Romanian Market Strategies in the Pharmaceutical Industry

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Abstract. Understanding the actions taken by pharmaceutical companies to counter competition requires information on how the pharmaceutical sector is built. The pharmaceutical market, mentioned in this paper, contains all companies that produce or develop pharmaceuticals or compounds that are used to produce drugs and all other participants that interact with those companies for the purpose of selling or buying a drug. It is also necessary to understand market participants and the importance of an economy for maintaining this growing sector by supporting its production and development, in order to understand the anti-competitive actions taken by pharmaceutical innovators. This case study will provide an overview of the market defined below, applied strategies, and the elements constitutive of the pharmaceutical supply chain.

Keywords: Pharmaceutical Industry, Supply Chain, Strategic Management, Strategy, Vertical Integration

Introduction
The main purpose of this paper is to understand what actions pharmaceutical companies can take to secure high-end revenues for their products for sustaining the research and development process behind and also making a profit for the business. Moreover, it is relevant to analyze how performance can be improved based on good strategic management. By having a good strategy, the company will perform in the market and bring a higher market share.

The pharmaceutical industry is intensively regulated worldwide, but still, small differences apply in every country. These regulations have the purpose of maintaining different prices in correlation with different financial potentials. Different actions are described further, but one of the most investigated processes in the pharmaceutical market still is related to parallel trading. This aims simply not to sell drugs bought from countries with lower prices and sold in countries with higher prices.

Another way of controlling sales prices within one country is vertical integration of the system. This analysis was made on the Romanian market and will provide information on how vertical integration is applied. In this analysis, public data has been used and the results were personally interpreted under discussions.

The methodology applied in the paper is quantitative, dealing with the analysis of secondary data, and it is exploratory. The data tools were public financial databases. All data were collected cross-sectionally, at the same time for all companies analyzed. Companies with the highest market share in their industry were selected.

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For the purpose of this study, market research has been conducted to better understand the pharmaceutical supply chain and the relations and conditions between each party. Differences in strategic management were highlighted and compared in terms of profitability. At the same time, a high relevance to the study is to understand what are the legal aspects that are governing competitiveness in this specific high impact for the quality of life industry. All financial data has been collected from official reports for each player, while regulations could be extracted as part of public access data on the European Medicines Agency and ANMDM.

1. Strategic management
Strategic management is considered the most dynamic of all the aspects that make it up to business management. It involves discussions and paradigmatic, theoretical, and methodological opinions. Aspects related to strategic change and interpretations of what constitutes success and failure change all the time. Almost as soon as they are written, case studies become obsolete, and theories are no longer relevant - usually to reappear later in another form. However, the basic ideas that have been developed over time from theories seminal and classical have long-lasting applicability.

“Strategic management can be defined as the management of the organization for its long-term general purpose.” This should not be confused with strategy, which is the general approach of an organization for directing operations to achieve the long-term goal of that organization. An organization's strategy should be used to guide and align the formation of sub-strategies in different parts of the organization (Kaplan, 2008).

Specifically for the pharmaceutical industry, strategic management plays a very important role, due to its regulations and not only because of competition. This means that every action that is taken in the industry must be an overview from two different sides.

This research aims to understand strategic approaches in the pharmaceutical market, as this industry has come under increasing government review. Allegations of anti-competitive conduct by drug manufacturers are the subject of the analysis. This is because innovative medicines are frequently offered by a single company with a dominant position in that market. Initially, such a position may be granted through patent rights and other forms of intellectual property (IP) protection. The market power (e.g., prices above variable production costs) established by IP laws helps pharmaceutical companies to earn revenues by covering research and development costs incurred not only for marketed medicines but also for medicines that never reach the market. In this sense, a certain degree of market power for a predefined period is required so that pharmaceutical companies invest in research in the first place.

Another aspect to consider in these analyses concerns the strategies of companies after a patent has expired, i.e., the type of strategies used by existing companies to prevent entrants from gaining access to the market.

The outcome of this research is complex even in other industries, let alone in the pharmaceutical industry. This industry is not only subject to control by antitrust authorities, but, is also protected by IP laws, regulated by government authorities, and characterized by powerful buyers such as health insurance companies.

In parallel with increased investment in innovation, there has been a significant increase in the production and prescription of cheaper substitutes, so-called generic medicines. This increase in both research, development and generic production is not contradictory but a mutual consequence. Increased innovation and patent protection lead to monopoly power and high profits for manufacturers (Bennato, 2014). Therefore, potential competitors have the incentive to participate in the market. With the end of patent protection competition emerges and substitute
products can enter the market. Consequently, the interest of innovators is to further invest in R&D in order to obtain patent protection and monopoly power (Garattini, 2008). As a result, generic entry not only imposes competition on innovator producers but also the problem of parallel marketing arises (Graslandt, 2004).

2. Regulations of the pharmaceutical industry and Romanian market overview

Several regulations in the pharmaceutical industry in Europe have implications for sales (IRP, 2021):

1. Advertising regulations: The European Medicines Agency (EMA) has strict rules regarding the advertising of pharmaceutical products. All advertising must be truthful, accurate, and not misleading, and must comply with the product's authorized labeling. The regulation of advertising also covers promotion to healthcare professionals and the general public and includes rules about the content, format, and distribution of advertising materials.

2. Pharmacovigilance regulations: Pharmacovigilance is the practice of monitoring the safety of medicines and taking action to minimize any risks. The EMA requires pharmaceutical companies to have robust pharmacovigilance systems in place, including processes for collecting and analyzing adverse event reports. Failure to comply with these regulations can result in fines or other penalties, which can affect a company's bottom line.

3. Pricing and reimbursement regulations: The pricing and reimbursement of pharmaceutical products are regulated at the national level in Europe. In some countries, such as the UK, the government negotiates directly with pharmaceutical companies to set prices for new medicines. In other countries, such as Germany, prices are set by an independent body. The pricing and reimbursement process can have a significant impact on a company’s sales, as it determines how much they will be paid for their products.

4. Clinical trial regulations: Before a new medicine can be approved for sale in Europe, it must go through a rigorous clinical trial process. The regulations around clinical trials are designed to ensure that the trials are conducted ethically and that the results are reliable. However, the process can be lengthy and expensive, which can affect a company’s ability to bring new products to market and generate sales.

The Romanian pharmaceutical market has seen significant growth and development in recent years, driven by factors such as increasing demand for healthcare services, rising chronic disease prevalence, and expanding access to healthcare across the country. With a market size valued at approximately 4.6 billion euros in 2020, the Romanian pharmaceutical market presents a range of opportunities for companies looking to expand their operations in the region (BMI, 2021).

However, the market is also highly competitive, with a large number of domestic and international players vying for market share. This has led to a range of challenges for companies operating in the market, including pricing pressures, regulatory complexity, and changing consumer preferences.

To succeed in this competitive landscape, companies must develop effective strategies that allow them to differentiate themselves from their competitors, while also addressing the unique needs and preferences of the Romanian market. This may involve investing in research and development to develop new, innovative products, building strong relationships with healthcare providers and patients, and adopting a flexible, agile approach to navigating the complex regulatory environment.
The Romanian pharmaceutical market is projected to grow at a compound annual growth rate (CAGR) of 6.3% from 2020 to 2025, according to a report by Market Data Forecast (GlobalData, 2021). The leading therapeutic areas in the Romanian pharmaceutical market are cardiovascular diseases, respiratory diseases, and cancer, according to a report by Business Monitor International. Romania has a strong domestic pharmaceutical manufacturing industry, with approximately 130 local manufacturers producing a wide range of generic and branded products (Euromonitor International, 2021). The Romanian pharmaceutical market is highly fragmented, with a large number of distributors and wholesalers operating in the country. The majority of pharmaceutical products are sold through retail pharmacies, of which there are over 5,500 in Romania. The Romanian pharmaceutical market is regulated by the ANMDM, which oversees the approval, registration, and distribution of medicines in the country. The ANMDM also monitors the safety and efficacy of pharmaceutical products and enforces compliance with relevant regulations and guidelines.

These are just a few examples of the key data points related to the Romanian pharmaceutical market. Overall, the market is expected to continue growing in the coming years, driven by factors such as increasing demand for healthcare services, rising chronic disease prevalence, and expanding access to healthcare across the country.

3. The competitive strategy in the pharmaceutical industry

The competitive strategy gives an organization an advantage to make above-average profits in its industry, creating unique value compared to that offered by its competitors. This thing requires a competitive strategy that is sustainable over time. Its role is to integrate and coordinate the activities of that organization that make the organization different from competitors in what it does and what it offers.

As an example of different strategies in the pharmaceutical industry, that can be described by Blue Ocean Strategy is that it will create a new market that will lack competitive focus, creates new demand, overcomes the cost-value difficulties for the consumer, and lastly focus on alignment of company activities based on differentiation strategy and reduction of costs. Worldwide known Viagra pill made by Pfizer was initially thought to be a medication dedicated to cardiovascular pathologies. By simply changing the market, Pfizer extended their patent of this substance and promoted it as a medication for erectile dysfunction.

There are many possible actions that companies can take and still be compliant with the regulatory system, as detailed below:

- **Actions against parallel export:**
  - Vertical integration
  - Price discrimination
  - Resale price
  - Product registration change
  - Different price
  - Reference price limitations

- **Actions against generics:**
  - Own generics
  - Drug update
  - Indications update.

For this study, different approaches related to vertical integration led to different outcomes in the market share of each company.
**Vertical integration as a strategy**

The expansion of an organization's activities in the industry has two directions: vertical and horizontal. Vertical integration is the extension of an organization's activities to a distribution chain or supply chain. Horizontal integration is the expansion of a side organization's activities in industry, achieved through the acquisition of competing companies in the same part of the supply chain (Acemoglu, 2003).

Vertical integration in retrospect allows an organization to control some of the resources that are used as inputs in the production of its products and services. Vertical integration into the distribution chain allows greater control of distribution centers and retailers. However, an alternative approach to controlling industry participants in a supply chain is to influence their bargaining power through purchasing power. This is often a preferred strategy if an organization wants to spread its risk to multiple vendors (Graslandt, 2007).

As well-known already, the sale market is represented by pharmacies. There are two types of pharmacies: The consecrated brands that have the most market share which is part of a pharmaceutical chain, and the smaller ones, also called individuals. As mentioned before, prices are regulated by authorities, but only for a part of them, while others may have different prices depending on each company. It is important to know that the producer cannot sell their products directly to the consumer and prices are not dictated by the producer. Only approximately 60% of it represents the actual costs of the drug. For the other 40%, the distribution system is responsible for (Figure 1):

![Figure 1. The pharmaceutical supply chain](source: Authors’ own research.)

In the pharmaceutical supply chain can be observed that there are four main components and each of them is dependent on the one above. Starting from the producer selling price, wholesalers and pharmacies are adding their margins, resulting in the final price for the patient.

The most applicable strategy to increase profit for each pharmaceutical unit, but also for the wholesalers is represented by vertical integration. The biggest chains of drug commerce in Romania invested their resources in owning as much of this supply chain. There are five main wholesalers with the specific or non-specific distribution. This results in maximizing profits that the company can register by controlling the price in the pharmacies and the price in the wholesaler too.
Table 1. Analysis of Romanian distributors of drugs

<table>
<thead>
<tr>
<th>Distributor</th>
<th>Pharmapharm</th>
<th>Farmexim SA</th>
<th>Fildas Trading SRL</th>
<th>Farmexpert DCI</th>
<th>Medimplus Exim</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of warehouses</td>
<td>7</td>
<td>/</td>
<td>15</td>
<td>300</td>
<td>12</td>
</tr>
<tr>
<td>No of pharmacies</td>
<td>2500</td>
<td>4100</td>
<td>3000</td>
<td>115000</td>
<td>-</td>
</tr>
<tr>
<td>Type of distribution</td>
<td>Non-specific</td>
<td>Non-specific</td>
<td>Specific</td>
<td>Non-specific</td>
<td>Non-specific</td>
</tr>
<tr>
<td>Integrated with</td>
<td>Gedeon Richter</td>
<td>Green Net SA, Help Net</td>
<td>Catena</td>
<td>/</td>
<td>Sensiblu, Dr. Max</td>
</tr>
</tbody>
</table>


As Table 1 shows, each distributor has different strategies regarding the number of warehouses, pharmacies, and type of distribution. Specific distribution means that they only sell to their own pharmacies, while non-specific distribution can include not only the owned pharmacies but any others, including individuals. While 4 of the 5 main distributors applied vertical integration on the whole chain, Farmexpert DCI did not approach the same strategy. This is the explanation for a much larger number of pharmacies.

Results and discussions
In this section, each company’s turnover and profit were analyzed (RISCO, 2022, Transilvania Business, 2021).

Table 2. Financial analysis of the top 5 drug distributors in the Romanian market

<table>
<thead>
<tr>
<th>Distributor</th>
<th>Pharmapharm</th>
<th>Farmexim SA</th>
<th>Fildas Trading SRL</th>
<th>Farmexpert DCI</th>
<th>Medimplus Exim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover (EUR)</td>
<td>250.630.334</td>
<td>512.289.003</td>
<td>874.930.704</td>
<td>776.270.980</td>
<td>825.567.945</td>
</tr>
</tbody>
</table>


Depending on their size and strategy all companies registered a profit in 2020, excluding Pharmapharm. Unknown factors lead to this result, but this will be excluded from the discussion. Multiple factors are influencing the company’s profit.

Judging by the type of strategy, the specific type of distribution showed to be the most efficient regarding profit. While focusing on their own pharmacies they have constant prices which conclude with the best margins. The other companies, with nonspecific distribution, might get higher margins when selling their products to other pharmacies, but lose profit on selling to their own at a lower price than initially bought. Further analysis can be made on this topic (Figures 2 and 3):
In the pharmaceutical sector described previously, vertical integration is a strategy that is applied to the top five drug distributors in the Romanian market. Depending on the type of distribution in the market of the products, differences can be observed in profit.

**Conclusion**

In summary, the Romanian pharmaceutical market presents a range of opportunities for companies looking to expand their operations in the region but also poses a number of challenges due to the highly competitive landscape and complex regulatory environment. To succeed in this market, companies must develop effective strategies that allow them to differentiate themselves from their competitors and address the unique needs and preferences of the Romanian market. This may
involve investing in research and development, building strong relationships with healthcare providers and patients, and adopting a flexible and agile approach to navigating the regulatory landscape. Overall, the market is projected to continue growing in the coming years, with leading therapeutic areas including cardiovascular diseases, respiratory diseases, and cancer. The market is highly fragmented, with a large number of distributors and wholesalers operating in the country, and the majority of pharmaceutical products are sold through retail pharmacies. The regulatory environment is overseen by the ANMDM, which monitors the safety and efficacy of pharmaceutical products and enforces compliance with relevant regulations and guidelines.

Antitrust laws and regulatory frameworks, which can vary significantly from country to country, as well as the complexity of the pharmaceutical market structure, influence the market exclusivity time of the original manufacturers. As innovators invest to develop new compounds, patent protection gives them up to 20 years of market exclusivity to generate profits to cover innovation costs. Especially in recent decades, generic manufacturers have found ways to circumvent patents to get to market earlier, increasing the availability of parallel-marketmedicines while branded medicines are still protected by patents. It is therefore in the interest of originators to prevent this generic and parallel trade competition. On the other side, regulators favor early competition for manufacturers of branded medicines, as healthcare costs can be reduced because alternative medicines are available at lower prices. There are a variety of anti-competitive actions taken by manufacturers to discourage generic and parallel-marketmedicines from entering the market.

Strategic management is a very important part of a company's success and strategy itself must be adapted taking into consideration internal and external factors. In the pharmaceutical sector described above, vertical integration is a strategy that is applied to the top five drug distributors in the Romanian market. Depending on the type of distribution in the market of the products, differences can be observed in profit. Important to be mentioned that there are also other perspectives and considerations to influence the company's profit. Also, it is important to understand the entire pharmaceutical chain. Producers are not selling directly to customers. The price is increased at every level of the four steps to the customer. Taking this into consideration, vertical integration helps any of the participants in the chain to increase profit. In this case, wholesalers and pharmacies are integrated to maximize profits by increased control of the acquisition price and margins.

This study has some limitations. Aspects that have been taken into consideration for comparative study for different strategic management were limited to public data. A more precise study would need to take into consideration more aspects. Collected data comes from multiple sources and could have been differently gathered, although it was possible to illustrate a coherent comparison of relevant data for the profitability and effectiveness of their strategies. Future research would include multiple aspects to be included for more precise evaluation. Another important direction of future research would be related to the benefits of the patients and the health care system to the detriment of challenging access to medication and increased prices that can sustain the pharmaceutical companies for continuous development.
References