



## **Making the Public Health and Industrial Objectives Balanced; the Big Challenge of Iran's Food and Drug Organization**

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### **Dear Editor-in-Chief**

Pharmaceutical industry is considered as a high profitable industry which could play a considerable role in local economies (1). In middle-income countries, development of this industry could also be a priority for governments because of supplying locally needed medicines at lower cost compared with importation. In spite of existing about 90 manufacturing companies participating in pharmaceutical production and many research-based pharmaceutical firms working on production of high-technology medicines, pharmaceutical industry and its market in Iran are relatively small compared with other sector. The recent financial sanction and limitation on international trade revealed the weaknesses of our domestic industry in meeting medical needs of society in political and international crisis (2). Empowering pharmaceutical industry therefore seems to be a necessity for economic, health and independency-following objectives and should be paid enough attention by government and Food and Drug Organization (FDO). On the other hand FDO and also ministry of health (MOH) are responsible for preparing conditions for achieving public health objectives. Reaching population health objectives could be managed by focusing on the functions of pharmaceutical system which are reflected in WHO framework for national drug policy (NDP): accessibility, quality, and rational use of medicines (3). In this situation, the Iran's Food and Drug Organization

(FDO) should be concerned about the both consumption (patients) and production (producers) sides by making proper policies and regulations. Some of these efforts in FDO seem to be in collision with each other and need to become balanced by an accurate approach (4). In this commentary we are going to discuss about these challenges in Iranian pharmaceutical system.

### ***Pricing of Pharmaceutical***

Making medicines affordable is one of the health objectives in pharmaceutical sector which is in contrast with industrial development goals. To improve affordability of medicines for population, policy makers in FDO have an effective measure: pricing. After 1979 Islamic revolution in Iran and implementation of "generic scheme" to ensure affordability and accessibility of medicines for all population, the price of all medicines has been setting by a committee in FDO using a "cost plus" approach (5). Although this pricing method has been relatively successful in achieving acceptable affordability for most of medicines (6), but it has always been criticized by manufacturers claiming that by this low level of prices they are not able to invest on R&D projects for production of innovative and higher technology medicines (7). The market evidences could be used to confirm these claims: as it is indicated by kebriee et al., the share of domestic produced medicines (by

value) from total pharmaceutical market has been dramatically diminishing (8) which could be as result of incapability of Iranian pharmaceutical companies in production of newer and mostly high priced medicines. In response to producers' requests, the FDO introduced "external reference pricing" in 2012 as the new pricing model of original brands and branded generic pharmaceuticals. In this method the price of medicines in five reference countries including Greece, Turkey, Spain, Saudi Arabia, and Aljazeera would be used as a reference for setting prices (9). An interesting point is that reference pricing has been used by many countries as a cost containment strategy but in Iran it is applied as a strategy for setting higher price.

As we discussed earlier, it is never easy to make a proper policy in this area meeting both industrial and public health objectives. If FDO prefers the past strategy in maintaining the prices at the lowest level it might be a threat for development of pharmaceutical industry and therefore long term accessibility to medicines as well, and if the industrial development approach be applied by FDO by setting higher prices, the affordability of medicines would be undermined.

### *Market expansion*

Another challenge is that for development of pharmaceutical industry in Iran we might need to allow more molecules- especially high price medicines- to be included in national drug formulary. There are many economic and ethical controversies around this issue that as a policy maker we need to make our mind about them. According to Iran's national drug policy (NDP) all medicines must have been registered in national drug list (NDL) before being available in the market by either domestic production or importation (10). In the registration process the efficacy, safety, quality and cost-effectiveness are considered by an authorized committee in FDO. In spite of cost controlling strategies obtained by MOH and also slow population growth rate, Iran's pharmaceutical market (value) has been experiencing double digit annual growth rates in recent decade (approximately 26% annually during 2001-2012).

This fact could be used to consider Iran as a pharmerging market. Availability of more medicines, increasing tends to use imported original brands and supplements are from probable reasons for this significant growth. It seems that making more medicines- including high technology and high price medicines- available in the market could lead to meeting industrial development goals as well as it is the «patients' right» from an ethical perspective. On the other side, because it is not possible to cover these medicines by health insurance and providing those to all in need population at an affordable price, it would lead to increase in out of pocket expenditure that is not desirable. Some argues could also be raised about the feasibility of this approach because there are too many new medicines and dosage forms in the world which is not feasible to provide all of them in the market, considering our limited national income as a middle income country.

The health system and also FDO have to be careful about their real mission that is ensuring the accessibility of quality and rational medicines with the aim of maximizing population health level. Technical and allocative efficiency of new medicines are important issues from economic perspective. The invisible hands of market do not necessarily allocate resources to the population health priorities, given the existed failure in healthcare market. The burden of disease studies and QALY league tables are developed for this aim. Another issue is that considering the current infrastructure of FDO for monitoring different aspects of market including quality of medicines, rational use of medicines and pharmacovigilance, it is not possible to let the market enlarge by this arbitrary pattern.

### *Supporting domestic industry*

Focusing on the capabilities of domestic pharmaceutical manufacturers has always been paid attention by government during the last decades. Variety of policies have been taken to approach this goal including prohibition of the import of similar products, tariff policies for making imported products uncompetitive, excluding imported product from reimbursement list when the

domestic one become available, etc. These policies are sometimes against health policies because these domestic generic medicines might be not as effective as the original products are, from patients' perspective. Although it is an economic saving for government, but the different quality of imported and domestic products could hurt patients and their family when the former original products are not available or affordable anymore. Another conflict between health goals and industrial development objectives rises when a third foreign generic enters the market with lower price and FDO prohibits its importation to support Iranian manufacturer. It could be a kind of cross subsidization in favor of domestic companies but from patients and third party payers' pocket that is not fair. So what should FDO do and which policy shall be followed regarding domestic industry to meet both economic and ethical rationales?!

## Conclusion

In any policy making for pharmaceutical sector, both short term and long term impacts have to be taken into consideration. A very strict regulatory approach on above mentioned issues could however ensure the affordability, quality and cost containment goals, but on the other hand may castrate the industries and obstruct it to enter newer areas in future; therefore the accessibility in future would be negatively affected. Making balance between health and industrial objectives should not also be interpreted as supporting the both sides' interests in a so-so way, as it has been in recent decades. The food and drug organization should reach a documented agreement with industry including a time table, in which the intermediate and long term goals for meeting international qualification standards is stated. The level of regulatory enforcements in each step has to be clarified in this agreement. The incentives and motivations by FDO including price concession should also be redesigned considering those goals. By this way our industry may be directed in a developing and improving way in term of international acceptability and reputation, competitiveness and innovation. In such situation, the goal of

achieving both industrial and public health objectives would be more sustainable.

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