

## Chapter 86

# Biopharma Innovation Models for Gulf Region in the Era of Globalisation

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### ABSTRACT

*Biopharmaceutical is the most upcoming segment of the pharmaceutical industry as the use of biotechnology has the potential to provide cures for the most life threatening and difficult ailments. At the same time for biopharma innovation, factors such as increasing costs, high continuous funding, and risk funding are of increasing concern for the emerging economies. This chapter measures the strength of biopharma innovation indicators in Gulf Cooperation Council (GCC) and explores the potential biopharma innovation models for gulf countries.*

### INTRODUCTION

The Gulf Cooperation Council (GCC) was founded in May 1981 by the heads of state of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates. GCC identified economic cooperation and integration as an integral part of its agenda (Abdulla, 2010). The Unified Economic Agreement (UEA), ratified in November of the same year, foresaw a gradual convergence toward an integrated economic bloc marked by harmonized legal, social, and economic systems and coordinated external commercial policies and trade relations. It also called for coordinating industrial policies and promoting joint projects to coordinate value chains of production and link transportation networks (World Bank, 2010).

All six GCC countries are members of WTO and committed to product patent system for biopharma innovation (see Table 2). Product patent system prohibits generic innovation of patented biopharma drugs and such commitment, which is associated with the cost skill and improved intellectual property property (Grabowski, 1986).

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In the old model of generic biopharma drug innovation, a biopharmaceutical company retained the entire drug discovery and clinical development process as that was simple and less expensive and without any risk, gave way to “go-it-alone” model (Kureishi, 2012).

Since enhanced innovations capabilities in the emerging markets the associated costs arbitrage and improved IP protection regime. TRIPs agreement disallowed generic manufacturing of patented drugs due to the effect of which product innovation had to be adopted by all the member countries of WTO (Kureishi, 2012). This in itself is a paradigm shift.

The diverse economic conditions, business practices and varying domestic manufacturing capabilities coupled with shifting disease profiles varying regulatory environment for the gulf countries is similar to developing countries such as BRIC. The same gave way to the “wheel-and-spoke” model of international partnerships and strategic alliances in BRIC (WHO and WTO, 2002). The model of international partnering has emerged as an important model of innovation as it was no longer suffice to develop an expensive new medicine all alone by developing countries as novel biopharma innovation is a complex, technical science and very expensive.

This paper examines the processes of catching up and the tentative leapfrog processes for biopharma innovation in gulf countries. The paper first measures the strength of GCC biopharma innovation and then explores the best model for the biopharma drugs innovation in GCC countries.

## **LITERATURE SURVEY**

Innovation has been long recognized as a significant source of national economic growth (Shupeter, 1942). It is a powerful element in the economic success of both developed and developing countries.

Innovation is the process by which firms master and get into the practice product design and manufacturing processes that are new to them whether or not they are new to the universe, or even nation (Nelson, 1993).

Each sector has different requirements for innovation and requires different institutional set up. Biotechnology innovation systems process certain characteristics that distinguish them from those of other sectors. Biopharma innovation is a complex science which needs greater scientific skills and knowledge and at each stage of biopharma innovation learning is required and such learning can come from different channels (Oyeyinka & Sampath 2006).

Biopharma innovation is capital intensive and requires high capital investment, long payback period. There is a long and risky gestation period before and an even longer payback period in biopharma innovation. Developing a new medicine is a long and complex process, with risk of failure at each step (Long and Works, 2013). It has been estimated that the average cost to yield a single FDA-approved drug is approximately \$1.2 billion (including the cost of development failures), and the entire research and development and FDA approval process time is between 10 and 15 years (Long & Works, 2013).

Biopharma drug innovation is staged in three successive phases.

Firstly, discovery and preclinical testing phase in which prior to testing in humans, a new drug candidate is considered to be a preclinical or discovery (rather than development) project.

The process of drug development is notoriously leaky on an average one drug emerges from 10,000 drugs targets and the FDA only approves 15% of compound that make it to the preclinical phase of testing (Madhani, 2007). Therefore biopharma innovation requires high continuous risk funding and need risk

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