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European Journal of Management and Business Economics





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#### ARTICLE INFO

Article history: Received 15 March 2015 Accepted 7 October 2015 Available online 17 December 2015

JEL classification: M16

Keywords: Pharmaceutical SMEs export Resources view based Institutional theory Multivariate methodology

#### Introduction

In recent years, companies have experienced a complex, dynamic environment. Permanent changes in customers' needs and preferences have appeared, new products have been introduced, competition has increased, uncertainty has become marked at the time of decision making, and new agents have appeared. The pharmaceutical sector is no stranger to this situation: it is a sector in which it is very difficult to predict the behavior of the environment. For this reason, companies have been forced to work intensively to keep up with the market's changes. One of the pharmaceutical sector's primary characteristics is that its environment contains a large number of agents and components, and new products have been developed as a result of technological progress (Rivera, Avila, López, Garzón, & Flores, 2010).

The pharmaceutical sector is also characterized by its requirement of large investments in research and development (R&D), its products' high renewal and differentiation rates, and the generation

#### ABSTRACT

In recent years, companies in the pharmaceutical industry have been confronted with a turbulent environment characterized by dynamism, complexity and uncertainty. To cope with these changes and achieve improved performance, these companies must generate the ability to make appropriate changes in their organizations. For that reason, we use a quantitative methodology linear regression model to investigate the multilevel resources, capacities and institutional aspects that influence the level of exports of companies in Colombia's pharmaceutical sector. The main findings that are highlighted include the significant role of the variables of supply costs, logistics, preview experience and the institutional environment in improving exports in the sector.

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of benefits for companies and patients, the latter through reduced treatment costs and hospitalization days.

These characteristics encourage interactions between supply and demand in a market environment that differs from other industries. On the consumer side, the participation of various agents in the acquisition of goods is noteworthy; on the retailer side, the market power that companies acquire through the establishment of legal monopolies, brand loyalty, and adverse selection is noteworthy. These features allow us to place the pharmaceutical industry in a complex market scenario with multiple failures, creating incentives for state intervention.

In Colombia, the pharmaceutical market features strong interactions between private producers and public-sector distributors because of the existence of a list of generic and essential medicines to which those affiliated with social security are entitled, multiple distribution channels, and a price regulation and market concentration policy that often ignores the particularities of the sector. In addition, the health care reform contained in Law 100 of 1993 modified some of the sector's rules without considering the impact of that change on the overall performance and achievement of the healthcare system.

Sixty-seven percent of the Colombian pharmaceutical sector is in the hands of national companies; international laboratories compose the remaining 33% (ANDI, 2014). The trade balance

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http://dx.doi.org/10.1016/j.redee.2015.10.004

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of the Colombian pharmaceutical market is characterized by a greater number of imports than exports because the sector relies on imports from raw materials to finished products. Therefore, Colombia's pharmaceutical sector has very strong international dynamics that are determined by this combination of exports and imports. Colombian companies in this sector must compete with foreign companies. To do so, Colombian companies attempt to cut costs by buying foreign raw materials and supplies.

In this paper, we present the dynamics of the Colombian pharmaceutical sector's export activity. Factors that Colombian companies confront in the pharmaceutical sector are identified, along with their influence in export growth. In addition, we identify resources, capabilities and institutional factors that influence the growth of exports in a quantitative study that achieves a close approximation of the sector's reality. According to the results of the Joint Survey of Industrial Opinions (Encuesta de Opinión Industrial Conjunta-EOIC) conducted by the National Businessmen's Association of Colombia (Asociación Nacional de Empresarios de Colombia-ANDI) among businessmen in the pharmaceutical sector during the third quarter of 2013, numerous problems affect the Colombian pharmaceutical sector. Based on that survey, this study aims to verify whether variables such as productive resources, logistic capacity, previous experience on the international market and the institutional environment influence the sector's export growth. Our hypotheses are supported by resource-based theory. Moreover, institutional theory and the regulatory function of institutions are incorporated as the theoretical basis to support our hypothesis that the institutional environment affects the growth of the sector's exports. This study finds that input costs, logistic costs, previous experience and institutional environment affect the Colombian pharmaceutical sector's exports, highlighting the sector's high dependence on imports of raw materials because of the advantages that other countries offer with respect to prices, leading to the domestic industry's lack of initiative to increase domestic production of raw materials.

#### The context of the Colombian pharmaceutical sector

The Colombian pharmaceutical industry is made up of national companies, which control 67% of the domestic market, with international laboratories or subsidiaries controlling the remainder. Nevertheless, these foreign industries have developed production and distribution strategies that have enabled them to reach regions that previously had a minimal industry presence, resulting in increased productive activity.

The Colombian pharmaceutical market is characterized by strong interaction between private producers and public-sector distributors; there is a list of generic and essential medicines to which those affiliated with social security are entitled; there are only two distribution channels, and there is a price-regulation and market-concentration policy that often ignores the sector's particularities (SENA, 2008).

In 1993, the National Health System (Sistema Nacional de Salud) was restructured, creating the General System of Social Security in Health (Sistema General de Seguridad Social en Salud) and incorporating two instruments of drug policy: (1) essential drugs, as the mechanism to select the best drugs for the most common diseases; and (2) generic drugs, as the mechanism to introduce market competition. Therefore, the Colombian drug market is composed of two markets derived from the two drug-distribution channels: (1) institutional, for the members of the social security system; and (2) private. In both cases, there are critical differences in the distribution channels to the final consumer and there are substitution possibilities.

The Colombian pharmaceutical industry has undergone major changes in recent years, particularly after the issuance of Law 100 of 1993. The social-security policy with respect to health that contains this law has increased demand in the sector, especially for generics. This law also defined the role of state regulators in drug-related issues. One of the highest-impact standards for producers is Decree 549 of 2001, which implements Manufacturing Best Practices (Buenas Prácticas de Manufactura—BPM) in all of the laboratories in Colombia, thus enabling the sector to be more competitive and productive (Bustamante, 2007).

Overall, the market for drugs has various classification criteria—e.g., mode of sale, type of products, therapeutic class, and place of manufacture. In Colombia, the pharmaceutical industry is very heterogeneous. It includes the production and import of semi-elaborated pharmaceutical goods for final consumption by humans and animals. The industry directs a very small percentage of its expenditure to R&D expenses both because foreign companies perform their research abroad and because domestic companies can be considered small and medium sized; they do not have enough resources to develop research programs to create new drugs (Bustamante, 2007).

Moreover, the presence of multinational companies in Colombia has declined in recent years. Several have taken their production to other countries that offer greater tax incentives and fewer quality and procedural regulations. This situation has encouraged national laboratories to develop new products that meet domestic demand for medicine (Stepanian & Tirado, 2013), thus transforming the sector into a strong exporter of drugs and an importer of raw materials (Angulo & Mosquera, 2008). Exports of pharmaceutical products have shown a growth trend since 2005, with a slight decrease during 2010 and 2011. In the last two years, although exports have continued to increase, there remains a trade-balance deficit. The sector's strengths are its regulations in line with international standards, freedom of prices, skilled labor, competitiveness, and high-quality products; its weaknesses are instabilities in the health system, counterfeiting and smuggling, and control and surveillance deficiencies (Angulo & Mosquera, 2008).

In recent years, Colombia has been characterized by a turbulent business environment, with continuous changes in customer needs and a resulting emergence of new products, increased price competition and new players in the market. The pharmaceutical sector has been affected by this dynamic; the behavior of its environment has become more unpredictable and companies must not only learn new skills to stay in business but also improve their performance in developing skills and managing their resources to adapt to new environmental conditions (Rivera et al., 2010). This series of problems is reflected in the Joint Survey of Industrial Opinions (Encuesta de Opinión Industrial Conjunta-EOIC) conducted by the National Businessmen's Association of Colombia (Asociación Nacional de Empresarios de Colombia-ANDI) among businessmen in the pharmaceutical sector during the fourth quarter of 2014. The survey results showed a series of problems that affect Colombia's pharmaceutical sector. The primary obstacles perceived by businessmen include high levels of market competition, low demand, the exchange rate, the cost and supply of raw materials, smuggling and unfair competition, and infrastructure and logistics costs. The survey results also showed the presence of positive levels of production and sales, stable inventories and a relatively favorable business climate. One of the major topics of concern is the tax reform being discussed in Congress because a higher income tax represents a substantial burden on companies whose tax capacity is at its limit. Another concern for entrepreneurs involves proposed labor initiatives that could result in slower growth, less investment, less employment and more informality (ANDI, 2014).

Starting with problems specific to the pharmaceutical sector, this study analyzes the effects of the resources available for production, logistics costs, previous experience and institutional environment on the sector's export growth. The following section Download English Version:

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