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The Policy of Subsidy Elimination from Currency Allocated to Pharmaceutical Sector in Iran; Concerns of Patients, Payers, and Industry

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ABSTRACT

Background: Pharmaceutical sector in Iran is a generic based market in which over 98% of sales volume and 85% of sales value are supplied by local manufacturers, according to latest published data by Iran Food and Drug Administration (IFDA) on 2021. Share of imported generics and original brands from the market has been decreasing due to Iran MOH's cost-containment and localization support policies

Methods: To analyze the data and estimate the real exchange rate uncertainty index, the generalized conditional heterogeneous variance self-regression econometric method (GARCH-M) is used.

Results: Strict and unfair cost-plus approach in repricing could cause margin loss for local companies and put sustainability of whole local generic industry at risk

Conclusion: Provided the consequences of subsidized currency on pharmaceutical and healthcare system, government decision for subsidy elimination from currency seems to be rational and defensible. However, all concerns of different stakeholders have to be heard and addressed before implantation of this policy. With sufficient budget raise for health insurances from the sources of subsidy elimination revenues (cross-subsidization), government should ensure that this policy will not burden any unaffordable cost or loss to either patients or industry. In addition, agility in processes of pricing, budgeting and reimbursement is a key success factor for MOH and IFDA to avoid any harm to stakeholders.

Keywords: Subsidy Elimination, Policy, Pharmaceutical industry

Introduction

The pharmaceutical sector in Iran is a generic-based market in which local manufacturers supply over 98% of sales volume and 85% of sales value, according to the latest published data by the Iran Food and Drug Administration (IFDA) in 2021. including the Share of imported generics and original brands from the market, has been decreasing due to Iran MOH's cost-containment and localization support policies (1). Furthermore, the affordability of medicines for patients is a concern for the government, so price setting has been defined as part of IFDA's responsibilities according to Iran pharmaceutical law (2). This regulated pricing, mainly implemented by controversial cost-plus mechanisms and with the aim of price control, is criticized by local manufacturers due to its weaknesses and negative impacts on their long-term development plans (3).

Economic sanctions raise many concerns about the affordability and accessibility of medicines because of their unavoidable impact on the value of the local currency. The experience of Iran dealing with such economic shock and the strategies to control the impact of sanctions on patients' affordability could be an experience to be shared with other healthcare systems.

In 2018, the United States withdrew from the Joint Comprehensive Plan of Action (JCPOA) nuclear deal with Iran and reinstated economic sanctions. Accordingly, Iran experienced a significant drop in Oil and gas exports and national revenues and a devaluation of the currency. In order to protect patients and payers from rising and fluctuating costs of treatments and prevent a catastrophic affordability crisis, the government decided to grant fixed-rate subsidized foreign currency to pharmaceutical and medical devices. The fixed rate of this currency was 42,000 IR Rials per US Dollar, and it was planned to be allocated to import both finished products and needed APIs/raw materials from local manufacturers (4). The same strategy was taken for a broader list of products (group1 or essential goods). However, most of them were gradually excluded from the list of this subsidy (5).

Since the start of this policy, over 2 billion euros has been allocated yearly to the pharmaceutical and medical device sectors. However, MOH has recently announced the new decision to abandon this subsidy in 2022 and switch the subsidized currency rate to the Nima rate (6). Nima rate is Iran's second official FX rate, sourced by non-oil export trade, which is very close to market rate currency. The comparative trend of the Nima rate and market rate of the US dollar versus the subsidized rate is provided in figure 1.

As illustrated, in the last two years, the difference between the Nima rate and the fixed subsidized rate has become significant because of the constant devaluation of the IR Rial versus the US dollar.

According to the graph, the Nima rate has increased from around 130,000 IR Rial per US dollar in April 2020 to over 230,000 IR Rial per USD on October 2021, while the rate of subsidized currency allocated to pharmaceuticals has been fixed at the rate of 42,000 IR Rial per US dollar. It indicates that the Nima rate is currently six times more expensive than the subsidized rate, and government decisions to eliminate this currency could be very challenging for all stakeholders.

This paper will review the policy's concerns from different perspectives, including patients, payers, and industry.

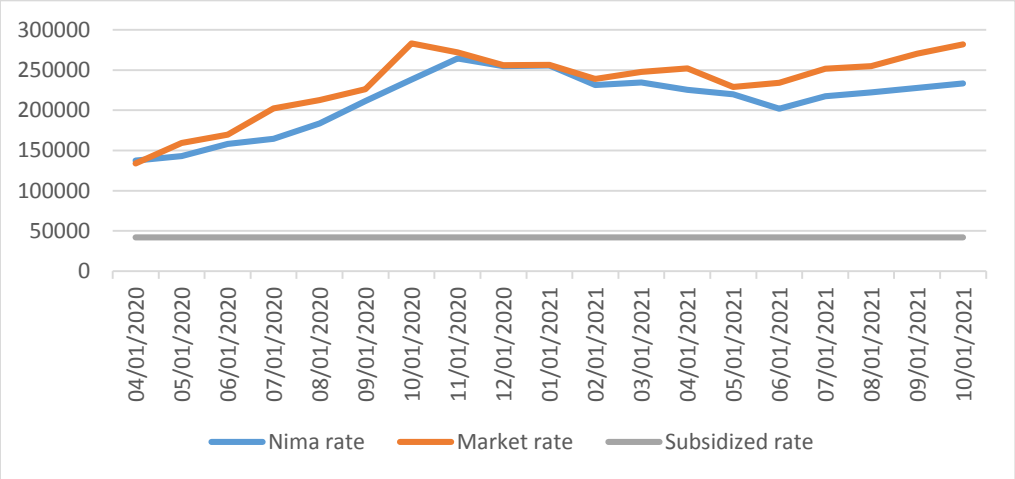

Figure 1. The trend of three different US dollar rates in Iran (2020-2022)

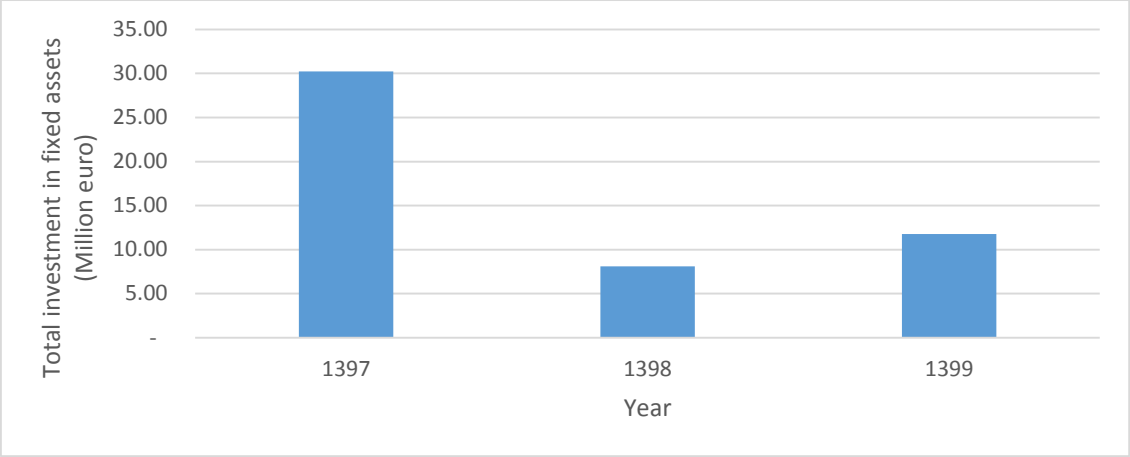

Figure 2. trend on investment in fixed assets by local pharmaceutical companies listed in the Tehran stock exchange market

The impacts of subsidized currency on the pharmaceutical sector

By allocating subsidized currency, the government controlled the increase in the price of prescription drugs and avoided financial burdens on both patients and payers. However, many concerns and criticisms were raised about the mid-term and long-term consequences of such a policy:

- *Supply Chain Disruption and accessibility issue*

  Despite exempting transactions for export payment and re-exporting medicines and medical devices (7), economic sanctions create accessibility issues because of imposed administrative and regulatory complexities (8-10). Since the process of subsidized currency allocation is also bureaucratic and time-consuming, and because of different controlling and advisory bodies involved in the processes, disruption of the supply chain becomes even worse (11). For instance, during the last few years, local companies could not receive currency for their API orders on time because of the long processes of the priority listing in IFDA and delays of currency allocation in the central bank due to a lack of currency resources. In such a situation, the shipment and arrival of APIs or other raw materials became quite unpredictable, causing shortages and inaccessibility to even typical medicines in the market (12).

- *Risk of corruption and parallel export*

  Health economists have always criticized the policy of fixed subsidized currency because of its potential for corruption and rent-seeking (5). In addition, by providing subsidized currency to pharmaceutical products, the prices of prescription drugs in Iran remained unreally low for neighboring markets and provided some opportunity for illegal parallel export.

- *Long-term impact on industry development*

  While all expenses and investments of local pharmaceutical companies varied based on free market trends, allocating subsidies to a minor proportion of costs (APIs) provided an excuse for IFDA to control the prices of medicines strictly regardless of the realities of the market. IFDA led the industry to run in place in an unreal economic context and become financially weaker for long-term development (13,14). In figure 2, the investment trend of 23 local pharmaceutical companies listed in the stock exchange market is displayed based on their published financial statements.

Iranian year conversion to Gregorian year: 1397~ 2018-2019; 1398 ~ 2019-2020; 1399 ~ 2020-2021

The pilot project of subsidized currency elimination during 2020-2021

In mid-2020, IFDA announced that in the first/pilot phase of subsidized currency elimination, importation of a limited number of products would be only allowed by Nima rate currency. Based on this decision, the importation of APIs for all under-licensed products (original brands and generics) and all OTC products, in addition to their intermediates for local API manufacturers, were switched to the Nima rate. Furthermore, those imported products for which one or more local suppliers were available, could only be imported, if allowed by IFDA, by Nima rate currency.

Table 1 presents the prices before and after executing this policy for a sample list of medicines. Repricing might occur more than once due to the devaluation of the Nima rate after the first pricing. So, the latest prices were considered for all items.

As summarized in table 1, the impact of this policy on the price of different types of products was different. This result could be explained by the mechanism of cost-plus pricing used by MOH for repricing local products and price negotiation with international suppliers (15). Since API is a smaller proportion of costs in local products versus imported or under-licensed drugs, they were less sensitive to variation of the currency rate if a cost-plus approach was used. For imported and under-licensed products, repricing was based on a reference pricing mechanism (comparing prices in Iran with prices in reference countries). Then CPT price cut discussions, so the new price could be driven by more factors than only currency rate.

Although this pilot experience could be beneficial to have a better view of the impact of this policy on price and access, it could only be easily generalized to the situation that subsidized currency allocation be abandoned for some products. Since fixed-rate currency elimination was implemented only for a limited list of products, hence some imported and under-licensed medicines had low-price local generic alternatives available in the market, and the others were non-essential OTC products; such pilot policy had fewer consequences for different stakeholders.

It is critical to be informed earlier about the challenges of different stakeholders and be fully prepared for such a significant change in the pharmaceutical system.

Affordability challenges for patients

Most reimbursed prescription drugs have a 70% introductory coverage rate in Iran. However, for some high-cost medicines, patients are supported with an extra 20% coverage (a total of 90%). The main concern of implementing this policy is how patients can afford this significant increase in their prescription cost when this 30% or 10% copayment becomes 2-6 times higher. This challenge would be more complex for those prescription drugs not already included in any essential reimbursement list (16). For some of these products, patients have already affordability; For instance, antidiabetics (i.e., DPP4 inhibitors, GLP1 receptor agonists, SGLT2 inhibitors), cardiovascular drugs (i.e., novel anticoagulants and new anti-hyperlipidemic agents), and new anti-cancers.

So, issues could become a more severe barrier to accessibility (17-19).

Resourcing challenge for insurance organizations

The role of insurance reimbursement for accessibility and protecting patients from intolerable out-of-pocket payments is crucial, especially for low-income households. There is a concern in insurance organizations if the government will allocate sufficient extra budget to them before implementing this new policy and will sustainably provide this extra budget in the future. As one solution, the government has to allocate the difference between the Nima rate and the subsidized rate to insurance organizations to cover new expenses. Nevertheless, this budget can only cover currently reimbursed products. An extra budget is required to cover the other imported or local products not already included in the list (20). Otherwise, the new prices could make a barrier to accessibility. Furthermore, as is displayed in figure 1, fluctuation in the Nima rate could also cause less predictability on the budget for

Products	Class	Former unit price	New price	Change (%)
Metformin	under licensed brand	3,000	13,700	350%
Clopidogrel	under licensed brand	20,600	116,800	466%
Tamsulosin	under licensed brand	29,000	84,400	190%
Solifenacin	under licensed brand	33,000	116,000	250%
Esomeprazole	under licensed generic	11,000	58,000	427%
Sertraline	under licensed generic	8,500	2,1500	150%
Azithromycin powder for suspension	imported brand	400,000	1,567,000	290%
Follitropin alpha	imported brand	8,530,000	38,590,000	350%
Valsartan	imported brand	27,100	88,200	225%
Bisoprolol	imported brand	8,800	42,480	380%
Cetirizine Syrup	Local OTC*	45,000	70,000	55%
Acetaminophen	Local OTC	1,350	2,500	46%
Acetaminophen drop	Local OTC	45,000	85,000	88%
Omeprazole	Local OTC	3,600	5,000	39%

Table1. Prices of a sample of medicines in Iran

Abbreviations: over-the-counter (OTC)

insurance companies, and it must be taken into consideration by the government.

Business sustainability challenges for local generic companies

Local pharmaceutical companies are worried about the timeline and mechanism of repricing after subsidy elimination from the currency of API importation. The main concern is that the government put all or part of this burden on the pharmaceutical industry through unfair pricing and suppression of their margins (21,22). A strict and unfair cost-plus approach in repricing could cause margin loss for local companies and put the sustainability of the whole local generic industry at risk (23). Furthermore, since subsidy elimination from the currency of APIs will significantly affect the required cash flow of local manufacturers, and considering the variability of the Nima rate, agility in the repricing by MOH is a crucial factor to avoid supply issues and financial loss, especially for low and medium-sized manufacturers.

Conclusion

Given the consequences of subsidized currency on pharmaceutical and healthcare systems, the government's decision to subsidy elimination from currency seems rational and defensible. However, all concerns of different stakeholders must be heard and addressed before the implantation of this policy. With a good budget raise for health insurance from subsidy elimination revenues (cross-subsidization) sources, the government should ensure that this policy will not burden any unaffordable cost or loss to either patients or the industry. In addition, agility in pricing, budgeting, and reimbursement is a critical success factor for MOH and IFDA to avoid harming stakeholders.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the ethical committee of the Tehran University of Medical Sciences (TUMS). All the participants accepted enrollment in the study orally and all of the data that were gathered was considered confidential.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declare no conflict of interest

Reference

[1] Cheraghali A. Trends in Iran pharmaceutical market. Iran J Pharm Res. 2017; 16(1):1-7.

[2] Zaboli P, Hashemi-Meshkini A, Varmaghani M, Gholami H, Vazirian I, Zekri HS, et al. Pharmaceutical laws and regulations in Iran: An overview. J Res Pharm Pract. 2016; 5(3):155-61. [DOI:10.4103/2279-042X.185709]

[3] Ashrafi Shahmirzadi N, Abdollahiasl A, Kebriaeezadeh A. Assessment of influential variables in the pricing of locally manufactured pharmaceuticals: Current challenging situation in Iran. Iran J Pharm Res. 2021; 20(1):283-95. [DOI:10.22037/ijpr.2020.112288.13662]

[4] Yousefi N, Moradi N, Dinarvand R, Ghiasi G, Inanloo H, Peiravian F. Policies to improve access to pharmaceutical products in shortage: The experience of Iran food and drug administration. Daru. 2019; 27(1):169-77. [DOI:10.1007/s40199-019-00259-2]

[5] Eghtesad Online. Iran gov't to continue supply of subsidized essential goods [Internet]. 2020 [updated October 2022]. Available from: Iran Gov't to Continue Supply of Subsidized Essential Goods (2020/09/28) Online available at: https://www.en.eghtesadonline.com/Section-iran-economy-67/33640-iran-gov-to-continue-supply-of-subsidized-essential-goods

[6] Central Bank of the Islamic Republic of Iran. Online available at: http://www.sanarate.ir/Default.aspx

[7] Setayesh S, Mackey TK. Addressing the impact of economic sanctions on Iranian drug shortages in the joint comprehensive plan of action: Promoting access to medicines and health diplomacy. Global Health. 2016; 12(1):31. [DOI:10.1186/s12992-016-0168-6]

[8] Cheraghali AM. Impacts of international sanctions on Iranian pharmaceutical market. Daru. 2013; 21(1):64. [DOI:10.1186/20082231-21-64]

[9] Kheirandish M, Varahrami V, Kebriaeezade A, Cheraghali AM. Impact of economic sanctions on access to noncommunicable diseases medicines in the Islamic Republic of Iran. East Mediterr Health J. 2018; 24(1):42-51. [DOI:10.26719/2018.24.1.42]

[10] Hosseini SA. Impact of sanctions on procurement of medicine and medical devices in Iran; A technical response. Arch Iran Med. 2013; 16(12):736-8.

[11] Jaberidoost M, Olfat L, Hosseini A, Kebriaeezadeh A, Abdollahi M, Alaeddini M, et al. Pharmaceutical supply chain risk assessment in Iran using analytic hierarchy process (AHP) and simple additive weighting (SAW) methods. J Pharm Policy Pract. 2015; 8(1):9. [DOI:10.1186/s40545-015-0029-3]

[12] Bastani P, Dehghan Z, Kashfi SM, Dorosti H, Mohammadpour M, Mehralian G. Challenge of politico-economic sanctions on pharmaceutical procurement in

Iran: A qualitative study. Iran J Med Sci. 2022; 47(2):152-61. [DOI:10.30476/IJMS.2021.89901.2078]

[13] Masoumi M, Ebadi Fard Azar F, RezaPour A, Mehrara M. Economic and non-economic determinants of Iranian pharmaceutical companies' financial performance: An empirical study. BMC Health Serv Res. 2019; 19(1):1011. [DOI:10.1186/s12913-019-4735-4]

[14] Masoomzadeh M, Shirafkan M. The effect of exchange rate on the Iran's pharmaceutical industry balance: Vector error correction approach. Journal Healthc Manage. 2017; 8(3):17-28.

[15] Ahmadiani S, Nikfar S. Challenges of access to medicine and the responsibility of pharmaceutical companies: A legal perspective. Daru. 2016; 24(1):13. [DOI:10.1186/s40199-016-0151-z]

[16] Zarif-Yeganeh M, Kargar M, Rashidian A, Jafarzadeh Kohneloo A, Gholami K. Out of pocket payment and affordability of medication for geriatric patients in Tehran, Iran. Iran J Public Health. 2019; 48(6):1124-32. [DOI:10.18502/ijph.v48i6.2924]

[17] Vasheghani Farahani A, Rasekh H, Najafi S, Rahimi F, Akbari M, SalehniaF,et al. Evaluationof affordabilityandimpoverishment effect of cardiovascular medicines in Iran. Iran J Pharm Sci. 2018; 14(2):65-74. [DOI:10.22034/IJPS.2018.33739]

[18] Varmaghani M,Hashemi-MeshkiniA,AbdollahiaslA,HeidariE, Zekri H-S, Yaghoubifard S, et al. An overview topharmaceuti-cal financing in Iran. J Pharmacoeconomics Pharm Manage. 2016; 2(1/2):45-9.

[19] Zarei L, Peymani P, Moradi N, Kheirandish M, Mirjalili M, Zare M. Affordability of medication therapy in diabetic patients: A scenar- io-based assessment in Iran's health system context. Int J Health Policy Manag. 2022; 11(4):443-52. [DOI:10.34172/ijhpm.2020.152]

[20] Delpasand M, Olyaaeemanesh A, Jaafaripooyan E, Abdollahiasl A, Davari M, Kazemi Karyani A. Eliciting the public preferences for pharmaceutical subsidy in Iran: A discrete choice experiment study. J Pharm Policy Pract. 2021; 14(1):59. [DOI:10.1186/s40545-021- 00345-4]

[21] Rahimi F, Rasekh HR, Abbasian E, Peiravian F. A new approach to pharmaceutical pricing based on patients' willingness to pay. Trop Med Int Health. 2018; 23(12):1326-31. [DOI:10.1111/tmi.13157]

[22] Ebadi Fardazar F, Sarabi Asiabar A, Safari H, Asgari M, Saber A, Ebadi Fard Azar AA. Policy analysis of Iranian pharmaceutical sector; A qualitative study. Risk Manag Healthc Policy. 2019; 12:199-208. [DOI:10.2147/RMHP.S209318]

[23] Hashemi-Meshkini A. Making the public health and industrial objectives balanced; The big challenge of Iran's food and drug organization. Iran J Public Health. 2014; 43(5):693-5.