*Letter to the Editor*

# Vaccine production industry in Iran and the necessity for policy coherence

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## INTRODUCTION

Bio-products were among the first high-tech industrial productions in Iran which have succeeded to develop various innovations in the first half of their one-decade operation. In spite of the past successes, improved scientific capabilities of the country and even few success stories in export, studying of the current situation indicates that there are bottlenecks that have led this industry to fail in achieving its national objectives of the "Resilient Economy" and "Knowledge-Based Economy Program".

The beginning of the vaccine production in the country dates back to the establishment of the Pasteur Institute of Iran in 1921 [1]. For 50 years, various product innovations (manufacture of new products), process innovations (producing by new processes), and organizational innovations (establishment of spin-off institutions) occurred on an acceptable pace. Many vaccines were massively produced and were added to the mandatory immunization program of the country, although by less-developed methods of the time. An analysis of innovation policy for developing these vaccines at that time can be investigated; however, it should be borne in mind that practically, until the beginning of the 1990's, no new domestic vaccine was added to the mandatory immunization program of the country. At a historical opportunity, recombinant Hepatitis B vaccine was added to the program which its consequences and interests for the country could be served as an example [2, 3].

The first half of the vaccine manufacturing activities in Iran can be attributed to the innovation accumulation and path dependency that caused a lock-in to the old technologies. During this time, success in production of the vaccines was achieved by traditional methods such as live attenuated and inactivated microorganisms, as well as toxoid or plasma derived products which were mostly proved to be unsafe for human consumption by emergence of later technologic advancements [4]. Various studies have been conducted by some local entities or foreign researchers with the subject of identifying bottlenecks in biotechnology or analysis of technological capabilities in this area [5] and the necessity of trouble-shooting of commercialization processes and transforming the research to product were mentioned [6].

Three sets of measures, namely improving the national innovation system, elevating the local technological capabilities and stimulating of governmental actions (by granting tax incentives or supporting R&D activities) were highlighted as well [7]. Based on a study entitled "identifying key innovation challenges in the health biotechnological entities", redesigning of sectoral system of innovation and social capabilities (consisted of government role and technological capabilities) were addressed [8]. Metelka (2008) has also pointed out to a necessary for shifting from dependence on oil revenues to innovative products in the biotechnology sector [9]. Means to promote technological capabilities in order to produce innovative products were investigated in separate studies by the Ministry of Science, Research and Technology and the Presidential Scientific Deputy in Iran [10, 11]. The Iranian Ministry of Health, Treatment, and Medical Education has also developed a series of intensive reports on situation of health and medicines in past decades, as well as the biotechnology master plan of the country [12, 13].

It should be noted that the history of pharmaceutical industry in the country and the use of chemical raw materials in medicine production dates back to the mid-1950s (approximately 35 years after the first vaccine production). Before the Islamic revolution, domestic companies in Iran did not play an active role in producing innovative products and a few foreign companies which contributed to the establishment of pharmaceutical plants, produced merely products under a parent company brand and not new products. Since the physical infrastructures for the development of vaccines were mainly provided in the country's pharmaceuticals industry, it would be crucial to carefully examine the preparedness of the infrastructure, as well as the characteristics and limitations of the industry. Reviewing the existing challenges requires knowledge of the institutional structure of this industry. Hence, it would be advisable to appoint active agencies in this sector which may contribute to creation of the required behavioral and operational characteristics.

Studying the institutional structure of the pharmaceutical industry in Iran reflects the existence of a complex structure with numerous institutions which complicate the communication and interaction between the components [14]. In this structure, the role of the Ministry of Health, Treatment and Medical Education in all

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aspects of policy-making is a maximum while the role of the Ministry of Industry, Mining and Trade in implementing the country's industrial development program is a minimal. Hence, an appropriate adjustment to the current roles will be an opportunity to improve the situation [15]. It seems that with a different canonical point in the focus of the industrial strategic plan as compared to the health system development plan (*i.e.* adopting the supply side policies instead of demand side), the plans must be redesigned and more coherent policies in this area should be implemented. The promotion of the country's institutions in the pyramid of the technological capabilities will be one of the other operational requirements in this regard.

There are various policy tools and leverages in this regard; however, making priorities for the production of advantageous products, imposing investment policies instead of broking and merchandizing cheap imports and economic reorganization of production and import, can make a balance between the business policies/export development with industrial policies/upgrading industrial productions. The vast majority of educated human resources in the country and their employment potentials are significant advantages for the development of this industry and the rearrangement of different resources in this domain will accelerate the required improvements.

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