



Technological catch-up in the biopharmaceutical sector: Evidence from Iran

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ABSTRACT

This paper addresses the market and technological capabilities required for technological catch-up in the biopharmaceutical sector using a multi-case study method. The paper reveals that the firms that are catching up in biopharmaceuticals first developed their production capabilities (including API production, formulation and obtaining health approvals), then entered the process innovation. Iranian companies have locally re-produced existing products in the market in exact accordance with global standards, and then entered into the introduction of new strains by intensifying their R&D efforts. The paper observes that the existence of strong R&D efforts from the early stages is a prerequisite for technological growth. It also argues that assimilated migratory knowledge can not only complement indigenous efforts, but also stimulate further technological capability-building efforts by local firms. The paper shows that technological development in the Iranian biopharmaceutical industry was firstly geared towards the home market, which we refer to as the 'test-bed', before entering into international markets. A key strategic point here is that, despite the maximum use of domestic market capacity, our study considers it necessary to try to enter international markets. Therefore, presence in these markets and the development of capabilities in the biopharmaceutical industry are two blades of a pair of scissors.

1. Introduction

Biopharmaceuticals as a science-based sector [1] refers to drugs produced using biotechnology. Despite the dominance of advanced countries in the biopharmaceutical market, a number of developing countries have made serious efforts to enter the competition, and have focused on biosimilars. Biosimilars are almost identical copies of biopharmaceuticals produced by companies other than the original producer. After the expiry of the original producer's patent, other companies are allowed to produce the biologics. Unlike small molecules, the production of biosimilars is not easy, as in many cases a minor change in the final molecule could lead to a different safety and efficacy profile [2].

Biopharmaceuticals such as Interferon beta, factor VII, and factor VIII have been produced for the second time in Iran after the country of origin. In terms of the number of biopharmaceuticals, Iran is in a better position than competing countries such as India and China [3].

Currently, in the field of biosimilar production, Iran is ranked first in the region and fifth in Asia [4]. However, there are still many problems in the technological catch-up of biopharmaceutical firms in Iran, including the low value of bio-pharma exports [5] and the weakness of Iranian firms in the field of developing new biopharmaceuticals. Such problems denote the existence of a technological capability gap among Iranian firms and the worldwide technological frontiers. In the literature, filling technological gaps is often referred to as technological catch-up [6]. However, there is no unique process for technological catch-up [7]. In fact, the existing literature on catch-up is more oriented towards Gerschenkron's approach [8] which emphasizes that every country should find its own prerequisites for catching-up [9], and thus, based on this approach, each country has its own specific prerequisites. The process of technological catch-up depends on the efficiency of the indigenous innovation system [10] and indigenous R&D efforts [11] on one hand, and on mechanisms to learn through overseas technology transfer on the other [12,13]. A number of recent studies have focused on the important

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