Iranian Journal of Biomedical Law and Ethics

Regulatory Challenges in Pharmaceutical Industry: An Economic Analysis

Mojtaba Ghasemi *

Assistant Professor of Law and Economics, Economic Law Department, Shahid Beheshti Faculty of Law, Tehran, Iran

Original Article

Received: Apr. 7, 2019 Accepted: Jun. 12, 2019

Keywords:
Monopoly, Pharmaceutical industry, Pharmaceutical innovation, Regulation,

To cite this article:
Ghasemi M. Regulatory Challenges in Pharmaceutical Industry: An Economic Analysis. Iran J Biomed Law Ethics. 2019; 1(1):60-71.

Abstract

Background: The importance of pharmaceutical industry in improving the quality of human life and the specific features of the cost structure of pharmaceutical agencies mandates proper regulation in this industry. However, the complexity of this process has made the regulation of this industry multifaceted, complex, and sometimes difficult for policymakers. This research seeks to illustrate the typical challenges and the behavioral patterns of various countries facing such issues.

Methods: This research is based on the study of regulatory models in different countries.

Results: The high cost of research and development of new drugs has culminated in perceiving the inescapable necessity to provide the legal context for supporting drug innovations, so that in the absence of these contexts to create a temporary monopoly in the market for a new drug agency, there will be no incentive to invest in research and development of new drugs.But the creation of monopoly will be accompanied by imposing prices higher than competitive prices with increasing dead loss and reduced social welfare. In such condition, the policy maker regulates the prices for reducing the pharmaceutical costs in both private and public sector in order to decrease the dead loss and control the legal market power of innovative pharmaceutical agencies.

Conclusion: The regulation in pharmaceutical industry can be regarded as the art of establishing a balance and trade-off between these forces. American policy makers in this field have held innovation in high regards in comparison to their European, Canadian and Japanese counterparts, which has led the country to be the vanguard in pharmaceutical innovation.

* **Corresponding author:** Mojtaba Ghasemi, Tel/Fax: +98 21 29901761, Email: Mojtaba_ghasemi@sbu.ac.ir