



## Policies and measures implemented to reduce the impact of international sanctions on Iran's pharmaceutical sector

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### Abstract

**Background and purpose:** Continuous evaluation of the policies and interventions could explore their efficacies in improving the accessibility and availability of medicines in the local market. This study explained the health system policies of the Islamic Republic of Iran concerning the impact of the economic sanctions on the local pharmaceutical market and addressed the issue of whether these policies were able to improve patients' access to medicines.

**Experimental approach:** In this study, qualitative and quantitative research methods were used. In the qualitative part, semi-structured interviews with pharmaceutical system experts were used. In the next step, the structural analysis method was used. In the quantitative part, numerical sales data of the selected medicines were extracted and analyzed.

**Findings/Results:** Reported statistics regarding the presence of the medicines in the market indicates the obvious fluctuations in the numerical sales of medicines in the studied years. This may indicate that the policies implemented are not able to fully compensate for the negative effects of sanctions and improve access to medicine. In addition, according to some experts, policy, and management weaknesses are mainly rooted in unresolved domestic hurdles which have exacerbated the effects of international sanctions on the country's pharmaceutical market.

**Conclusions and implications:** Effective policy-making in response to economic sanctions can reduce the negative effect of international sanctions and result in drug shortages. Results of this study showed despite efforts made by the Iran health sector to subside the impact of sanctions on the pharmaceutical sector, there is an obvious disruption of the medicine supply chain in the market.

**Keywords:** Economic sanctions; Iran health sector; Medicine access; Policy evaluation.

### INTRODUCTION

The United States has long used economic sanctions as a tool to impose its political goals against Iran, *e.g.* in 2005 and 2012 and following the abolition of the Comprehensive Joint Action Plan in 2018 (1-3). Although humanitarian goods such as food and medicine should be exempted from any sanctions, sanctions against Iran's banking system along with scarcely of foreign currencies caused a devastating impact on Iran's health and pharmaceutical sectors. In addition, the lack of cooperation of some European and American companies in the delivery of raw materials and

medicine and transfer of technical know-how exacerbated the dilemma (4,5).

Effective policy-making in response to sanctions can reduce the negative effect of international sanctions and drug shortages (6). Therefore, evaluation of the policies of the national health system makes it possible to identify the strength and weaknesses of the efforts to subside the impact of sanctions on the health and pharmaceutical sector.

#### Access this article online



Website: <http://rps.mui.ac.ir>

DOI: 10.4103/1735-5362.343081

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Policy analysis through the analysis of data and documents makes it possible to evaluate the policy without being influenced by the prejudices of experts. It can also help empower policy formulation and implementation and support the use of technical evidence in policy processes (7). Ensuring access to medicines is one of the key indicators of the health systems worldwide. Access to medicine includes the availability of drugs in the country, affordability, geographical access, and patient acceptance and satisfaction (8). Therefore, access to the medicines' index could be used as a valid indicator for policy analysis of the Iran health sector to combat the impact of sanctions on the pharmaceutical market. In this research, the policies of the national Iran pharmaceutical system, with a focus on the drug access index amidst international sanctions have been evaluated.

## **METHODS**

In this study, both qualitative and quantitative methods have been used to reach more accurate results (9). In addition to descriptive methods (interview with pharmaceutical experts), policy evaluation was also performed by analyzing data published by Iran Food and Drug Administration (IFDA). In this study, semi-structured interviews with experts and policymakers were used and information provided through these interviews was used for structural analysis.

### ***Design interview questions***

Initially, 13 extended questions were designed in the following five dimensions:

1. The most important effects of sanctions on the pharmaceutical system
2. Strategic planning and the most important interventions to deal with the effects of sanctions
3. The role of other organizations (other than IFDA) in intensifying or mitigating the effects of sanctions
4. Role of patients' purchasing panic in medicines' shortages

5. Government financial strategies in drug market during sanction

Then, in order to evaluate the content validity, seven experts reviewed and evaluated questions in terms of the necessity, relevance, and clarity of the question. Based on their comments 10 questions were selected as the final interview questions.

### ***Interviews with experts and policymakers***

In this research, 13 experts and specialists who had experience in various fields of the pharmaceutical market were interviewed in person. The interviewees were selected from available experts in the field of policy-making, regulation, local production, and importation of drugs and raw materials.

### ***Selection of medicines and therapeutic groups***

For the quantitative part of this study 31 drugs were selected from cardiovascular, antidiabetes, respiratory tract, neurological, anticancer, and medicines used for rare diseases (Table 1). The selection criteria were based on high-consumption medicines (according to data published by IFDA) and their importance for the management of prevalent diseases, which their shortages will have a negative impact on public health. These medicines were selected from both domestically produced and imported medicines in order to evaluate the impact of sanctions on both imported and locally produced medicines (10).

### ***Data collection and analysis***

Numerical sales data were extracted from the Iran Drug Statistics published by IFDA, for the years 2013 to 2018. The trend analysis of data was used as an indicator of medicine supply in the market. IFDA has also reported an "emergency list" of drug shortages during 2013-2018 which has been used to verify results from the data analysis for drug shortages. IFDA gave urgent priority for the importation of medicines on its "emergency list".

**Table 1.** Selected therapeutic categories and medicines with numerical sales of medicines (million).

Therapeutic Category	Selected medicines	2013	2014	2015	2016	2017	2018
Cardiovascular	Aspirin 80 mg/tablet	851	995	1,212	1,350	1,336	980
	Atenolol 50 mg/tablet	289	244	235	197	200	133
	Atorvastatin 20 mg/tablet	456	415	724	702	670	470
	Captopril 50 mg/tablet	51.5	61.5	68.2	66.3	67.5	53
	Clopedigrol 75 mg/tablet	86	105	127	151	134	186
	Nitroglycerin 2.6 mg/tablet	268	269	399	404	387	294
	Warfarin 5 mg/tablet	53.5	52	44.5	65	57.5	50.5
Anti-diabetes	Gliclazide 80 mg/tablet	32.5	50.9	88.2	151.5	175.5	179.5
	Insulin aspart injection	1.3	4.3	4.9	6.7	7.1	7.3
	Insulin glargine pen	0.88	2.5	3.9	6.2	7.9	9.5
	Insulin regular vial	2.1	2.95	1.9	1.6	1.5	1.2
	Metformin 500 mg/tablet	1424	1004	1529	1518	1255	1178
	Pioglitazone 30 mg/tablet	22.5	26.5	27.2	37.3	26.7	15.2
Respiratory tract	Budesonide/formoterol 320/9 µg/inhaler	0.4	0.54	0.74	0.9	0.95	0.88
	Formoterol 12 µg/capsule	1.8	4.7	2	6.2	7.8	6.4
	Beclomethasone 50 µg/spray	1	1.5	1.3	1.2	1.3	0.8
	Salbutamol inhaler	4.3	8.5	5.6	6.4	6.2	4.5
Neurological disorder	Bupropion 75 mg/tablet	7.1	12.2	20.7	19.8	20.5	20.2
	Clonazepam 1 mg/tablet	229	207.7	275.3	292	261.9	164.2
	Fluoxetine 20 mg/capsule	135.5	132.5	176.8	164.6	152.3	127.3
	Nortriptyline 10 mg/tablet	129	128	141	138.5	124.5	61.3
	Phenytoin 100 mg/capsule	22.5	18.4	32.1	31.1	29.2	22.9
	Valproate 500 mg SR tablet	6.05	6.2	13.1	17.8	108.5	102.3
Rare diseases / Anticancer	Venlafaxine 75 mg/capsule	2.9	2.5	3.1	4.3	10.6	10.3
	Deferoxamine 500 mg/vial	4.4	8.5	5.6	6.5	6.3	4.6
	Flutamide 250 mg/tablet	2.9	2.8	1.9	2.3	2.2	1.5
	Raloxifene 60 mg/tablet	3.6	5.1	2.7	2.6	2.43	1.18
	Rituximab 500 mg/vial	0.014	0.011	0.064	0.04	0.08	0.075
	Tamoxifen 10 mg/tablet	13.8	11.8	11	12	11.1	7

## RESULTS

### *Strategic planning and the most important interventions to counter the effects of sanctions*

There are two different points of view among the interviewees in this regard. Some believe that instead of managing the crisis, preventive actions should be implemented and this requires strategic and long-term planning and believe that there are weaknesses in the pharmaceutical system in this area. However, they believe plans were not commensurate with the critical situation due to sanctions.

The second group believes that the main approach should be to strengthen domestic production of medicines and reduce dependence on importation of the medicines, and in this regard, national planning

shows some weaknesses in its implementation. They explained the important weakness of the national strategic management and interventions of the Iran pharmaceutical system in dealing with the effects of sanctions as the following.

1. Lack of efficient management model and planning strategies proportionate with the intensity of the sanctions
2. Inconsistencies and contradictions in the policies of IFDA
3. Short managerial life of IFDA managers and the challenge of frequent replacement of the managers
4. "Action and reaction" and cross-sectional strategy to deal with everyday challenges.

Table 2 also summarizes the opinion of the experts on the most important implemented decisions to subside the impact of sanctions on the pharmaceutical market.

**Table 2.** Most important implemented decisions to subside the impact of sanctions on the pharmaceutical market.

Main categories	Subcategories
Supporting domestic production of medicines and strengthening the production infrastructure	Prohibition or restriction on the importation of medicines that have similar domestic production Support for domestic knowledge-based companies Encourage localization of imported medicines Facilitate administrative bureaucracies in order to speed up local production of medicines
Inter-organizational cooperation	Custom clearance of medicines and APIs with minimum required documents Memorandum of Understanding between IFDA and the Central Bank on the allocation of currency according to the priorities set by IFDA Memorandum of Understanding between the Ministry of Health and Health Insurance Organizations to increase insurance reimbursement for certain expensive medicines for some chronic and rare diseases
Cooperation with multinational companies	Cooperation and encouragement of multinational companies to invest in Iran as one of the ways to escape sanctions Encouraging multinational companies for localization of their products in Iran
National Health Insurance	Removal of OTC medicine from the basic insurance list Strengthen regulations that improve rational prescription of medicines
Reducing the amount of “subsidized” hard currency for some medicines	Removal of APIs for OTC medicines from “subsidized” hard currency list Removal of excipients and packaging material of all medicines from “subsidized” hard currency list Elimination of supplements from “subsidized” hard currency list
Supply chain management	Precise supply chain monitoring and control Investigate daily market shortages all over the country to update possible medicines shortages in the country. Announce emergency procurement for shortage list

API, Active pharmaceutical ingredient; IFDA, Iran Food and Drug Administration; OTC, over-the-counter.

### **Health insurance organization**

The health insurance scheme is an important contributor to the affordability of medicines. However, since sanctions have reduced total national income and, of course, reduced the annual budget of the national insurance organization, it affected their policies and performance *e.g.* shrinking the list of medicines covered by the insurance scheme. This policy in fact reduced the income of the pharmaceutical companies as well and increased the debt of insurance organizations to the providers which in turn disrupted the medicine supply chain and production in the pharmaceutical industry due to lack of liquidity. Also, this has substantially reduced retail pharmacies' income. This may cause some pharmacies to violate professional principles related to the medical prescription and rational use of medicines to compensate for greater sales.

One of the positive interventions of the national health insurance scheme is the removal of OTC (over-the-counter) medicines from their reimbursement list, which is effective in controlling drug expenditure costs. The national health insurance scheme allocated the

saving from this intervention to increase coverage for other therapeutically important medicines in order to reduce the patient's out-of-pocket payments. However, most of the interviewees believe that insurance scheme in Iran needs to reform their laws and policies in order to increase efficiency, quality, and justice in their reimbursement policy according to international experiences (11).

### **The role of other organizations**

All interviewees believe that the coordination of other organizations including the Ministry of Industry, Mine, and Trade; Central Bank and Customs with the Ministry of Health (MOH), and IFDA has a significant role in ensuring timely access to the medicines. Mismanagement, inefficiency, and lack of coordination can even put the country under what they call “internal sanctions” and could intensify the effects of sanctions. Table 3 summarizes the interviewees' points of view and reasons for the important role of organizations other than MOH and IFDA to relieving the impact of international sanctions on the pharmaceutical market.

**Table 3.** Factors that intensify or relieve the impact of sanctions on the pharmaceutical market.

Roles	Main categories
Intensifier	Instability in policies and regulations imposed by IFDA IFDA bureaucracies Lack of timely allocation of hard currency by Central Bank Delays in customs clearance of items Corruption related to the allocation of “subsidized” hard currency Lack of effective coordination between IFDA, Ministry of Industry, Mine and Trade, and the Central Bank in the commodity tariff code.
Reliever	Custom clearance of medicines and APIs with minimum required documents

IFDA, Iran Food and Drug Administration.

### ***Effect of panic purchasing***

Panic purchasing and bullwhip effect could also impede access to medicine. In the realm of medicine, some interviewees believe that patients, especially those with chronic and incurable diseases, are sensitive to any signal that interferes with their access to medication and treatment. Therefore, it is expected that drug shortages and cost rising could cause panic in buying of the medicines by patients. Of course, panic buying is not necessarily related to sanctions, but sanctions can exacerbate this problem and cause goods to be accumulated in homes more than their real needs (12). In this case, the bullwhip effect could also transmit signals from pharmacies as the final step of the medicine supply chain, to the beginning of the supply chain (factories and the pharmaceutical industry) and disrupt production, planning, and supply chain (13).

Media and fake news in cyberspace could disrupt the market, which requires close monitoring by the responsible authorities. In some cases, these shortages are manipulated to increase the prices and profitability of the brokers (14). However, some interviewees believe that because subspecialty drugs require a doctor’s prescription, the effect of panic buying is not significant on drug shortage.

### ***Hard currency allocation***

For decades ago, the Iran government used to allocate subsidized international currencies to the pharmaceutical market in order to keep medicine prices low. The most important current advantage of the subsidized currency of medicine is the reduction of out-of-pocket payments of patients, but it also has many

disadvantages. Obviously, the difference between the subsidized and free-market prices of hard currency will lead to economic corruption and even the smuggling of cheap medicines from the local market into the neighboring countries. Manufacturers may also procure raw materials from low-quality, low-cost sources that meet minimum pharmacopoeial standards for greater profitability. Therefore, the quality of medicines may have been compromised and caused treatment failure or extra side effects to the patients. Also, reducing the quality of domestic drugs can boost the smuggling market.

The time-consuming process of allocating subsidized foreign currencies by the Iran Central Bank is one of the main problems of all drug suppliers in Iran. Interviewee believe to prevent economic corruption and the sustainability and development of the domestic pharmaceutical industry, the subsidized currency should be removed from the medicine supply chain and in order to prevent patients’ out-of-pocket payment, the National Health Insurance system should receive an extra budget. However, it should be noted that the implementation of this plan requires liquidity and exchange rate stability for the local pharmaceutical industry.

The interviewee also express different points of view on policies to allocate subsidized hard currencies. One group believes it should be based on a planned policy to allocate hard currencies to the local producer and importer for in advanced planned policy to provide medicines in a timely manner. They believe this approach would create more trust from the patients’ side to the health policies.

In this approach, authorities should ignore sporadic medicine shortages.

The second group believes providing hard currency to cover the current medicine shortage in the market should be the main policy of IFDA. They believe this “action and reaction” policy may work more efficiently and prevent panic buying and the bullwhip effect.

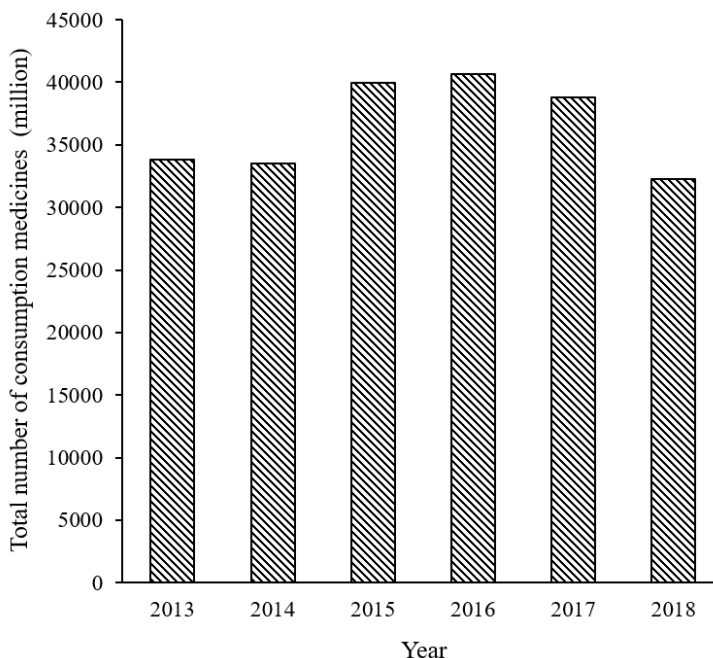
#### **Pharmaceutical market data**

Examining the results of numerical sales of the market reveal that since late 2018 when there was the peak of economic sanctions by the United States against Iran, the total numerical sales of medicines compared to 2017 has decreased by 16.6%. Also, if we divide 2018 into three four-month periods, sales in the last two months of the year when all sanctions against Iran were reinstated, were decreased by 70% compared to the first four months of the year. (Fig. 1).

In a separate attempt numerical sales of the selected more therapeutically important medicine groups were also evaluated during the years 2013 to 2018. In addition, the trend of consumption of the most used medicines in each of these groups is listed in Table 1.

#### **Anti-diabetes medicines**

Despite a 51.7% increase in sales of anti-diabetes in 2015, a decrease in sales of these medicine in 2017 was reported (Fig. 2). The decrease in numerical sales trend in 2017 and 2018 was mainly due to the decrease in metformin and, with less importance, pioglitazone consumption (Table 1). Also, the presence of gliclazide in the list of “emergency list” of drug shortage of IFDA in 2013 and 2014 confirms the decreasing trend of anti-diabetes in these years. There is also a decreasing trend in the sale of regular insulin.



**Fig. 1.** Total number of medicines’ sales over the years 2013-2018.

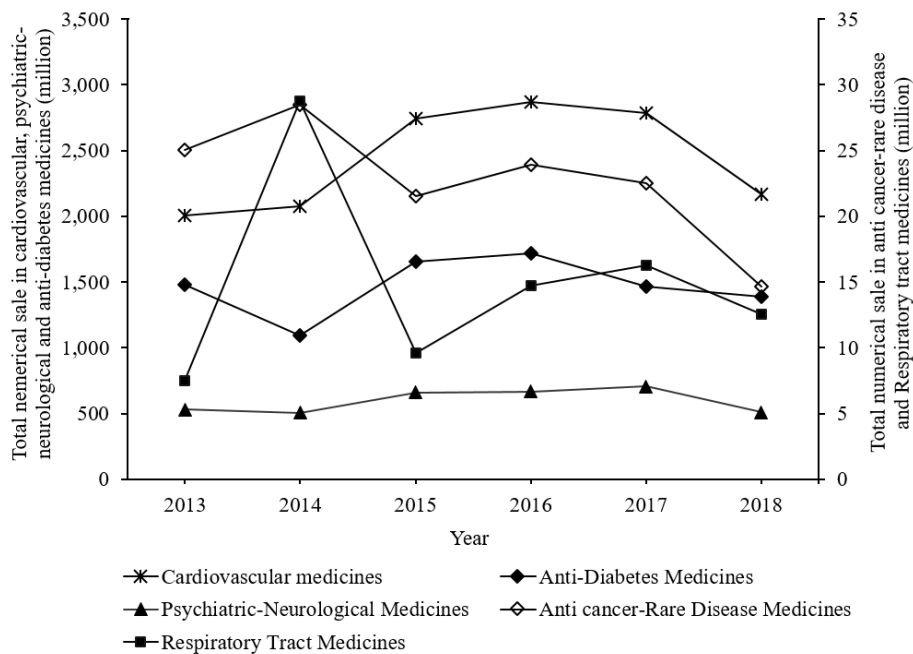


Fig. 2. Total number of medicines' sales (million) during 2013-2018 based on therapeutic groups.

**Respiratory tract medicines**

In the group of respiratory tract medicines, all medicines showed a decrease in numerical sales in the market in 2018. Formoterol capsule, which is imported, had a significant decrease in numerical sales in 2013 and 2015, and its presence in the list of emergency drug shortages of IFDA in 2013 and 2015 confirms the downward trend in the sale of this drug (Table 1).

**Cardiovascular medicines**

The results of this study showed that the use of selected cardiovascular drugs was growing until 2017. In 2015 the total number of sales increased by 31.8% compared to the previous year. However, in 2018 it was observed that the total number of sales has decreased by 22.1% (Fig. 2). Also, the presence of warfarin in the list of emergency drug shortages of IFDA in 2013 and 2018 confirms the downward trend in sales of this drug (Table 1).

**Psychiatric-neurological medicines**

In this category, sales in 2015 increased by 30.4% compared to 2014, and again in 2018, we faced a decrease of 28.1% (Fig. 2). Sodium valproate, bupropion, and venlafaxine from 2013 to 2016 are among the list

of emergency drug shortages that indicate medicine access disruption.

**Anticancer/rare disease medicines**

In the category of rare and difficult curable diseases, it was found that the numerical sales of tamoxifen, raloxifene, and flutamide were declining during these years. The use of bevacizumab and rituximab was growing (Table 1). It should be noted that deferoxamine, bevacizumab, rituximab, and blood coagulant factor VIII were associated with impaired geographical access in the country for most of the years.

**DISCUSSION**

According to the interviewees, the main obstacle of the current Iran pharmaceutical system arises from the economic sanctions imposed on the country. Therefore, in order to subside the impact of such sanctions on the pharmaceutical system, the implementation of strategic planning is essential. Medicines are a very important commodity in the country's health system and long-term planning should be done for macro goals in the field of access and supply.

According to pharmaceutical market data, all therapeutic groups showed a decrease in numerical sales in 2018. Anti-diabetic medicines showed the most reduction in consumption trend mainly due to metformin shortage. The lack of raw material and intermediate for local production of active pharmaceutical ingredient (API) of metformin, the tendency to prescribe fixed-dose combination medicines which include metformin also contributes to the shortage of metformin in the market. The presence of gliclazide in the “emergency list” of drug shortage in 2013 and 2014 also indicates the shortage of this medicine in the market. The decrease in the numerical sales of regular insulin since 2014 could be due to the change in the pattern of consumption insulin from vials to insulin pens, which has increased significantly over these years.

Most of the medicines in the respiratory tract medicines group are imported medicines, and sanctions had the most effect on the imported medicines.

In cardiovascular medicines, warfarin shows a considerable decrease in numerical sales in 2014 and 2015 compared to 2013 and 2018.

In an anticancer/rare disease medicines group decrease in the numerical sale of tamoxifen, raloxifene and flutamide are obvious and they have also geographical access problems. However, the prescribers’ preference for prescribing high-tech drugs may also contribute to their decreased consumption. Local production of biotechnology-derived medicines and further reduction of their cost compared to the imported ones are among the reasons for the increase in numerical sales of these medicines in recent years.

In general, imported drugs seem to be more affected by sanctions compared to locally produced medicines, and the most important reason for the shortage of domestically produced drugs is due to API procurement. Therefore, currently, the main approach of the pharmaceutical system in Iran is the growth and prosperity of the domestic pharmaceutical industry and reducing dependence on importation (15). However, in line with the decisions implemented in order to achieve this goal, the following points were raised by the

experts which may need some revisions by the national policymakers.

1. Policy inconsistencies will deter investors to enter this sector. Therefore, a clear and consistent policy could encourage investors, especially from the private sector enter into the pharmaceutical sector and boost local production of the medicines which could finally ease the impact of international sanctions.

2. Although banning and restricting on importation of medicines could create saving on needed international currencies, there are issues such as patient choice and the need to access new medicines. Lack of more efficient medicines in the market could cause more misery to the patients. Also, it should be noted that local pharmaceutical companies should do their best to produce high-quality medicine and avoid meeting the minimum standards of pharmaceutical pharmacopeia.

3. One of the most important challenges that cause damage to local production infrastructure is the pricing debate. Pharmaceutical companies are primarily economic enterprises whose remnants require profiteering. Many local manufacturers believe that the IFDA pricing system does not consider any share for the difference in quality between the products of different companies and the research and development sector. Price control should not be such that the reasonable credit of the main actors of the supply chain is not provided. It seems that in order to ensure cost-effective drug access and sustainability of the pharmaceutical industry, pricing policies should be reviewed and improved (16).

4. Based on the experiences of other countries, improving the index of rational use of medicines and increasing the level of health literacy among prescribers and patients could be very effective in controlling medicines’ expenditure (17). Also, the decisions and policies adopted, if properly communicated and announced, will enable patients to understand and accept the prioritization by policymakers and to better accompany the health system in times of crisis (16).



## CONCLUSION

Based on the results of this study, international economic sanctions have disrupted the medicine supply chain in Iran and endangered timely access to medicines. This is mainly manifested in the form of fluctuations in the supply of medicines. Distortions of numerical sales of the medicines in 2018 indicate that the policies implemented by IFDA were not able to fully compensate for the negative effects of sanctions on the pharmaceutical market and sustain access to medicines in the country. According to experts' opinions policy and management weaknesses which are mostly rooted in unresolved domestic policies, have exacerbated the effects of sanctions.

In a country like Iran, which has always faced international and regional challenges and crises over the years and given that sanctions, directly and indirectly, have a negative impact on the health sector, strengthening the field of policy-making, using experienced managers and proper strategic planning are strategic tools to ensure stability in the national pharmaceutical market. Also, due to the long period of sanctions against a country, it is essential that IFDA constantly reviews and revises its policies and strategies based on learning from its past and international experiences, in order to optimize its action to ensure timely access of the patients to the needed medicines. There is no doubt that experiences of other countries in similar situations (sanctions and economic crisis) can help health care providers to better manage crisis situations. Sharing information and exchanging experiences on policy implementation between policymakers, including failures, can be very useful for countries to make better-informed decisions (15).

## Acknowledgements

We are very grateful to all interviewees for their cooperation in this study. We would like to thank IFDA for the provision of access to the required data.

## Authors' contributions

F. Emami and A.M. Cheraghali contributed to conception and design, investigation, analysis, and interpretation of data, and manuscript writing; A.M. Cheraghali defined the intellectual content and supervised the study. The final version of the manuscript was approved by the authors.

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