IRAN
PHARMA MARKET
&
REGULATORY REPORT

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

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DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Middle East bordering the Gulf
2	Country	Iran
3	Capital	Tehran
4	Population	84,923,314 (July 2020 est)
5	Population growth rate (%)	1.1%(2020 est)
6	GDP (purchasing power parity)	**$**1.64 trillion **(**2017 est.)
7	GDP - real growth rate (%)	3.7 % (2017 est.)
8	GDP - per capita (PPP)	$ 20,100(2017 est.)
9	Epidemiology	Cardiovascular diseases, Cancer, cholera, COVID-19 and HIV AIDS.
10	Population below poverty line	18.7 %(2007 est)(No update)
11	Age structure (%)	0-14 years: 24.11%
		15-24 years: 13.36%
		25-54 years: 48.94%
		55-65 years : 7.72%
		65 & above: 5.87%
Source: CIA World Fact Book updated on 01st April 2020		

MARKET REPORT

Introduction:

Various reasons like political, economic has slightly pushed Iran, otherwise a well-developed and regulated pharmaceutical market on the back foot.

Iran's Pharma market is of the size $2.47 billion in 2019 with just 7.6% growth.(Growth in internal currency is far greater). Forecast show that the market might negatively grow and touch $ 2.4 billion by the end of 2020.

Latest Updates

- In February 2020, Health Minister Saeed Namaki announced that the value of domestically-made pharmaceuticals increased 30% in the current Iranian year (started March 2019), with about EUR600mn less spent on the import of medicines.

- In February 2020, the Danish ambassador to Tehran announced that Denmark's largest pharmaceutical company will start production at a factory in Iran, as part of plans to develop bilateral trade despite US sanctions.

SWOT

Strengths:

- Large pharmaceutical market in regional terms, supported by large population.
- Wide-ranging public healthcare coverage, including in most rural areas.
- Antiretroviral (ARVs) distributed free of charge.

Weaknesses:

- Low per-capita spent on healthcare and pharmaceuticals results in a focus on basic treatments.
- Strict import regime.

Opportunities:

- Low taxes on foreign-made drugs that are not manufactured locally.
- Rising regional demand for generic medicines.
- Improved intellectual property and regulatory conditions to attract some investment local facilities.
- Gradual modernization of healthcare facilities.
- Plans to improve drug registration times.
- Privatization of importing companies.

Market Scenario

As a result of the imposition of sanctions and the depreciation of the Iranian Riel, the cost of importing raw materials has risen significantly. Iran's diversified economy enabled the Iranian Riel to largely weather the storm of depressed oil prices when the sanctions were lifted.

By 2024, the market size is expected to rise to a USD3.4bn, corresponding to CAGR of 6.5%.

Sanctions have dealt a blow to Iran's ambitions to achieve pharmaceutical self-sufficiency, and the government is developing parallel trade channels to ensure the procurement of vital pharmaceuticals. For example, it was announced in January 2020 that a humanitarian trade

channel had been established with Switzerland for the export of food and medicine. The Iranian government highlighted this as evidence that sanctions are limiting medicines and foodstuffs from reaching the country, in contravention of international law.

Iran has one of the largest production capacities of generic medicines in the Middle East and North Africa, and the sector is capable of meeting the local needs of essential life-saving drugs. Lower medicine prices, improved customs clearance and growing domestic production have helped to better access of Medicines. Highlighting this, Nasser Riyahi, head of Iran's Drug Importing Union, stated in 2017 that a large number of previously imported medicines are now manufactured by domestic companies and the health ministry's policy to restrict imports will further support the domestic pharmaceutical industry.

Access to basic healthcare in Iran is widespread, with about 90% of the rural population and almost the entire urban population covered. The outlook for generic drug sales in Iran is favourable, as a result of the habitual prescription of lower-value medicines and a reasonable level of public awareness.

In September 2017, four new domestic generic drugs were introduced at Iran University of Science and Technology. They included *Sofosbuvir*, an antiviral drug for treatment of Hepatitis C; *Clopidogrel*, an anti-clot drug for brain stroke and heart disease; *Atorvastatin*, a lipid-lowering drug; and *Nifedipine*, a medication used to stabilise high blood pressure. The four new drugs will soon be mass produced by domestic pharmaceutical companies, after receiving the Good Manufacturing Practice Certificate from the Health Ministry to ensure proper production standards.

Generic market

The outlook for generic drug sales in Iran is uncertain amid the latest wave of sanctions imposed by the US government with generic drugs habitually prescribed and sanctions having already put upward pressure on price, volume sales for the generics segment will decrease in the short term. Despite this, robust internal drug production capabilities should level out supply problems in the medium term. Generic medicines currently account for over half of the market by value, though the lack of reliable data will remain an issue regarding our historical valuations and forecasts.

Generic Registration

Generic drugs have traditionally been encouraged in Iran, and until recently, drugs could be registered only under their generic name as opposed to their brand name. However, Iran has recently significantly changed its policy on generic medicines. According to the National Pharmaceutical Scheme, all medicines are required to be distributed under a ‘special generic system’.

There are four approval tracks based on the number of licensed producers of the product. Drugs on the NDL that do not currently have a local producer are able to apply for Track 1 (the fastest track). It generally takes four months to review the dossier for this track. Registration time for other tracks ranges from six to 24 months depending on the number of license-holders for the product.

Pricing

According to a report authored by Dr Akbar Abdollahiasl from the MOHME for the WHO, the average mark-ups for locally manufactured generic drugs are 29-37%, including an IRR5,000 (US$0.5)dispensing fee charged by pharmacists regardless of drug price. However, the mark-up for imported pharmaceuticals ranges between 63 and 174%, although the study admitted that it did not have a sufficiently large sample size to make a reliable prediction of average mark-up value.

Local Industry

Iran's domestic pharmaceutical manufacturing sector is among the most developed in the Middle East and North Africa region, with 89 local drug makers present. These pharmaceutical producers enhanced their capacity during the period of sanctions and now produce many sophisticated products for the treatment of cancers, diabetes and multiple sclerosis among others, with the government's pro-domestic company stance limiting market access opportunities for Western drug makers. Leading domestic companies include Darou Pakhsh, Sobhan Oncology, Tofigh Daru, Farabi Pharmaceutical and Zahravi Pharmaceutical.

Epidemiology

Communicable diseases are on the decline. The prevalence of respiratory diseases and cancers in Iran is increasing at a significant rate, according to the Tehran Times. Iraj Harirchi revealed that the MoH plans to raise spending on chemotherapy drugs. Cancer costs the government USD2.5bn each year.

It is estimated that 70% of those with HIV in Iran do not know they are infected. Iran has the highest incidence of diabetes in the region.

Statistics

India Pharma exports to IRAN by Category $ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	119.01	83.67	66.09	111.12	68.15
Drug Formulations & Biologicals	39.85	46.65	37.53	43.45	15.78
Ayush	0.33	0.30	0.20	0.78	285.23
Herbal Products	2.67	3.46	2.12	1.53	-27.87
Surgical	3.48	3.78	5.21	6.46	23.94
Vaccines	15.16	22.48	12.90	17.81	37.98
Total	180.50	160.33	124.05	181.14	46.02

India's Pharma Exports to IRAN $ Million during April-March			
Category	Fy-19	Fy-20	Change%
Bulk Drugs & Drug Intermediates	111.12	137.37	23.62
Drug formulations & Biologicals	43.40	47.65	9.79
Ayush	0.78	1.78	129.74
Herbal Products	1.53	2.93	91.82
Surgical	6.46	10.13	56.82
Vaccines	17.86	5.10	-71.46
Total	181.14	204.95	13.15

REGISTRATION AND REGULATORY REQUIREMENTS

- **Regulatory Authority** : Ministry of Health and Medical Education (MOHME)
- **Website of regulatory Authority** : https://www.fda.gov.ir/
- **Fees for Drug Registration** : USD 6000
- **Normal time taken for registration** : 01 year
- **Registration Requirement [Dossier Format]** : CTD
- **Whether plant inspection is mandatory** : No
- **Requirement of Local agent/ Subsidiary:** Local agent is required for registration

Regulatory Regime

The main regulatory body in Iran is the Ministry of Health and Medical Education (MOHME), which operates a department responsible exclusively for medicines. All manufacturing, distribution and imports of medicines are supervised by the General Pharmaceuticals Bureau and require prior approval from the MOHME.

A local agent is required to register a product in Iran. If the imported drug is already included in the Iran National Formulary (INF), the import is only subjected to the approval of the MOHME's accredited laboratories. Otherwise, the importer has to follow the process of getting the drug registered.

The following documents are required for product registration:

- Legalized authorization letter.
- Legalized Certificate of Pharmaceutical Product.
- Legalized list of importing countries or free sale certificate.
- Drug master file (for active pharmaceutical ingredients, or APIs), otherwise registration dossier.
- Certificate of analysis (for APIs).
- Drug importing application form.

The Consulate of Iran must certify the documents, and these are then forwarded, together with the quality control certificate from the manufacturer of the imported batches to the MOHME. A specific commission then decides whether the product may be imported. Officially, registration takes up to one year. However, in reality, the process might take significantly longer.

The drug registration fee is US$6,000 per product. Imported drugs must display their Iran Registration Code (IRC) and have both English and Farsi on leaflets and packaging. The Farsi leaflet requires approval from the MOHME.

The National Drug Selection Council (NDSC) is responsible for approval of medicines based on their pharmaco-economics. All drugs must be approved by the NDSC before being listed on the National Drug List (NDS). There were 2,400 drugs registered by the ministry of health as of 2008. Of these, 3,370 were locally produced, 465 were imported and 357 were herbal medicines.

All drug imports need prior approval from the MOHME. The first batch of an imported drug must pass the batch release process by the Quality Control Laboratory of the MOHME before the product can be legally distributed. Further batches are also subject to random testing for importation.

Iran's FDA formed an expert council to identify and mandate new drugs for import in September 2015.
Imported medicines that have domestically-produced cheaper equivalents will not be allowed into the country, while new drugs that may not be available domestically will be imported but only within the framework of national policies. Both due to the improving quality of domestic pharmaceutical production, and the country's ability to meet total medicine demand from domestic drug production, the Ministry of Health announced a new policy to restrict the importation of foreign medicines in February 2018.

For the year March 2018 - 19, the Iranian Food and Drug Organization announced new restrictive policies for foreign suppliers of health and medical related products including OTC and prescription pharmaceuticals. The new rules are designed to increase transparency by preventing foreign suppliers from appointing different local importers for imports in the Iranian market. This will encourage foreign suppliers to set up their directly owned offices and entities by essentially taking over the import marketing authorisation from the local Iranian importers.

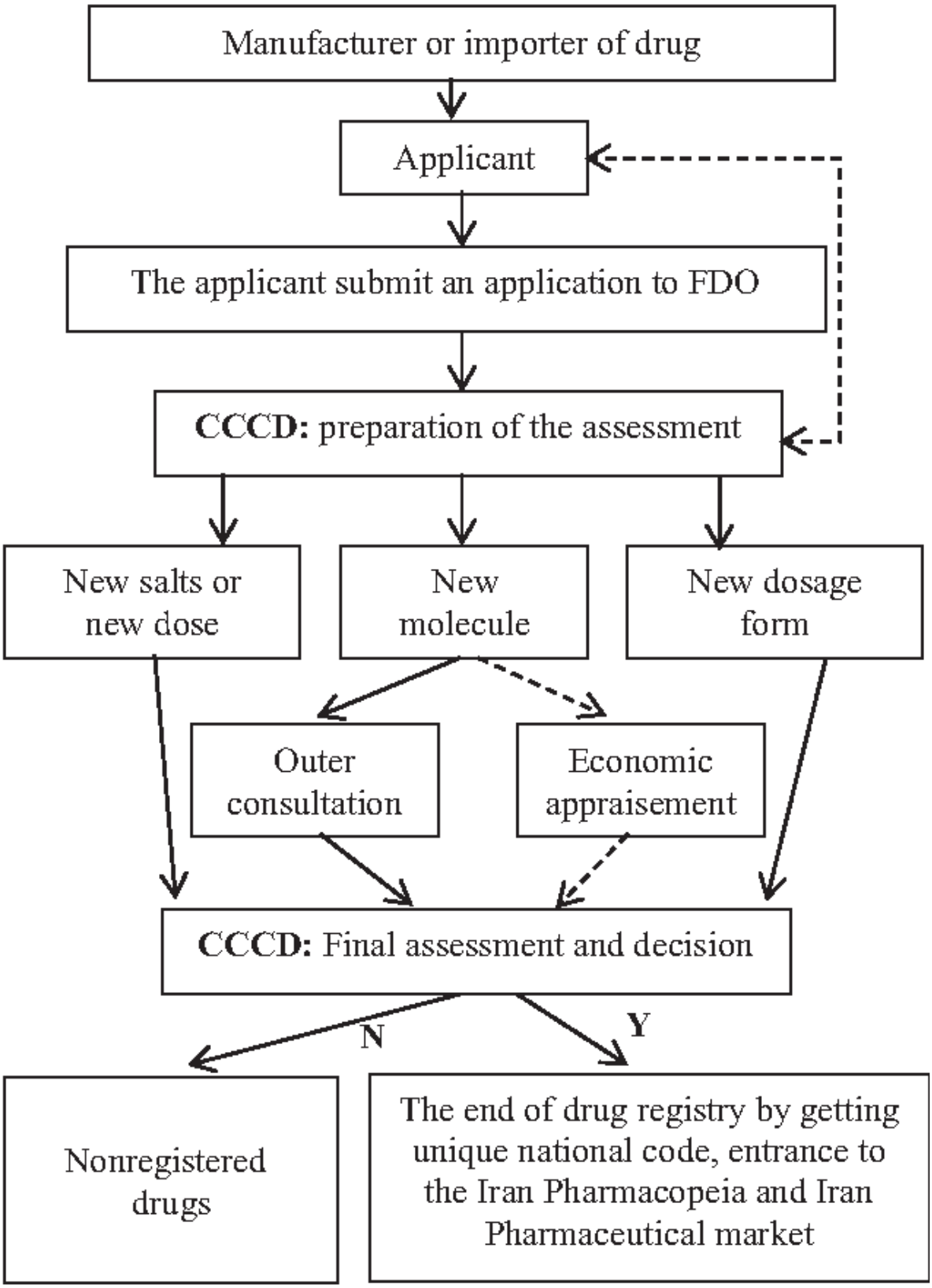
All new drugs (except orphan drugs, with a disease prevalence of 1 or less in 200,000 people) must be registered by the Council to Consider and Compile Drugs (CCCD) before they can become available in Iran. This council is part of the FDO, which is responsible for drug policy, which, in turn, is supervised by the minister of health and medical education. All CCCD members are Ministry of Health and Medical Education employees, and most of them are clinicians or pharmacists.

The first step in the registration of any new drug that is produced or imported is the completion of three to four drug registry forms. The applicant (e.g., Drug Company, group of physicians, and specialist society) must prepare documents that address the following items: efficacy, safety and adverse events, comparative efficacy with similar drugs, approval history, contraindications, warnings, precautions, monitoring parameters, pharmacokinetics, patient compliance, and pharmaco economic studies.

The CCCD, however, may exclude one or more of these items on the basis of the kind of drug and the availability of data. Applications fall into three categories: 1) new molecules, 2) new dosage forms, and 3) new salts or new doses of any drug if the base has already been approved by the CCCD.

If the application involves a new molecule, consultation will be sought from the heads of medical and pharmaceutical societies, national research centers, and medical universities. Approval of the drug by other organizations (such as the Food and Drug Administration, the European Medicines Agency, and the Therapeutic Goods Administration) and its use in at least five countries (including the United States, European Union countries, or other countries with a gross domestic product similar to Iran's) have an important role in the evaluation. Once a drug is approved, it is given a unique national code and can be distributed, prescribed, and used throughout the entire country. Patients using the drug, however, will have to pay 100% of the drug costs until the drug is added to the reimbursement list.

Overview of Drug registration in Iran:



NATIONAL DRUG POLICY OF IRAN:

National Drug Policy (NDP) constitutes the specification of mid-term and long-term pharmaceutical objectives by the government and the determination of major strategies

warranted achieving such objectives. Stated in other words, NDP determines the frameworks for the pharmaceutical activities of private and state sectors. The specification of these policies and strategies will be an effective means in encouraging investors (state and private) to invest in the pharmaceutical industry.

In a country where the drug policies and strategies are unspecified and are not stated unequivocally, the development of the pharmaceutical industry and convenient accessibility to drugs in the health and remedy system are unjustified expectations. Since drug is one of the fundamental bases of the health and remedy system and it is widely applied in the processes of diagnosis, prevention, and cure of diseases, a National Health Policy (NHP) is required to be established before the specification of national drug policies. Therefore, an effective and adequate NHP as a principal infrastructure is prerequisite to an effective and adequate NDP.

The most important base of the national drug policies in any country is the National Drug List (NDL) of that country which is established on the basis of NHP principles and the therapeutic protocols of the National Therapeutic Guidelines (NTG). A drug registered in the national drug list of a country must meet the qualitative and accessibility standards and requirements. Furthermore, the rules governing the prescription and consumption of drugs must be established on a logical basis. Since the development of the charter for drug admission to the drug list of Iran and its official approval in 2000, the three aforementioned principles have been considered as the most fundamental criteria for a certain drug to be admitted to the National Drug List. Therefore, and for the purpose of meeting the aforementioned requirements, all authorities who may affect the accessibility, quality, and rational prescribing of drugs are consulted when an admission request (for the registration of the drug in the National Drug List) is processed in order to place the drug in the National Drug List.

Meanwhile the National Drug Committee secretary will negotiate and debate the entry of the drug with members of the Committee, which is a national committee with about 20 specialized committees, after the preliminary evaluation of the submitted documents and ensuring the safety, efficacy, and cost-efficiency of the nominated drug and the cost-efficiency assessment in comparison to the same rank drugs. If the specialized committee approves the safety, efficacy, and cost-efficiency of the drug and if the drug has been prescribed for a minimum of 3 years in North American or West European countries, it will be referred back to the National Drug Committee for final approval.

The members of the Committee include the insurance, industry, and Deputy of Health representatives and a number of pharmacological and clinical specialists designated by the Ministry of Health. If the Committee approves the entry of the drug to the National Drug List, the due process will be executed and the due procedures will be announced to the Medical Association, insurance companies, pharmaceutical manufacturers, and drug importers.

The manufacturer or the importer of the drug is then allowed to submit the required documents for registration for the marketing of drugs in the country to the General Department of Medicines Affairs in compliance to additional regulations.

The following criteria are emphasized when registering the drug for marketing:

(1) The drug is accessible throughout the nation and in all times. The National Drug Distribution Charter has been established and announced on the basis of this principle.

(2) The drug should be reasonably-priced so that the majority of people can afford it and if the drug has high demand in the national health and remedy network and its prescription

requires special regulations, the due regulations and usage of the drug must be developed and announced.

(3) Attempts are undertaken to rationalize the consumption of drugs through informing the physician's community and the people (through the Drug Information Centres located in 22 centres throughout the nation), re-training programs, journals and the mass media.

(4) Quality assessment of the manufactured or imported drug. For this purpose, careful supervision at the time of registration and the assessment of the drug master file (DMF) and site master file (SMF) are carried out and quality control test on the drug samples at the National Control Labs (NCL) and supervising the drug production line are implemented to ensure the safety and quality of the first batch of drugs into the market. Furthermore, periodic samples are also collected from the consumer market and tested at the NCL or other accredited laboratories to ensure the primary quality of further batches of the drug.

Furthermore, physicians, pharmacologists, and nurses through Adverse Drug Reaction Center may immediately report any adverse effects of the drugs through the provided Yellow Forms to the Ministry of Health so that proper measures are taken. In addition, all manufacturers, importers, and distributors of drugs and pharmacies are required to hire a trained pharmacologist qualified by the Ministry of Health as the technical manager.

Therefore the Ministry of Health requires all pharmaceutical companies to form a quality assurance team under the supervision of the technical manager so that through procedures such as documentation, validation, Good Manufacturing Practice (GMP), Good Laboratories Practice (GLP), the quality of the products in the processes of production, marketing and during consumption cycle is preserved and ensured.

(5) The unequivocal announcement of regulations and pharmaceutical practices is another principle of the Iranian National Drug Policy which will be carried out though their regular publication in periodicals, yearbooks, electronic networks, and the Internet. Currently all regulations concerning investment, manufacturing, importing, distribution and supplying of pharmaceutical raw materials and off-the-shelf products are available on the Deputy of Food and Drug website at www.fdo.ir. In addition to the current regulations, users may also find the latest statistics about drug consumption in the country.

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- The Drug Reimbursement Decision-Making System in Iran in Eleisveir
- Iranian Journal of Pharmaceutical Research (2003) I-II Overview of National Drug Policy of Iran

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Details of Indian Embassy abroad: https://www.indianembassytehran.gov.in/

Details of importing country Embassy in India: www.iranconsulatehyd.org