

## **New National Drug Policy in Iran leading to Expanded Pharmaceutical Market and Extended Access of Public to Medicines**

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### **Abstract**

Pharmaceutical market in Iran has been expanding since 2001 when the new development act was approved in the parliament of the Islamic republic of Iran. The pharma market size has annually increased 6.8% in terms of volume and 18.5% in terms of value. However, the growth rate of imported items has been greater than locally produced items both in terms of value and volume. This may be mainly due to the introduction of free market regulations at macroeconomic point of view that has influenced the pharmaceutical market as well. The expansion of pharmaceutical market is welcomed by the industry which is investing heavily in the manufacturing and research and development capacity of pharma sector in Iran. However it does also mean greater access of the public to essential and vital medicines. In the same situation the presence of extra choices in the market may be a challenge for the local industry as the demand for higher quality medicines grows. Market forces are always a challenge for the advocacy of rational prescription and use of medicines.

**Keywords:** *Pharmaceutical market, National drug policy, Availability, Accessibility, Market trend, Iran*

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### **Introduction**

The mission of Ministry of Health and Medical Education of Iran (MOH) as mandated by the 55 yr old law of Medical and Pharmaceutical act of parliament and its further amendments along with acts regarding the establishment of the Ministry, is to ensure the availability, accessibility of safe and affordable medicines. Not only all medicines need marketing authorization from MOH, activities in pharma business such as production, distribution, import and export and sale of medicines is subject to prior approval by MOH (1-2). To ensure the safety and quality of medicines, prior to marketing, medicines are registered at Pharmaceutical and Narcotics Office, and their quality is controlled by National QC Lab. To ensure the affordability, drug prices are set by the pricing commission chaired by deputy minister of health for food and drug. Also National Drug Selection Council (NDSC) has the authority to approve or disapprove medicines based on their pharmacoeconomic evaluations (3). No medicine can be registered without prior approval by the NDSC. All items approved by NDSC are listed and published annually as National Drug List (NDL).

### **Discussion**

Approximately 4200 medicines including chemical, herbal and biological dosage forms have been registered and granted marketing authorization. These items corresponds to nearly 2400 dosage forms or just over 1000 drug entities on the NDL as shown in the Table 1.

**Table 1:** Total drug items registered by MOH, Iran as of 2008

<b>Subject</b>	<b>n</b>
Drug entities included in the NDL	2400
Locally produced marketing authorization issued	3370
Iran registration code (marketing authorization) for imported items	465
Herbal medicines	357

Since the 1979 Islamic revolution, a full generic-based National Drug Policy (NDP), with high emphasis on local production of essential drugs and vaccines was adapted in Iran. The manufacturing companies were nationalized and drug imports were limited to only 3 state owned companies (4). However since the establishment of 3<sup>rd</sup> National Plan of Development in 2001, the NDP was modified to allow room for

more competition in the Pharma market. Although the regulation still favors locally produced generic products that are usually far cheaper than branded products, the door is open for international and multinational companies to register their products in Iran. All medicines on the NDL may be registered for marketing authorization regardless of their country of origin. However items on the list with lower number of licenses are given fast track registration. Currently there are four tracks for registration of medicines. Track 1 is regarded as the fast track with only 4 months time for reviewing the drug dossier. This track is allocated to items on the list without local producer. The time lag for registration at other tracks varies from 6 to 24 months depending on the number of license holders for any item.

Currently close to 70 pharmaceutical companies produce more than 95% (in terms of volume) of medicines on the market in Iran. Although this level of self-sufficiency in drug production has not changed since 2001, the share of local manufacturers from the pharma market value has decreased markedly (Table 2).

**Table 2:** The share of locally produced and imported items from total value of pharma market

year	The share of pharma market (in terms of value)	
	Imported items (%)	Locally produced (%)
2001	17.8	82.2
2002	20.5	79.5
2003	22.2	77.8
2004	24.6	75.4
2005	27.9	72.1
2006	29.6	70.4
2007	31.9	68.1
2008	33.6	66.4

The main reason for the increase in the value of market share of imported medicines is the expansion of the NDL to include more chemical and biological entities that have not been produced locally due to their high tech nature such

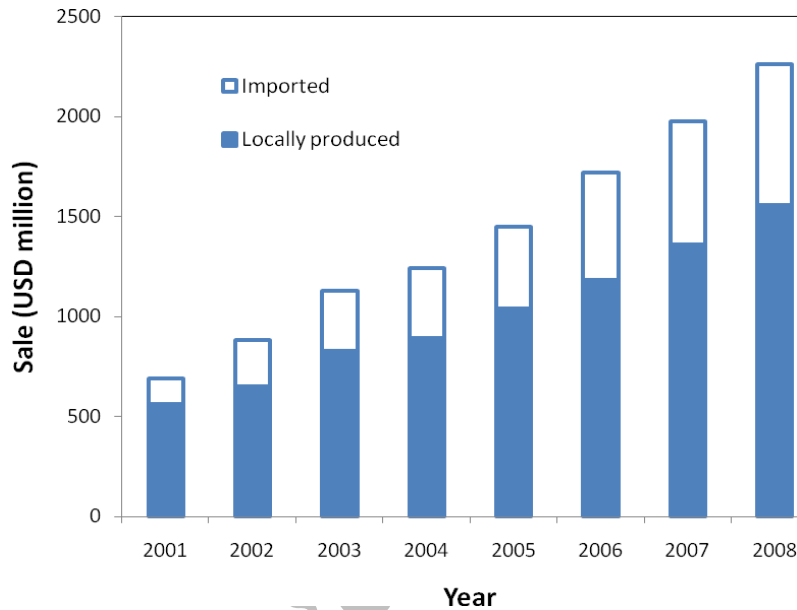
as new monoclonal antibodies, new anticancer agents, new recombinant proteins and etc. Though very expensive, they have been supported by governmental subsidies and health insurance coverage. In 2008 more than USD 300 million was allocated by government to cover the drug subsidies by MOH. Drugs for hemophilia, thalassemia, transplant and multiple sclerosis patients are the major items that are subsidized by MOH. The majority of subsidized drugs are not locally produced. Although only 25% of the total value of imported medicines on the market is for the items that are in competition with locally produced generics, this has allowed far more choices for patients and doctors. Therefore many original brand or branded generic products from international and multinational pharma companies have entered the market. As can be seen in Fig. 1 since 2001 the pharma market, according to MOH statistics, has expanded from USD 690 million to USD 2250 million in 2008. The annual growth rate from year 2001 to year 2008 for locally produced items has been 16.6% while the sale of imported items has annually increased 26.7% since 2001.

However when the number of items sold in the market is taken into consideration, the total sale of pharmaceuticals only shows a moderate 6.8% annual growth. The sale of locally produced and imported items has annually increased 6.7% and 9.4% since 2001 (Fig. 2).

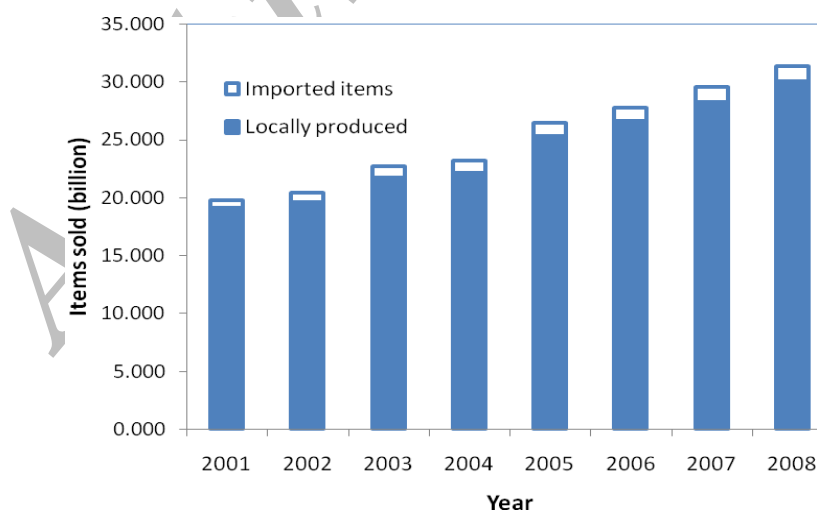
The market expansion has been a major driving force for a wave of new investment in the pharma manufacturing sector in the country. More than 30 companies have applied for permission to establish production sites for pharmaceutical manufacturing in the country. Their total investment surpass USD 1 billion which is a huge investment considering the size of the market value of pharma business in Iran. Comparing with other countries with similar population and GDP, the market size of USD 2.2 billion is regarded as low. One reason for the lower size of the market may be the lower price of locally produced medicines which cover

95% of market needs by volume. With no eminent membership of the country in WTO, the pharma sector is trying to take advantage of the situation. Many patented products are produced locally by generic manufacturers at very low cost. The production of biosimilar products such as alpha, beta and gamma interferons, GCSF, ery-

thropoietin, and etc in recent years is a sign of technological advances in this field. With the support of MOH and high interest and involvement of academia and research people, the pharma industry is becoming more active in the high tech end of pharmaceutical research and development rather than off-patented generic production.



**Fig. 1:** The value market size of pharmaceutical products in Iran



**Fig. 2:** The volume market size of pharmaceutical products in Iran

### Conclusion

The expansion of pharma market is not only beneficiary to the industry but also to the pa-

tients that will have access to low cost but high tech products. However the issue of quality remains a real challenge for the industry as the

patients have access to top quality branded generics and original brands from international and multinational sources and expect higher quality products from local manufacturers.

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