusive rights of production, importation and exportation, supply for sale, sale, utilization and stocking with intention for sale.[3]

Patents will be valid for 20 years as of the application submission.[4]

Any interested party can apply for a nullification order from the court if he or she can prove that any of the terms relating to the inventions are not observed, or the holder of the patent paper is not the inventor or their legal representative.[5] Also, any person who willingly violates the rights granted through the patent and the rights caused by the registration of industrial design or trademark is considered to be an offender and in addition to compensation shall be fined from 10 to 50 million Rials or shall be imprisoned from 91 days to six months or both.[6]

1.2 Trademarks

According to the Act on Patent, Industrial Designs and Trademarks Registration, the owner of a trademark shall have the exclusive right to make use of it, subject to its registration.[7] Please also note that any changes of the trade mark have to be also registered and shall not lead to public misunderstanding or deception otherwise registration would not be valid.[8]

Generally, some trademarks cannot be registered including misleading marks of commercial and public canters for origin or goods and services specifications.[9]

The term of trade mark protection is 10 years, which is renewable upon the request of the owner. Also, considering that Iran is a member of the Paris Convention, protection of recognized marks is possible.[10]

According to the mentioned Act, the owner of a registered trademark is entitled to bring a complaint before the court against any person who has utilized the mark without consent or has carried out an activity which consequently leads to the violation of the rights caused by the registered trademark.[11]

Any beneficiary can apply for nullification of the registered trademark through the court, if he can prove that this mark cannot distinguish the goods and services of natural or legal persons or is considered as a mark that cannot be registered.[12] This right also applies to collective marks. Also, if he can prove that the registered mark has not been

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[2] Article 2 of the Act on Patent, Industrial Designs and Trademarks Registration.

[3] Article 15 of the Act on Patent, Industrial Designs and Trademarks Registration.

[4] Article 16 of the Act on Patent, Industrial Designs and Trademarks Registration.

[5] Article 18 of the Act on Patent, Industrial Designs and Trademarks Registration.

[6] Article 61 of the Act on Patent, Industrial Designs and Trademarks Registration.

[7] Article 31 of the Act on Patent, Industrial Designs and Trademarks Registration.

[8] Article 48 of the Act on Patent, Industrial Designs and Trademarks Registration.

[9] This also includes marks such as flags, military insignia, country indications, or official marks belonging to country and indications contrary to Islamic precept, morality or public order, Article 32 of the Act on Patent, Industrial Designs and Trademarks Registration.

[10] Article 40 of the Act on Patent, Industrial Designs and Trademarks Registration.

[11] Article 40, paragraph B of the Act on Patent, Industrial designs and Trademarks Registration.

[12] Article 41 of the Act on Patent, Industrial Designs and Trademarks Registration.

used for at least three years (if not caused by force majeure), the beneficiary can apply for nullification through court. In case utilizing collective marks can cause deception regarding the source or any other properties of the goods or services, application for nullification to the court is possible.[13] This option includes utilizing a mark similar to the registered mark or using it for similar goods or services which can cause public misunderstanding.

We always recommend that our clients register their trademarks and even similar trademarks in Iran (in Farsi and their language). This will provide more protections to the clients in Iran.

1.3 Industrial designs

According to the mentioned Act, industrial designs can be registered if they are new and original. Utilizing (which includes manufacturing, selling and importing the items bearing that industrial design) any industrial designs which are registered in Iran is subjected to its owner's approval.

The validity period of industrial design is five years from the date of submitting its registration application, and the registrar can apply for a registration extension for two consecutive five-year periods.

Please note that any beneficiary can apply to revoke the registration of industrial design through the court, as long as it is proven that the design is not included in the definition of the industrial design or is not new and original, or the registrar of the industrial design is not its creator or his legal representative.

1.4 Trade secrets

Please note that trade secrets are not generally protected under Iran's legal system. The Electronic Commerce law has only banned illegal acquisition of trade or economic secrets of agencies and institutions or the disclosure of such secrets to third parties in "electronic environment."[14]

The scope of this law is only limited to electronic trade secret and trade secret should be obtained through electronic means.[15]

The maximum penalty for illegal acquisition of electronic trade secrets is imprisonment from six months to 2.5 years in prison or a penalty of 50,000,000 IRR (approx. €1250).

1.5 Copy rights

In accordance with Iran's laws, including the Act on the Protection of the Rights of Authors, Composers and Artists (1970), the economic and moral rights of the authors of literary, scientific and artistic works—such as written and audio-visual works, artistic works and handicrafts—are protected, and the authors enjoy the exclusive right to exploit, reproduce, publish, broadcast, communicate to the public and perform their works (Arts. 2 and 3). The exercise of these rights is not contingent on the registration of a work (Article 21).

Under Articles 4 and 5 of the Act, the moral rights of authors have no spatial and temporal limitations and are not transferable, but the authors can transfer all of their economic rights, such as rights of translation, reproduction, recording, publication and broadcasting, communication to the public and performances to others.

Despite the legislative provisions provided by the law, in practice the Iranian courts are not inclined to protect foreign IPR against Iranians counterparties. Moreover, the punishments are minimal. Therefore, we also recommend inserting

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[13] Article 43 of the Act on Patent, Industrial Designs and Trademarks Registration.

[14] Article 64 of the Electronic Commerce Law (2004).

[15] Electronic trade secrets are defined as "data messages consisting of information, formulas, patterns, software and programs, means and methods, techniques and procedures, unpublished writings, business and transaction methods and procedures, strategies, plans, financial information, customers list, trade projects and the like which have an economic value by themselves, are inaccessible to the public and reasonable efforts have been made for their protection." Articles 64 and 75 of the Electronic Commerce Law (2004).

monetary damages provisions and/or liquidated damages clauses in any contract with an Iranian counterparty to give greater certainty to the enforcement of IP rights in Iran.

Foreign investment in Iran

Dentons has published a detailed guide on Doing Business in Iran containing key information for those considering investing in the country (including options available to investors in terms of setting up a presence in the country). Given the somewhat unique circumstances that prevail in the relationship between Iran and the international community, all investors should, however, also be made aware of the on-going sanctions regime applicable to Iran and, at a high level the protections available to investors in the country. These matters are covered below.

Sanctions

Prior to Implementation Day (16 January 2016), there were multiple UN Security Council (UNSC) resolutions in place imposing sanctions on Iran for its nuclear proliferation activities, with numerous restrictions on dealing with Iran and Iranian individuals or entities. As of Implementation Day, however, UNSC Resolution 2231 (2015) (Resolution 2231) terminated the provisions of these UN resolutions.

The only remaining UN measures currently in force are those provided in Resolution 2231 (including "snap-back" provisions as outlined below). The UNSC has lifted all sanctions, with the exception of certain restrictions on dealing in sensitive material and technology.

The residual EU sanctions broadly mirror the surviving UN restrictions (imposing restrictions on dealing in nuclear proliferation technology, dual use goods, military equipment, etc.).

Notwithstanding that a large portion of the energy and financial sector sanctions have now been lifted in the EU, the US sanctions aiming at US persons, equipment and technology remain (US Primary Sanctions) while US sanctions on non-US persons (US Secondary Sanctions) have been lifted. This makes sanctions compliance for global organizations with global workforces challenging. Dentons has guided many international organizations through the patchwork of remaining sanctions prohibitions against Iran.

Given that US Primary Sanctions remain in force, companies will need to take care not to involve US nationals or green card holders on the project. Project costs cannot be denominated in USD, and care will need to be taken when working with US equipment and any contractors, insurers, banks, software providers and others who are based in the US or otherwise subject to US Sanctions. "General License H", issued by the US Office of Foreign Asset Control (OFAC), permits foreign subsidiaries of US companies to engage in trade with Iran but does not allow US companies to assist non-US companies to engage in Iranian trade. Projects therefore need to be carefully structured with these restrictions in mind.

Although establishing a company does not legally require an Iranian partner, foreign companies are likely to find establishing an Iranian partnership beneficial. Given the on-going sanctions regime, companies will need to take care to undertake thorough independent due diligence in respect of their proposed business partners. For a prospective solar project with an Iranian partner, it will be essential from the outset to understand the ownership structure and control of all Iranian counterparts and this issue should be considered alongside legal advice as to any potential

exposure to sanctions. While it is possible to obtain the names of key company representatives (such as the Chairman, CEO, and Board members), the ownership structures and shareholdings of Iranian-registered companies are not publically available.

Investor protection

Protection for Foreign Investors / Bilateral Investment Treaties (BITs) and multilateral investment treaties provide comprehensive, effective protection for investors against political risks. Investors are protected from Government interference, which may include expropriation without compensation, unfair or inequitable treatment, less favorable treatment than nationals or other investors and restrictions on currency transfers.

Appropriate corporate structuring to take advantage of treaties can provide rights of action directly against a State under international law. This type of structuring is not expensive or burdensome, and may simply involve inserting a holding company in the corporate chain. It can create significant savings as compared with political risk insurance. As described further below, there are a number of ways this type of protection can be obtained:

- Bilateral Investment Treaties (BITs);
- Multilateral Investment Protection Treaties; and
- Iranian Investment Protection Legislation.

Iran has 48 BITs in force with other countries and has signed a further 11, which are not yet in force. These BITs are not all the same and can contain different protections and have different requirements for protection. In general, the BITs with Iran offer:

- An undertaking of fair and equal treatment;
- A guarantee of free transfer of funds outside the country; and
- Recourse against Iran, in an ad hoc international arbitration outside Iran in case of expropriation or loss of investment due to a decision or action of an Iranian governmental body.

Certain of these BITs require investments to be approved by the Iranian investment authority. This requires that foreign investors register investments and obtain a certificate of admission or an investment licence under FIPPA (see below) which sets out the conditions on which an investment is admitted into the country.

Iran is a signatory to two multilateral investment protection treaties: (i) the Agreement on Promotion, Protection and Guarantee of Investments amongst the Member States of the Organization of the Islamic Conference 1981 (OIC Treaty) and; (ii) the Agreement on Promotion and Protection of Investment among Member States of the Economic Cooperation Organization 2005 (ECO treaty). The protections in these treaties are more limited in nature, and BIT protection is usually preferable.

Iran also has a Foreign Investment Promotion and Protection Act (known as FIPPA) and Implementation Regulations. FIPPA is designed to encourage and protect foreign investments in Iran, whether by way of equity investment in Iranian companies or in the financing of Iranian projects.

Pursuant to FIPPA, all areas of the Iranian economy are open to private sector investment, under Build, Operate and Transfer (BOT) Schemes, buy-back agreements and Civil Partnership. In these areas, foreign investors benefit from the same rights and exemptions available to local investors. FIPPA contains provisions whereby foreign investors cannot be deprived of their ownership rights unless such expropriation is in the public interest/benefit, and then only in accordance with a prescribed procedure and the payment of fair compensation. Generally speaking, however, FIPPA does not grant sufficient protection unless supported by the protection of a BIT (as described above).

Our experience shows that the FIPPA license reduces bureaucracy and facilitates certain administrative issues, such as residency and work permits for employees of the foreign investor.

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