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A study based on the perspective of the healthcare industry on the contribution of the medical device market and its significant growth to the Chinese economy

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Abstract

It's true that there's a rising interest in investing in China, but the medical device industry has been slow to expand. Despite this, the sector is gaining in significance as more people realize that investing in the health technology field, in comparison to a literature study, several papers give important information about China's medical device industry and investment climate. Investment in medical device technology and market is a topic that is under-researched. Foreign investment theories are used to derive the technology investment theories. Since the Chinese government pays more attention to healthcare than ever before, appropriate rules on medical device investment will become increasingly important for helping those that conduct business in the region. Business research in the future will increasingly focus on medical device investments. The medical device laws, notably the new Chinese medical device regulations, which came into force in 2014, receive minimal attention.

That's why we're here to help you bridge that gap with our proposal, which aims to disclose the major drivers of the Chinese medical device industry, determines the viability of investments, and gives some insights on Investors interested in joining the Chinese medical device industry might benefit from a comparison of the old and new medical device laws. Location quotient is used for the first time in the medical device industry study. Despite the fact that the Chinese medical device market is one of the most promising industries in the world, this study provides a large amount of significant materials”

Keyword: Medical Device Industry, Investment Policies, Stakeholders

INTRODUCTION

Although international investment in China has increased since Beijing opened its doors to the globe, the medical equipment industry has received little attention. The worldwide medical device industry is one of the most lucrative sectors of the global economy, according to the

World Bank. The Chinese medical device industry has grown significantly in recent years, and is now the world's second-largest market.

To help with medical device market investment and regional economic growth in China, this proposal aims to examine the new rules for medical devices that came into effect in 2014. It also makes a clear statement about the changing medical device regulations in China, which came into force in 2014. Investment theory and medical device market development are proposed together in this study.

Literature Review

To better understand the motivations and drivers of foreign direct investment (FDI) from advanced industrialised nations, academics began studying multinational corporations' (MNCs) investments in the 1960s from various viewpoints and at various levels. Some of the most well-known FDI ideas had their origins in that period.

Foreign investors, according to Hymer, have some type of proprietary or monopolistic advantages that local businesses do not have. It is essential that these advantages be based on economies of scale or superior technology or marketing, management, or financial expertise FDI occurred as a result of product and factor market instabilities. With Hymer's study (1976) of foreign investment as optimization by the firm, we've achieved significant strides. In spite of this, the monopolistic advantages argument has several flaws. When he was doing his investigation, he only looked at the powerful

Klug (2006) argues that this monopoly theory only partially explains foreign direct investment. When a company invests abroad, it does so to take advantage of current benefits and to seek out further advantages, such as access to know-how or resources. Also, the monopolistic hypothesis explains why firms operate in foreign markets but does not explain why a subsidiary is more profitable than exporting.This is the notion of product life cycle that Vernon proposed in 1966. Entrepreneurs' awareness and response to opportunities, in Vernon's perspective, are a consequence of the ease of communication, which, in turn, depends on geographical closeness. Market-specific manufacturers are more likely to be aware of the potential for bringing new goods to their market than producers in other markets.It wasn't until 1980 that Michael Porter broadened the principles of PLC. According to Porter, an industry's life cycle is divided into four stages: introduction, growth, maturation, and death.To analyse the impact of industrial evolution, Hill and Jones developed a model of the industry life cycle. 5 different industry settings are included in the model: (1) an embryonic, (2) a growth, (3) a shakeout and (4) a mature.

Statement of the Problem

Thirty years of fast development have been enjoyed by China's economy since its major reforms and opening-up policies were implemented. In order to attract foreign investment, China's reform represents a major transformation and makeover of the country's value system, policy making, institutional infrastructure, and socio-economic structure. Chine provides long-term growth prospects that are no longer available in developed economies that are saturated

and extremely competitive. China's consumer market is large and growing rapidly, which makes it appealing to international investors.

In terms of technological sophistication, the medical device business is one of the fastest expanding sectors in the world.... The degree of a country's manufacturing and technological sector is reflected in the medical device industry. As a result, China's government encourages the growth of medical equipment manufacturing. medical device market size continues to expand at a quick pace in China, with a recent growth rate of 23%; in 2011, total production value was around 688,420 million yuan (RMB)

Objective of the Study

- To provide a background on the Chinese healthcare system, reforms and changing regulatory environment to describe the current situation of the Chinese medical device market

Research Questions

- What is the impact of the healthcare system, reforms and changing regulatory environment on the Chinese medical device market?

RESEARCH METHODOLOGY

The research methods such as: regression analysis; location quotient is to be used which will reveal the Chinese medical device market status, will provide suggestions for investors who are interested in entering the Chinese market. Investors or companies who want to enter the Chinese market need to understand the regulatory environment, comparison of the medical device regulations with the US and EU regulations provide investors with a clear understanding of the Chinese medical device regulatory regime.

RESEARCH DESIGN

The proposed study introduces location quotient method to assess which area is the best region for medical device investment in China. The location quotient and market share matrix will reveal the best investment regions. It would be the first time that the location quotient method will be introduced into the medical device market study, which may provide guidance for the study of medical device market in other countries or regions. The study will also provide SWOT analysis of the Chinese medical device market and analysis of the Chinese regional market competitiveness

Data Analysis

Regulation of medical equipment is handled differently in the United States, the European Union, and China. Here, we'll examine the similarities and differences between the United States, the European Union, and China in terms of registration, categorization, premarket, and post market restrictions.

However, only manufacturers can register medical devices in China; if the devices are imported, their Chinese representatives must register them. The Food and Drug Administration (FDA) in the United States is open to all firms associated to medical devices for all medical

devices (Class I, II, and III). Similar to the Food and Drug Administration in the United States, the European Union has a system for registering medical devices. Medical device makers and allied businesses must register their products with the appropriate regulatory bodies.
U.S. Food and Drug Administration (FDA) centralized registration system ensures
criterion for evaluation A Class I device is considered to have a low risk and is thus subject to merely general controls; Class II devices are considered to have a medium risk and so require specific controls, while Class III devices are considered to have a high risk and hence cannot be registered with FDA. The 510(k) premarket notification process is often necessary for the majority of these devices before they may reach the market; high-risk, all Class III devices must go through the PMA, a formal evaluation procedure, and adhere to stringent regulations. EU's method of registration relies on a network of 7422 independent agencies called "Notified Bodies," in contrast to the FDA's centralized registration process. The EU's decentralized framework allows its Competent Authorities to operate efficiently and quickly examine applications compared to the FDA. There are, of course, drawbacks to a decentralized system. Levels vary greatly amongst Member States. Due to the rapid pace of technological advancement, it is difficult to guarantee that the staff or reviewers of the Notified Bodies have consistent knowledge, cognitive level, and inspection standards, which can lead to inconsistency in the process for approving similarly categorized medical devices among Notified Bodies [178]. To get their products certified, manufacturers can pick from among several different Notified Bodies, and they are not required to use the Notified Body with the most stringent evaluation standards.
Thus, they may determine the most expedient path to obtaining the CE mark [179] and the subsequent market acceptance [134]. Additionally, decentralization hinders the collecting of patient safety data, making it harder to spot possible issues and identify adverse occurrences [180].
In China, the registration system follows a hierarchical structure. In theory, the processing speed and efficiency of this system should be very fast and very high, respectively. There are 31 provincial, 433 municipal, and 1,936 county agencies that make up the CFDA's network of local regulatory bodies. There are 16 technical organizations at the state level, 122 province organizations, 373 municipal organizations, and 436 county organizations [181]. Those organizations (above the county level) with the authority to grant registration certificates for medical devices.

CONCLUSION

Since China opened its doors to the world, the country has attracted a rising amount of international investment. However, although many academics have focused on foreign investment in well-known fields, very little has been written on investment in China's medical equipment business. As one of the most lucrative sectors of the global economy, the medical device market continues to expand. With the country's rising purchasing power, China's medical equipment market has exploded in recent years and is now the world's second largest.

The proposed research intends to extract theory on FDI and provide a synopsis of the current state of the international and Chinese medical device markets. The potential of the medical

device market can be seen via an analysis of the current state of the market in China from the point of view of the healthcare sector and the key market factors that influence it.

LIMITATIONS OF THE STUDY

Numerous shortcomings should be noted regarding the approach, topic recruiting, and data collection.

This research, like many others, has certain limitations. Three explanatory factors made the sample size too small for regression analysis. Another important market factor that is difficult to measure using regression analysis is illness and policy. Besides the ownership rate of medical equipment and the prevalence of illnesses, the market drivers include additional factors. For example, only 1996, 1998, 2000, 2001, and 2004 were recorded for the quantity and proportion of medical gadgets at China's leading hospitals. There is no easy way to find out how many medical equipment were installed in Chinese hospitals after 2004 using the Chinese Ministry of Health's database. Other limitations can also be identified. The sample size is insufficient for statistical analysis. This information is also limited to the years 2011 and 2012. As a result, LQ may not accurately reflect the real degree of specialisation. Ningxia has a high LQ yet appears to be an undeveloped region. However, the LQ technique isn't the only option to measure an industrial professional's level. It is possible to analyse the market using approaches such as net present value (NPV) and real options [208]. A reduction in LQ error is achieved by combining this approach with the MS method, making the results of this research more trustworthy. These limitations notwithstanding, the conclusions of this study give some recommendations for investors who wish to enter the Chinese medical equipment industry.

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