

Opinion

Impact of Sanctions on Procurement of Medicine and Medical Devices in Iran; A Technical Response

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Abstract

Following recent sanctions on foreign trade, financial and banking services, Iran has faced major difficulties for importing medicines (both finished products and pharmaceutical raw materials) and medical devices.

Problems with money transfer have made it extremely lengthy in time to import medicine and medical devices and these have negatively affected access to and affordability of medicines. Quality of pharmaceuticals and treatment of patients have also been affected due to changing the sources of imported medicines and raw materials for locally produced pharmaceuticals.

Several interventions have been employed during the past few months in Iran to overcome the effects imposed by recent sanctions and drug shortages have been managed to some extent with attempts made by Iran Food and Drug Organization (IRI FDO).

As recommended by the experts, a specific Society for Worldwide Interbank Financial Telecommunication line should be allocated for transferring money for medicines and medical devices and certain financial institutions are assigned for this purpose. It is also suggested that defining a white list of Iranian pharmaceuticals and medical device companies together with their foreign counterparts would facilitate this process.

It appears that, in a public health prospective, ordinary people and patients are hurt and paying the cost for current sanctions. It remains the responsibility of the public health and international communities to separate public health from politics and to ease the pain of public from sanctions.

Keywords: Access to medicines, Iran, procurement of medicines and medical devices, sanctions

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Introduction

Following the recent sanctions by the European Union and the United States in 2012, procurement and importation of medicines and medical devices has been a major concern of the Ministry of Health and Medical Education (MOHME) in Iran to protect Iranian citizens from effects of these sanctions. This issue will be addressed from a technical point of view in this report. Regulatory framework of pharmaceuticals and medical devices alongside an overview of the Iranian market of these health technologies will be reviewed. Interventions employed by the regulatory authorities in Iran Food and Drug Organization (IRI FDO), within the MOHME, to manage this situation will be addressed and current challenges in procurement and importation of pharmaceuticals and medical devices caused by the sanctions will be discussed. Technical recommendations will be made and the issue will remain for responses from international community.

Regulatory framework of pharmaceutical and medical devices in Iran

Iran National Drug Policy constructs the regulatory framework of pharmaceutical sector in Iran. Principles of the Iran National

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Drug Policy include recognizing a generic drug system in which all medicines have to be registered with International Non-proprietary Names, access to essential medicines, ensuring quality of locally produced and imported medicines, rational use of medicines, supporting national pharmaceutical industry, price control and market regulation, herbal and traditional medicines and encouraging pharmaceutical export.¹

In the current Iranian health sector, IRI FDO is the executive authority and regulatory body to regulate Pharmaceuticals and Medical Devices with responsibilities for: selection and registration of new drugs and medical devices; pharmacovigilance and rational use of drugs; subsidy allocation and procurement of vaccines and medications for special indications such as Multiple Sclerosis, Transplantation, Thalassemia, Hemophilia, certain Cancers and so on, in collaboration with relevant sectors.² These functions are achieved by a collection of decision-making commissions in IRI FDO, including Iran drug selection committee, Legal commissions on Article 20 which decide on market authorization of pharmaceuticals and importation of medical devices, Legal commission on pricing pharmaceuticals and Legal commissions for regulating pharmacies and wholesalers.

Access to medicines is fairly good in the public sector at primary health care level.³ However, it could be problematic if patients consult private physicians and get prescriptions for expensive drugs; indeed, the “catastrophic costs of illness” have been a concern for the lower middle class and the health system for years.⁴ Urban-rural differences have partially been addressed by rural health insurance and family physician program. Drug shortages in hospitals sometimes shift the costs to outpatient sector or private

Pharmaceutical Market Value 2005 - 2011
(Million \$US)

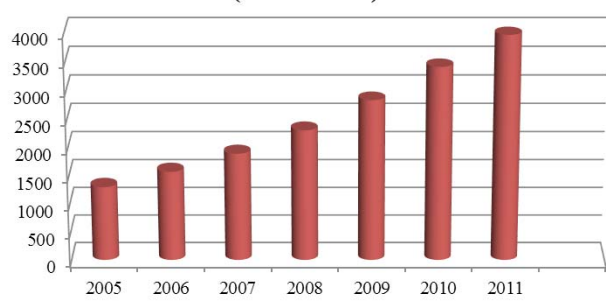


Figure 1. Pharmaceutical market value in Iran (2005 – 2011). Data were taken from deputy for pharmaceutical affairs, Iran Food and Drug Organization.

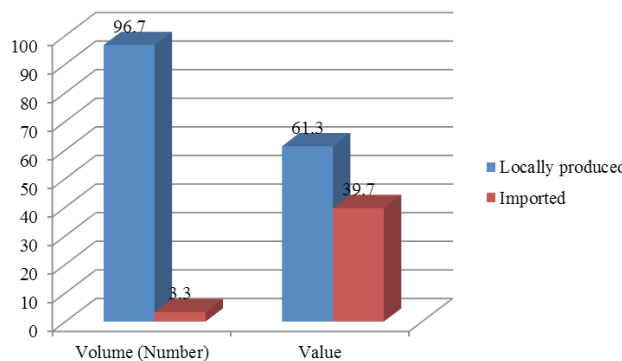


Figure 2. Locally produced vs. imported medicines. Data were taken from deputy for pharmaceutical affairs, Iran Food and Drug Organization.

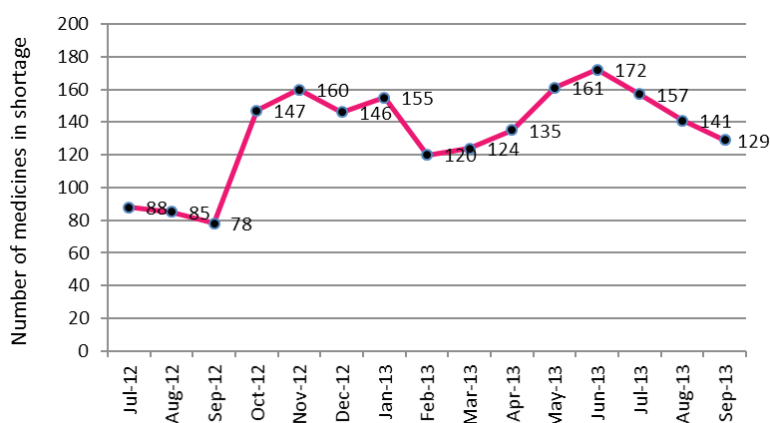


Figure 3. Number of medicines in shortage in pharmaceutical market from July 2012 to Sept. 2013. Data were taken from Drug Information Center of 13 Aban, Tehran University of Medical Sciences.

pockets. Reimbursement for medicines is limited to formulary drugs defined by the major insurance institutions Social Security Organization and Medical Service Insurance Organization. The pharmaceutical cost coverage is 70% of the retail price for outpatients and 90% for inpatients. There is no exemption from co-payments except for individual ceiling price of medicines. Costs exceeding the ceiling have to be pre-paid by patients, which can be claimed back from private insurance firms later. The average number of drugs per prescription is 3.4 with a high use of antibiotics and injectables.⁵ Comprehensive monitoring systems have been developed at Social Security Organization and Medical Service Insurance Organization to check for rational prescription of medicines.

Market Overview

In Iran, there are more than 85 pharmaceutical manufacturers; 20 active pharmaceutical ingredients manufacturers (API) and several knowledge-based, mostly biopharmaceutical, companies and the largest manufacturer has 11.5% of the market. There are 15 national and many regional wholesalers and more than 8000 retail pharmacies and some 800 hospital pharmacies are serving patients.⁵ The pharmaceutical market is largely a generic market and domestic industry supplies have very low and fixed prices. There are trade barriers against importers (tariffs up to 65% for branded medicines which are also locally produced). The private sector has been growing, leading to potential legal and gray im-

ports of branded drugs and risk of counterfeit/substandard drugs entering the market. The total pharmaceutical value currently exceeds 3.6 billion \$US with an average annual growth of 20% during the past few years (Figure 1).⁶

Of all medicines in the Iranian pharmaceutical market and in terms of number/volume, about 96% are produced locally and less than 4% are imported. However, the value of imported medicines accounts for about 40% of the value of the whole market (Figure 2).⁶ The types of imported medicines are those of high technology and vital nature such as medications used in treatment of cancer, anesthetics, drugs used in emergency hypertension, heart failure and cardiac arrest, plasma derived anti coagulants used for hemophilic patients and antibiotics. The nature and trend of importation of such imported medicines have remained almost the same over the time.

Moreover, the market value of medical devices in Iran is about 1 billion U.S. Dollar annually for importation of Hi Tech medical devices such as CT scanners, MRIs, cardiac stents, pace makers and so on, mainly from Europe and the US. Some 25% of medical devices used in Iranian health system are also produced in the country.⁶

Interventions for procurement of medicines after the sanctions

During the past 6–12 month and after the recent sanctions, procurement of medicines and medical devices has been the major

exhausting concern in MOHME and IRI FDO to the point of suppressing other functions.

Several interventions have been employed by IRI FDO to overcome this situation. Assessment of pharmaceutical market needs has increasingly become a continuous practice in meetings with both pharmaceutical producing and importing companies. Constant monitoring of pharmaceutical market is another activity of IRI FDO. Data on production, importation, distribution and sales of all companies are collected monthly and an alert system has been implemented to monitor the situation (Normal, Warning or Shortage). Information on drug shortages on provincial level are collected and responded to accordingly. Figure 3 demonstrates trend of drug shortage in the pharmaceutical market from July 2012 to September 2013. It is important to state that data on drug shortage demonstrated in Figure 3 represent both imported and locally produced pharmaceuticals on the outlet level and, as mentioned above, this has been a major challenge for IRI FDO to manage this situation. Since November 2012, an "Information Center for Drug Shortages" has been established which provides details on the pharmaceutical dosage form and whether or not a requested medicine is available on the outlet to health care providers and the public via short message service. According to the IRI FDO, the center receives some 20,000 hits per months.⁷ This intervention seems to have efficiently handled the public frustration caused by impacts of the sanctions on availability of medications for patients. A working group has also been assigned in MOHME to revise Iran Drug List according to the current situation and needs.

Current challenges for procurement of medicines and medical devices

Money transfer procedures for importation of medicine and medical devices are extremely lengthy and this has negatively affected the access to these health technologies. Some 150 million Euros worth of purchased medicines are on shelves in European companies because money cannot be easily transferred.⁷ It seems that despite politicians' claims to the contrary, medicines and health products are treated like any other products and there is no exception for medical needs of public. In addition, increasing complications of importation processes resulted in increased cost of procurement that has affected affordability of medical products for the public. Changing the sources of imported medicine and also the APIs for locally produced pharmaceuticals have negatively affected the quality of pharmaceuticals and treatment of patients. Vaccine production has been affected by problems for importation of media, materials and instruments necessary for production and renovation of facilities. There are difficulties obtaining media for cell cultures and cell lines for evaluation of biological activity of biopharmaceuticals produced by local manufacturers.

Another major obstacle is the financial institutions refraining from performing transactions with Iranian parties in fear of heavy fines imposed by the US government, even after relevant authorities approve these transactions. Iranian drug importers are losing their credit because of frustration of their foreign counterparts who ask for cash in advance to their business. Unofficial channels and websites, formed by individuals and non-governmental organizations (NGOs) usually outside the country, to provide medicines for patients resulted in an influx of counterfeit and substandard medicines into the market.

Of 30 radiotherapy machines for treatment of cancer patients,

11 are turned off, 11 are below standards and only 8 are working properly because obtaining and importing ⁶⁰Cobalt Source has been impossible to get these devices working. Importation and delivery of instruments such as PET-scan, Cyclotrons, and Gamma Knife etc. have also been extremely difficult. Even importation of liquid Helium to be used in MRIs has faced problems due to the sanctions.⁷

Technical recommendations

From a technical rather than political point of view, it is suggested that a specific Society for Worldwide Interbank Financial Telecommunication (SWIFT) line is allocated for medical purposes and certain financial institutions, Iranian and foreign banks should be assigned for transferring money for medicines and medical devices. A white list of Iranian pharmaceuticals and medical device importer companies together with their foreign counterparts are defined for procurement of medicines and medical needs of Iranian citizens.

It is unfortunate that recent sanctions which claimed to have targeted political leadership in Iran are affecting public health and ordinary citizens in their access and purchase power for medicines and medical needs. It remains the responsibility of public health and international communities to separate public health from politics and to ease the pain of public from sanctions.

Declaration

Major parts of this report were presented in a meeting with officials of the UN agencies based in Iran in April 2013 in the Iranian Academy of Medical Sciences in Tehran and the author was encouraged to publish it.

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