Chapter 8

The Interaction of Pharmaceutical Regulations in Saudi Arabia With the Presence of FDI: Facilitating FDI in Saudi Pharmaceutical Industry

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ABSTRACT

Recent literature on pharmaceutical regulations focuses on the apparently increasing scope for intimate relationships between the regulation framework and FDI opportunities in the pharmaceutical industry. This chapter deals with these interactions within the context of the Kingdom of Saudi Arabia (KSA). In 2015, Saudi Arabia was the largest market in the Middle East for drug companies and has one of the most sophisticated healthcare systems in the region. Yet, the Saudi drug regulatory regime have been criticized for having ambiguous procedures from both domestic and foreign companies. In addition, many international agreements have been signed by the Saudi government to encourage and protect foreign direct investment (FDI) in different sectors including the pharmaceutical industry. This research pursued to discover whether the international regulatory regime, based on the theoretical principles of free trade and applied to the international trade relations of KSA, interacts in any manner with the pharmaceutical industry’s trends.

INTRODUCTION

The Kingdom of Saudi Arabia (KSA) identified the importance of Foreign Direct Investment (FDI) to develop the country and grow the economy. As a result, many international agreements have been signed by the Saudi government to encourage and protect foreign investment. In early 1975, the Saudi government, along with the United States, signed an agreement on protection and investment guarantees...
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(Shoult & Anwar, 2009). KSA then ratified many bilateral investment treaties with different states such as Austria (2001), Belgium and Luxembourg (2001), China (1996), Egypt (1990), France (2002), Germany (1996), India (2006), Italy (1996), Malaysia (2000), Spain (2006), Philippines (1994), Turkey (2006), and Switzerland (2006) (ICSID, 2015). As a result, the 1996 accession of Saudi Arabia to the World Trade Organization (WTO) promoted the importance of international trade through specific agreements, including the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and service agreements through the Government Procurement Agreement (GPA) (World Trade Organization, 2005). Through this spectrum of arrangements, the Saudi government wished to improve public services and develop the country across different sectors.

This chapter seeks to ascertain whether the international regulatory regime, based on the theoretical principles of free trade and applied to the international trade relations of KSA, interacts with the pharmaceutical industry’s emerging trends in KSA. The chapter identifies a knowledge gap in academic research literature, pointing to the need to prove or disprove the impact of the application of international investment regimes and their respective national regulatory implementation upon sectoral integration and, in particular, the pharmaceutical sector.

BACKGROUND

While medications are likely to be as old as humankind, the need to guarantee their quality has developed gradually. The antiquated Egyptians, Old Indians, Greeks, and Muslims dedicated considerable effort to ensuring the use of safe and effective medication, and their advanced efforts paved the way for later medicinal traditions. However, Rägo and Santoso (2008) referred to two noteworthy disasters that globally reshaped the WHO administrative framework.

Firstly, in 1937, more than 100 individuals in the USA died of diethylene glycol poisoning as the chemical was used as a solvent without any safety testing (Ballentine, 2010). This prompted the 1938 establishment of the Federal Food, Drug, and Cosmetic Act with the premarket warning necessity for new medications. The second disaster, more than any other in history to impact the advancement of medication regulation, was the thalidomide debacle (Fintel, Samaras & Carias, 2009). Thalidomide was a calming and trancelike substance that was first promoted in Western Germany in 1956. During the period between 1958 and 1960, it was made available in 46 countries. Following its maternal use during pregnancy, some 10,000 infants were born with phocomelia and other deformities (Fintel et al., 2009). These medical disasters played a key role in forming stringent medication and pharmaceutical regulation frameworks worldwide.

In general, health indicators of a country directly link to the growth of the country, which makes the part of pharmaceuticals more prominent on different international schemas. For effectual regulation of contributing factors, the pharmaceutical governing bodies have indicated selective structure indications. These can be responsible for arranging different functions in a positive manner. However, the foreign investments generally in any country, motivated by the flexible systems and protection policies. Accordingly, these systems provide mechanisms for committing to the foreign investors that their assets will be treated well. Thus, they are able to reassure the investors and increase the amount of investments (Al-Khalifa, 2010).

International trade agreements, such as the General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO), focus on FDI as one of the fundamental market-entry in the pharma-