



## An overview to pharmaceutical financing in Iran

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### ABSTRACT

Pharmaceutical expenditure is a substantial part of the health-care system budget. In Iran, people are paying about half of total pharmaceutical expenditure out of their pocket. In this study, we reviewed the Iranian pharmaceuticals financing system including the current situation and the relevant policies. We also provide an overview about the new health-care system reform and its challenges ahead.

**Keywords:** Pharmaceutical; Financing; Iran

**Citation:** Varmaghani M, Hashemi-Meshkini A, Abdollahiasl A, Heidari E, Zekri HS, Yaghoobifard S, et al. **An overview to pharmaceutical financing in Iran.** J Pharmacoeconomics & Pharm Manage 2016; 2(1-2): 45-9.

### 1. Introduction

There is a common old expression among Iranian people: "hope not to pay for doctors and drugs." This is a simple example, regardless of its negative interpretations, implying the Iranian's historic concerns about financial aspects of health-care services. There are lots of individual observations confirming this claim that it is still a big deal for considerable proportion of the population how to deal with their prescription bills. The question "who and how should pay for healthcare services?" Is an old question overlapping with many economic and ethical areas including efficiency, equity, and equality. Developing a fair financing process is suggested as an answer to this question. Fair financing is among health system objectives in the World Health Organization conceptual framework of health system and its performance assessment [1]. This fairness should cover different parts of financing system including fund collection, pooling, and purchasing [2].

Pharmaceutical expenditure is an important part of health-care expenditure in all countries [3]. It seems necessary to frequently evaluate the pharmaceutical financing process and judge whether it is working well or not. To evaluate financing system in pharmaceutical sector, three main data sources including National Health Account (NHA), Household Expenditure Survey, and also Amarnameh (Annual Data of Pharmaceutical Sales) are available in Iran which could be used by researchers.

### 2. A Brief Review of Pharmaceutical Financing System in Iran

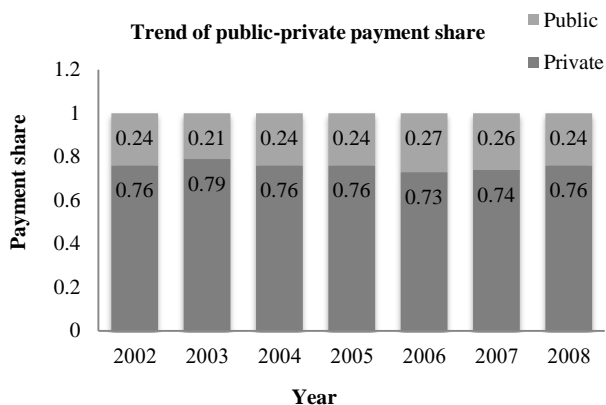
Total pharmaceutical expenditures in Iran has experienced an annual growth rate of about 28% between 1997 and 2010 [4], and the share of pharmaceuticals in total health expenditure has been averagely around 17.5%. The pharmaceutical financing in Iran has been mostly dependent on the private sector. According to Iran NHA, public sector including three main insurance organizations and some other state-owned supportive institutions has been paying only 20-30% of total outpatient pharmaceutical expenditure during 2002-2008 (Figure 1), however, they are formally responsible for paying 70% of them. Furthermore, in the private sector, the role of complementary insurance plans in pharmaceutical expenditure is trivial and households are bearing almost this entire financial burden. The contribution trend of four main payers of Iranian health system in pharmaceutical expenditure is shown in figure 2. We observe that the role of households is several times more than the sum of those insurance organizations. Households have averagely spent about 20-30% of their health expenditure on pharmaceuticals during the investigated years [5].

### 3. Pharmaceutical Financing Problems in Different Settings

There are some financing problems in Iran's pharmaceutical system both in inpatient and outpatient sectors, however, the type of dysfunctions are not totally the same. In inpatient services, according to the insurance law, patients are ought to

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Article information: Received date: 16/11/2015, Accepted date: 25/03/2016, Available online: 14/06/2016

pay only 10% of total pharmaceutical costs and the remaining 90% must be paid by insurance. However, in the reality, much more percentage of the pharmaceutical costs is paid by patients. There are many reasons for this high economic burden on patients:

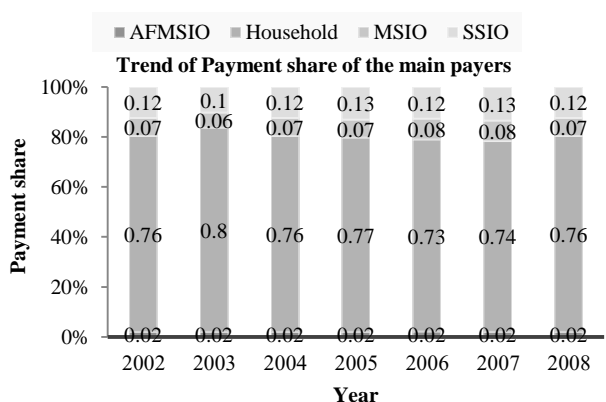


**Figure 1.** The contribution trend of private and public sector in pharmaceutical financing in Iran during 2002-2008

- The same as outpatient sector, there are increasing pharmaceutical products out of health insurance positive list, for which patients have to pay the expenses out of their pocket. These uncovered medicines are mainly expensive imported products without any cheaper alternative or domestic equivalent.

- Some physicians prefer to prescribe imported products or more expensive original brands rather than domestic produced or imported generics. Considering the strategy of insurance funds in covering the lowest priced available generic products, the patients would be persuaded to pay for the difference of covered products and uncovered one.

- Inadequate regulation in hospitals pharmacies supply chain and lack of defined formulary and clinical guidelines for hospitals (even public hospitals) for obtaining medicines that are not available in the hospital pharmacy, forced the patient’s family to provide the prescribed medicine from public pharmacies out of hospitals.



**Figure 2.** The contribution trend of four main payers in total pharmaceutical expenditure

- In these cases, more economic burden would be

imposed on patients because they must pay 100% of the price out of pocket (the insurance does not reimburse the cost of inpatient prescriptions dispensed in outpatient pharmacies).

**4. The Policies Affecting Pharmaceutical Financing in Iran**

There are four main policies influencing pharmaceutical financing at both micro and macro levels:

**Registration Policy:** According to national pharmaceutical policy and Iran pharmaceutical law, all pharmaceutical products must be registered in National Drug List (NDL) before being available in the market [6]. The inclusion and exclusion criteria for this list could control total pharmaceutical expenditure in Iran. For instance, cost-effectiveness assessment has been added to the criteria of reviewing the applications of new pharmaceutical products for entering to NDL and applicant companies are obligated to conduct a cost-effectiveness analysis in Iran and submit it to FDO.

**Emergency import:** The products out of the list could also be available in small scale via a system called “emergency import.” There are several emergency import centers authorized by FDO to import those pharmaceutical products out of ND. This mechanism could lead to increase in pharmaceutical expenditure. The number of these centers has increased during the past years led to considerable growth in unregulated market. As these products are not registered in ND, there is not any insurance coverage and the patients have no other way but paying for them out of their pocket. The increasing trend of these emergency importations is expected to increase the out of pocket expenditure.

**Pricing Policy:** Pharmaceutical pricing in Iran is conducted by pricing commission in FDO. Lately, pharmaceutical pricing process was based on production cost (cost plus method). The manufacturing companies used to offer a suggested price to the commission where medicines prices were determined based on the claimed production costs plus the markup of manufacturer, distributor and pharmacy. The mark ups are set based on a regressive model [7]. Table 1 presents different mark ups for medicines in Iran. Although the mark up setting for pharmaceutical products follow a regressive method, it cannot compensate the considerable differences between the price of domestic generics and imported original brands; therefore, it makes incentives for pharmacies to convince patients to buy expensive brands rather than cheaper generics [8].

**Table 1.** Different mark ups for medicines in Iran

Drug cost	Pharmacy mark up	Distributor mark up	Importer mark up
Drugs cost less than one million Rials per unit	15	10	15
Drugs cost more than one million Rials per unit	8	5	15

According to the current method, the pharmaceutical pricing in Iran is as follows:

- The method of pricing for main drugs (main pharmaceuticals)

The recommended method of pricing for main pharmaceutical products (imported or domestic) during patent

protection period is to compare their price with the consumer price of the same products in the manufacturer and reference countries. Accordingly, consumer prices in the reference and manufacturing countries are compared with that of Iran; the suggested price in Iran should not be higher than the lowest consumer price in the reference countries.

For the main pharmaceutical products (imported or domestic) with an expired patent, the product is priced at least 20% lower than its price in the last sale in Iran. In addition, the reference and manufacturer prices are also reviewed; if the new price in reference country is < 80% of the previous price during the patent period, the price in Iran will be determined based on the lowest price. Therefore, at the time of registering main brand pharmaceutical, it is necessary to declare the patent's expiration date in the manufacturer's country and it should be recorded in pharmaceutical documents and profile.

- The method of pricing imported and domestic generic drugs with a particular brand name.

When the original drug has been already registered in Iran, the upper limit of consumer price for the imported generic drugs and also for the first domestic generic with a brand name, for high-tech drugs or drugs for rare diseases the prices will be at least 40% cheaper and for other drugs will be 60% cheaper than the latest consumer price of the same drug in reference countries and from the same manufacturer in the reference or manufacturer countries (Whichever is cheaper).

When there are three active manufacturers in the market, the price of a new specific generic drug with the same active pharmaceutical ingredients and the same pharmaceutical form will be 5% less than the lowest prices available for the drug.

- Pricing of domestic generic drugs with international non-proprietary name.

This group of drugs is priced based on cost plus method [9]. The pharmaceutical pricing in Iran in the past decades has had a valuable achievement on making medicines affordable for almost all lower income population [10]; however, some challenging subjects including weaknesses in development of pharmaceutical industry and increasing concerns about the accessibility to high-tech medicines in the future convinced policy makers to give higher price to manufacturers letting them to develop themselves in the new pharmaceutical areas [11]. This new approach could cause to unaffordability of medicines for low-income people and affect financing policies dramatically.

### 5. Importation Licensing Policy

According to Iranian pharmaceutical regulation, all imported products must apply for importation license to FDO. By this approach, the market share of imported products and their value in the market could be controlled by this organization via non-tariff measures. Iran FDO also uses import tariff rate as a measure to control importation level. Currently, tariff rate about 30% is considered for the products in which its domestic equivalent generic has at least 50% of total market share. By using these measures, government tries to control pharmaceutical total expenditure in the country. Figure 3 represents the market trend based on imported-domestic issue.

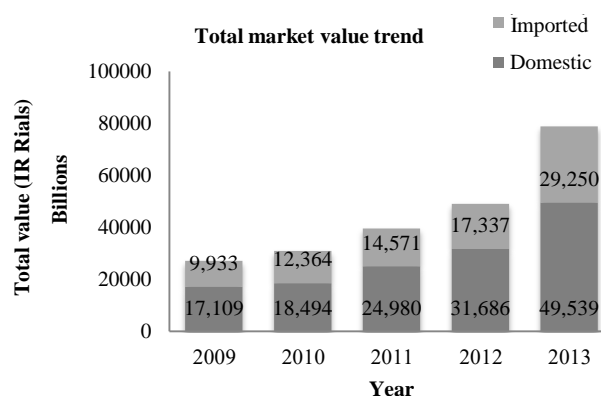


Figure 3. The domestic-imported market trend pharmaceuticals in Iran (2008-2012)

### 6. Reimbursement Policy

**The Structure of Health Insurance in Iran:** Taken as a whole, there are four main health insurance organizations in Iran including the Social Security Insurance Organization (SSIO), the Medical Services Insurance Organization (MSIO), the Armed Forces MSIO (AFMSIO), and the Imdad Committee Health Insurance (ICHI) [12]. In addition to these four major insurance organizations, there are governmental companies such as National Iranian Oil Company, governmental banks, and airlines which provide health care services for their employees and their families under specific medical insurance systems using a number of health-related organizations or private sectors which are financed by their own internal financial resources [13].

**Insurance Coverage in Iran:** The exact data on insurance coverage from four main organizations are not available.

According to high council of insurance in Iran, SSIO has covered about 24.90 million people, MSIO has covered about 31.99 million people, AFMSIO has covered about 2.62 million people and ICHI has covered about 0.74 million people, and other insurances have covered about 1.86 million. In addition, there are 16 small insurance agencies independently have provided insurance services for the population under its coverage [14].

**Reimbursement Level:** In Iran, most of over the counter pharmaceuticals are under the coverage of insurance system and their prices, similar to those of pharmaceutical generics, are determined by pricing commission. All hospital pharmaceuticals are also priced via the same method, thus despite the differences in the volume of procurements in hospitals or their payments conditions, there is no difference in hospital procurements pricing [15].

**Cover the Expenses of Patients with Some Life Threatening Diseases:** In Iran, some selected diseases are defined as specific diseases and the affected patients receive their prescribed medicines without any co-payment. The list of specific diseases differs between insurer organizations however their common diseases include transplantation, thalassemia, hemophilia, and dialysis. On the other hand, a group of disadvantaged and poor people in Iran that are covered by the ICHI receive more supports and pay lower rates of money, than other people under the coverage of other organizations [16].

In most countries, private insurers have decreased the rate of patients' out-of-pocket payments to some extent, however in Iran private, insurers have a limited coverage and the scope of their activity is confined to the coverage of hospital medicines [15]. In Iran, pharmaceutical expenses reimbursement is basically offered by SSIO, the MSIO, and the AFMSIO. These organizations are committed to reimburse the cheapest registered medicines. Complementary insurance companies have limitation for the coverage of pharmaceutical expenses. There is a pharmaceutical insurance positive list in Iran which includes all the medicines needed for refractory disease which is fully covered by the government [4].

### 7. The New Health Sector Reform Plan

To overcome these challenges in pharmaceutical financing area and other health-care system problems, the government has just implemented a reform plan in 2014. The Ministry of Health (MOH) has declared some major goals for this reform plan including reducing out of pocket payment and increasing quality and equity of care. The actual out of pocket payment in public hospitals is aimed to be at maximum 10% by supplying all needed pharmaceuticals and medical devices inside hospitals. There is also an additional package for supporting highly cost diseases (known as special disease), and these patients could access their medicines with up to 90% reimbursement from MOH subsidy. Another aim of this reform is achieving universal coverage goal and cover the people who are not insured by any funds [17].

### 8. The Budget of Reform Plan

The government has allocated a considerable budget to implement a reform in healthcare system: 33 billion IRR (129,077 USD) for reducing out of pocket payment in public hospitals, 9500 billion IRR (37,158,726 USD) for supporting special disease patients, and 5500 billion IRR for covering people who do not have any insurance coverage. In the other word, Iran government has decided to increase the share of health expenditure from gross domestic product to improve the level of health-care services.

### The New Plan in Pharmaceutical Area

According to this plan, about 250 high price pharmaceutical products including many imported branded ones went to reimbursement list by an agreement between MOH and health insurances. According to this agreement, all listed products would be reimbursed up to 90% with the aim of reducing the out of pocket payments.

### The Main Challenges of New Reform Plan

*Sustainability of resources:* There are many concerns about how the government is going to supply adequate resources for continuing this model, given its general revenue-based budget structure. If the government faces budget constraints or deficiency in future, what will happen to the public health?

*Vanishing the boundary between payers and providers:* By this model, the role of third-party payers in the financing is getting less, and therefore, providers are free to impose an expense on healthcare budgets without any special monitoring or goalkeeper mechanism.

*Potential induced demand:* The combination of two main

reasons is playing an undeniable role in increasing induced demand in pharmaceutical market as well as other health-care goods and services markets: decreasing patients' actual copayment and fee for service payment mechanism in hospitals. By continuing this approach, many important concerns will arise in term of efficiency of health-care system.

### 9. Conclusion

Pharmaceutical financing in Iran is more dependent on private sector, in which out of pocket expenditure is dominant. The gradual changes in some policies including pricing, reimbursement, and registration during the last years could lead to decreasing trend in accessibility to medicines especially for poor people. Although the new health-care system reform that has been started recently in response to financing challenges of health system has shown some positive signs such as lowered patients out of pocket payments and their satisfaction, there are many concerns about the sustainability of this new approach, given the increasing needed budget and efficiency of the whole system.

### 10. Conflict of Interests

Authors have no conflict of interests.

### 11. Acknowledgments

We would like to thank all of the professors and colleagues, who kindly help us for completing this research project.

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