



Iran Pharmaceutical Market

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Abstract

Iran is a developing country in Middle East which has experienced some political and economical turbulence during the past decades. Government of Iran, after the 1979 Islamic revolution, has devoted considerable resources on national health, including the pharmaceutical sector. As a result, health indicators have improved substantially over the past two decades and the availability and affordability of medicines have also been greatly improved. In order to fulfill the MOH mission in providing access to a sufficient quantity of safe, effective and high quality medicines that are affordable for all population, after the 1979 Islamic revolution Iran has adopted a full generic based medicine system and local production of medicines and vaccines has become one of the main goals of the national drug policy. Government of Iran has invested considerably on the pharmaceutical industry over the past decades. However, it seems that this investment, mainly due to the lack of R&D activities and unanimous subsidies, has not been proportionately fruitful for Iran's health system. Iran drug market, especially in recent years, experienced a sharp growth and in 2004 the value of the market, including direct government subsidies to the imported medicines, became over USD1.2bn. The market has increased annually, on average more than 30% , during 1993-2003.

Keywords: Iran, local pharmaceutical industry, drug market, local production.

Introduction

Iran is a country of over 68 million population, with a substantially young population, located in Middle East. Although Iran is an oil rich country, most of its developmental indices has fallen into the "middle income countries" category (1). Despite this, Iran has fairly advanced primary and secondary health care systems. Some of Iran's demographic data are presented in Table 1 (1- 3). After the 1979 Islamic revolution, Iran has adopted a full generic-based medicine system and local production of essential medicines and vaccines has become one of the main goals of the national drug policy (4, 5). Over the past decades, the government subsidized local production of medicines in order to increase the availability and affordability of the medicines. Essential medicines are available and affordable for more than 90% of population (6).

However, convincing data exists that prescribing medicines is excessive. Evidences of irrational use of medicines, high number of medicines per prescription, as well as excessive high use of injectables and antibiotics are present in prescribers' behavior (6, 7).

The first supervising law on the regulations of pharmaceuticals in Iran was passed by the parliament in 1955. According to current laws in Iran, Ministry of Health and Medical Education (MOH) is the

nodal agency for the regulation of the pharmaceutical sector, including biological and herbal products. As stated in the national drug policy (NDP), MOH's mission is to "provide access to a sufficient quantity of safe, effective and high quality medicines that are affordable for all population" (4). In light of new political and economical developments in Iran, MOH has revised the NDP and new version of Iran NDP has released on 2004. The main characteristics of the Iran NDP are as follows:

- Regulation of drug market (production, importation and distribution)
- Generic-based medicine policy
- Promotion of local production of medicines
- Price control
- Formulation-based national industry
- Herbal medicine industry
- Promotion of self-sufficiency in vaccine production
- Licensing for all locally produced and imported medicines.

MOH operates a department specifically responsible for medicines. The national regulatory system of Iran consists of two main sectors, which are the Pharmaceutical affairs and the national control laboratory (8). All manufacturing distribution and importation of medicines are supervised by the office of pharmaceutical affairs. The main documents required for registration of medicines are Drug Master File (DMF), health and free sale certificates and product sample. Registration is the main prerequisite for marketing of medicines in Iran. However, the office register products which are already on the Iran Drug List. New medicines have to be first evaluated by the Iran's Drug Selection Committee, for inclusion in the list. The committee evaluates applications for new medicines, based on their safety, efficacy and cost-effectiveness. Generally speaking, no comparison on the safety, toxicity or cost-effectiveness of the medicine with an existing therapy is required as part of this evaluation process (9). Registration, as in many other developing countries, may take up to one year and even longer. However, the registration process is not always clear and based on the announced guidelines (10).

In developing countries, medicine expenditures, in particular, account for 25%-65% of the total public and private health expenditures, and for 60%-90% of out-of-pocket household expenditures on health (11). Therefore, access is hugely facilitated by making these medicines available as inexpensive as possible. Pricing regulation and national policies on health insurance can provide a good basis for equitable right of entry, if they are effectively enabled (12). In recognition of the need for government assistance in the health care system, some countries including Iran have adopted a subsidy mechanism for pharmaceuticals. In Iran, the national health insurance system is the main tool used by the government to improve affordability of medicines. Once a product is approved for marketing and added to the Iran Drug List, it may be prescribed but not automatically subsidised. The medicines included in the Iran Drug List will be evaluated by the Medical Insurance Council and if approved, would be included in national health system and reimbursed by the national insurance scheme. More than 85% of the population in Iran are covered by the medical insurance, which reimburse the cost of medicines to the patients up to 90% for inpatients and 70% for outpatients. Despite the presence of medical insurance scheme, some of the imported medicines, mainly hi-tech pharmaceuticals, receive direct governmental subsidies at the point of entry. This means that the government pays direct subsidies to the importers of these medicines in order to reduce their costs. Although this may improve accessibility and affordability of the medicines, it could cause problems such as smuggling cheap medicines to neighboring countries, irrational drug use and over purchasing of medicines within the country. Due to the price control policy in Iran, prices of medicines are identical throughout the country and both in private and public sectors.

Local Pharmaceutical Industry

Local production of medicines aims to improve access to high-quality, and low cost medicines. However, a key challenge is to determine whether the circumstances for successful local production of

quality medicines are met. In Iran, the modern pharmaceutical industry is about 80 years old and started with the production of vaccines in Razi Institute in 1925 and Pasteur Institute in 1920. However, for decades European and US pharmaceutical companies were the major players in the Iran drug market and importation was the main source of providing medicines for Iran's market (14). Up to the 1979 Islamic revolution, substantial numbers of international pharmaceutical companies were presented in Iran. By that time, the country's pharmaceutical sector had been transformed into a market worth 300 MUSD per year. During 1970,s there were nearly 4000 brands of pharmaceutical products available in Iran, 70% of which were imported and 30% formulated locally. There was no substantial investment for local production of pharmaceutical products (13-14).

Currently Iran, compared to other developing countries, has a fairly well developed pharmaceutical industry. The chemical pharmaceutical industry in Iran started its activity by licensing the products and process from multinational pharmaceutical companies and then manufacturing them locally. The operations mainly involved importing the raw materials of bulk medicines and formulating them locally.

The Islamic revolution of 1979 was the first turning point for pharmaceutical industry in Iran. After the revolution, multinational companies left Iran and further political and economical developments created difficulties for local pharmaceutical industry to access new technology and the required raw materials. At this point, all the pharmaceutical companies were nationalized and government took over control of the pharmaceutical industry. The government then invested substantially in maintaining and developing the industry and this was performed mainly through the allocation of subsidized hard currency to purchase raw materials and machineries. However, no substantial investment was made in the research and development (R&D) field and therefore the technological capabilities of the pharmaceutical industry were mainly limited to the areas of formulation.

After the 1979 revolution, the main importers of medicines were also the state owned Iran Pharmaceutical Inc., Red Crescent Society and Daru Pakhsh, a company belonging to the National Social Security Organization (NSSO). The revolution changed many aspects of economic and political development. Primary goals became self-sufficiency and non-reliance on foreign intervention. The result was the departure of multinationals and a steep decline in investment. Therefore in 1980's this policy created a big hurdle for introduction of some of the new pharmaceuticals into the Iran market (10). The responsibility for the nationwide distribution of pharmaceutical products was also passed on to six state owned companies.

Despite the fact that Iran is one of the major oil exporters of the world, since until recent years it did not have a well developed petrochemical industry, it had to depend mainly on import of raw pharmaceutical materials. Invasion of Iran by Iraq in 1980 and a subsequent eight years war period (1980-1988) was also a major turning point for the pharmaceutical industry in Iran. During the war period, an acute shortage of resources caused shortage of medicines and this forced the government to move towards the production of generic medicines only. The government was mainly involved in the importation of medicines as finished products, raw materials and machineries. Provision of local pharmaceutical companies with hard currency at the subsidized rate was the most direct support of the government from pharmaceutical system during the 1980-1993 period. All pharmaceutical companies, private and public, were entitled to take advantage of this favored exchange rate (14).

The obvious and inevitable implication of such system was an absolute and heavily bureaucratic centralization in policy and decision making within the pharmaceutical sector of Iran. Therefore, MOH was in charge of making decisions on policies and resource allocation, particularly allocation of subsidized hard currency. The price of pharmaceutical products was also strictly controlled by the government. Currently, in Iran the pricing system is based on cost analysis and rigid profit margins for producer, distributors and pharmacy outlets.

Following the termination of the war, the government started its first five-years development plan in 1984. The plan introduced the first steps towards privatization of industry, including the pharmaceutical industry (15). The privatization policy is given additional emphasis on subsequent five-

years development plans. However, some national organizations, such as NSSO, National Retirement Organization, charity foundations and banks purchased most parts of the pharmaceutical industry. At the moment, NSSO alone owns more than 45% of the market share in Iran's drug market.

At present, there is around 65 pharmaceutical companies in Iran with 20 of them considered as large ones. However, the market is fragmented among the companies in such a way that no one dominates the market (14). In parallel with privatization, the government tried to reduce its interference in the industry and provides a competition environment. In order to control the price of medicines, the government provided the industry with heavily subsidized hard currency. The government partitioned the national pharmaceutical market between the companies and each company had a fixed share of the market which was determined, based on the production capacity of the company. Although this method may provide some degree of guarantee on availability of the medicines, quality of the medicines could be compromised. This was mainly due to the fact that any rejection of produced medicines by the national regulatory authority could cause shortage of the medicines in the market. The fact that the government subsidized manufacturers to buy raw materials and equipment, reduced the motivation to innovate. Therefore, the government gradually removed subsidies from the industry. This trend started since 1997 and in 2002 the subsidies completely removed from the local industry and only a few imported medicines, such as blood factors and some of the anti-cancer medicines, still enjoy government subsidy.

Local production of hi-tech biological products is a new development in Iran's pharmaceutical sector. In recent years some private companies have started to produce biological pharmaceuticals, using novel biotechnology methods. Among the biopharmaceuticals produced in Iran over the recent years are interferons, growth hormone and erythropoietin (16). However, still the overall technological capacity of Iran's pharmaceutical industry seems to be limited to formulation of the medicines.

Starting in 2001, MOH lifted the compulsory generic production of the medicines and encouraged pharmaceutical companies to produce branded generic medicines. This policy tended to create a more competitive environment for pharmaceutical companies, which eventually expects to improve quality of locally produced medicines (16).

Iran has a fairly well established herbal medicines sector. It has a vast variety of flora and as a result, the government is putting emphasis on developing herbal pharmaceuticals. The regulation and production of this sector comes under the authority of MOH. Iran is one of the few countries, which has regulation for herbal medicines. Regulation of the herbal medicines started in 1994 in order to ensure that GMP is followed in this sector. However, in contrary to the conventional medicines, there is not any subsidies or direct support of herbal industry on the government side. At present, there are more than 150 registered and hundreds of non-registered herbal medicines in the market. Although registered herbal medicines do not have a substantial share in the market, there is an increasing trend in sales of these products.

Iran's Pharmaceutical Market

Although Iran is one of the largest markets in middle east, chiefly due to the size of its population, it has one of the lowest per capita spending on medicines which is about USD15 (13). As a result of government's policy to provide universal access to cheap healthcare, involving the use of strict price control on pharmaceuticals, the market has been characterized by low pricing levels and generics dominate the market. This low cost status has made Iran a cheap source of medicines; hence export activities have been an area of notable development (10). However, Iran drug market especially in recent years experienced a sharp growth and in 2004 the value of the market, excluding direct government subsidies to the imported medicines, became over USD1bn (Figure 1 and 2). The government annually pays about 220 MUSD as direct subsidies for the imported medicines, which would increase the overall value of market in 2004 up to USD 1.2 bn. As presented in figures 1 and 2 Iran pharmaceutical market has experienced sharp increases both in total value and per

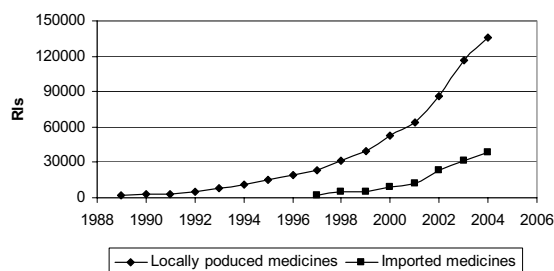


Figure 1. Growth of per capita consumption of medicines in Iran, from 1989-2004. Direct government subsidies for some imported medicines is not included (1USD= 9100 RIs; 2005).

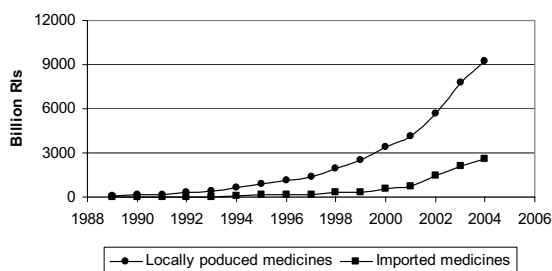


Figure 2. Growth of Iran's pharmaceutical market from 1989-2004. Direct government subsidies for some imported medicines is not included (1USD= 9100 RIs; 2005).

capita consumption. Although increasing consumption due to an increased number of prescribers and population is a significant contributory factor to this, most of the growth observed during the period of 1997-2003 is due to the removal of government subsidies and devaluation of national currency (13). The market has increased annually, on average more than 30% between 1993-2003 (Figure 1). However, the growth rate has substantially decreased (to 19% growth rate) in 2004, which may indicate some degree of stabilization in the market. Although price of some imported medicines is substantially subsidized, sometimes up to 90% of its real price before entering into market, consumption of imported medicines has shown a significant increase in recent years. This is mainly due to the fact that local manufacturers do not produce novel and hi-tech medicines and as a result a demand for imported medicines exists from prescribers and consumers side.

Although prescription of medicines accounts for the vast majority of sales, the distinction between prescription and OTC medicines is not clear. A significant number of prescription only medicines are available in pharmacies, without the need for prescription (10).

Output of local manufacturing sector in Iran comprises predominately of cheap and basic medicines, and hence the market is reliant on imports, in particular at the hi-tech end of the scale. The dependence on imports places considerable pressure on national healthcare budget and allows little reinvestment in industry. In terms of quantity/volume, Iran's local pharmaceutical industry supplies more than 95% of the market needs. Only less than 5% of medicines are imported as finished product. But in terms of cost, these imports account for more than 50% of the pharmaceutical market value (13). This is mainly because imported medicines are expensive. The government of Iran encourages local industry to locally produce imported drugs. While it may not reduce the overall drug bill, it will reduce the outflow of valuable foreign currency and reliance on imports which could always be affected by political turbulences.

Based on to the 3rd five-years development plan, started in March 2000, the government is obliged to optimize resources allocation, replace unanimous medicine subsidies with targeted subsidies, support private sector activities and promote national and international investment in pharmaceutical industry. Transfer of subsidies from manufacturers to public insurance systems, along with the new policy of MOH in promoting the use of branded generics for locally produced pharmaceuticals may encourage competition and improve the quality of medicines. Such a transfer will also reduce red tape and potential for corruption associated with direct subsidies.

Sector modernization, along with improving healthcare awareness and access to medicines would lead to an increase in demand for medicines. Sector modernization could be a catalyst for growth in the branded products as the demand for the latest, more sophisticated medicines rises.

While the present national medicine policy is working well to serve the local health needs, it is not clear from this policy whether the government plans to build a competitive pharmaceutical industry. MOH's main focus is health care and perhaps is not able to provide conditions required for building up a competitive industrial sector. At present the government of Iran heavily supports the local pharmaceutical industry through imposing a high tariff on the imported medicines. Although the

Table 1. A few important demographical data of Iran.

Population	68,000,000 (2005 est.)
Percent of 15-64 years old population	68%
Population growth rate	1.3% (2003)
Infant mortality rate	41.58 death/1000 live births
Life expectancy	69.98 Yrs
Literacy rate	79.4%
GDP per capita (PPP)	7700 USD (2005 est.)
Health expenditure (% GDP)	5.5 (2003)
Total numbers of prescribers	105000 (2004)
Total numbers of pharmacists	11200 (2004)
Total numbers of pharmacies	7200 (2004)
Total numbers of pharmaceutical manufacturers	65 (2004)

tariff is imposed only on imported medicines, which are also locally produced by the nation industry, Iran has the highest tariff on imported medicines in the world (17).

Since 1925, Iran has set laws for protecting patents and intellectual property rights. However, still there is no comprehensive law to protect full protection of innovations, especially in the pharmaceutical sector. Trade marks are registered for medicines and a separate law governing the pharmaceutical industry mandate that along with the brand name, the generic name of the product must be published on the labeling. However, currently MOH licenses medicines from different producers and importers. A pharmaceutical company can market or manufacture a product, only after obtaining a license from the MOH. Such licensing is given to more than one company in any case. The protection of product patents is an ongoing battle for companies throughout the world's emerging market and Iran is no exception. At present, there is no developed patent protection, especially for imported medicines in Iran, and MOH will register "copied" products based on patent medicines (10).

As from mid 2005, Iran has become an observer member of WTO. Although the joining process may takes up to 10 years, this would have drastic impacts on pharmaceutical industry and pharmaceutical market in Iran. In such a situation, due to restrictions on the presence of "copied" patent medicines in the health sector market of Iran, the government has to allocate further resources for medicines, specially novel and hi-tech ones.

Conclusion

Although history of modern pharmaceuticals in Iran dates back to about one hundred years ago and started with the production of vaccines, most of the activities in this sector over the past two decades, have been carried out by the government. However, no substantial investment has been made within the R&D field and therefore the technological capabilities of the local pharmaceutical industry are mainly limited to the area of formulation. Despite some new activities in producing new compounds, especially in the biological field which could turn to some value added medicines in the future, output of Iran's pharmaceutical industry is limited to the formulation of cheap and fairly old medicines. The pharmaceutical market in Iran is heavily dependent on the importation of new and hi-tech medicines and due to a significant growth rate of the market, MOH should allocate new resources for providing medicines at affordable prices to the population.

In the past two decades, the government of Iran has devoted considerable resources to the pharmaceutical sector as direct and indirect subsidies. Although the present national medicine policy is working well to serve the local health needs, it was not able to build a competitive pharmaceutical industry. Transfer of subsidies from manufacturers to public insurance systems, along with the new policy of MOH in promoting the use of branded generics for locally produced pharmaceuticals may

encourage competition and improve the quality of medicines. Such a transfer will also reduce red tape and the potential for corruption associated with direct subsidies.

Despite all deficits presented, Iran's pharmaceutical sector, backed by its fairly advanced national industry, inexpensive labor and energy, advanced petrochemical industry, as well as highly educated and trained expertise, could have an optimistic future. However, the industry needs an essential upgrading in its hardware and software. Iran's industry have had a substantial progress in the production of biotechnology derived medicines, and hence proper investment in this area will boost the national biopharmaceutical industry.

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