

## LIFE CYCLE OF THE PHARMACEUTICAL PRODUCT AND PRIMARY STRATEGIC GOALS

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### **Abstract:**

*In addition to innovation, production at high standards, market and marketing policy, pharmaceutical companies need strategies that could cope with apparent contradictions, convergences and divergences, centralisation and involution, at the global and local level, focus and liberty, domestic production and external supply, ownership and alliances, networks and hierarchies, science or market orientation, all these being part of the essence of a profitable and expanding pharmaceutical company.*

*Specialists appreciate that the 20<sup>th</sup> century will remain in the collective memory for its technological achievements, including a better understanding of the atomic structure, „information explosion” encouraged by the progress of the computer technology, the news from space exploration. If one wants to evaluate its importance in terms of impact on people’s lives, the 20<sup>th</sup> century could be called THE DRUG AREA. Many experts agree that, at the end of this century, pharmaceutical products would have a higher importance for our lives due to the special progress in neurobiology, immunology, molecular biology, cellular differentiation, cell membrane and genetic studies. In the pharmaceutical industry, important funds are directed towards research and development, while few understand and appreciate the contribution brought by the pharmaceutical marketing system and by the professionals in this field. These ones make the drug accessible at the right time and place, in the required quantity, at a reasonable price and with all the information required.*

**Key words:** pharmaceutical, drugs, strategy, innovation, generic.

**JEL classification:** I15

### **INTRODUCTION**

The purpose of this paper is to outline the importance of the pharmaceutical market to Romania’s economy and society, as well as that of European Union. Depending on the lifecycle of each pharmaceutical product, Pharma companies must develop proper strategies and marketing programs for maintaining their position on the market and their competitiveness at the highest levels.

### **PHARMACEUTICAL MARKET OVERVIEW**

The pharmaceutical market, as a variety of the consumption markets and an element compounding the health services and pharmaceutical products market, includes all its subjects (manufacturers, wholesalers and retailers, consumers), pharmaceutical professionals and other employees, and also information flows and technologies used in the pharmaceutical activity. Unlike other fields, the specific feature of the pharmaceutical marketing consists in the fact that the pharmaceutical industry creates and manufactures the drug, which is not like any other product as it cannot be bought freely or at the consumer’s discretion. For a patient, the drug is a special product used to cure diseases, to protect or to improve his/her health.

Nowadays, the pharmaceutical companies are facing new challenges. Despite high demands, changes are to be done generated by the instability of the global economic situation and attracting the attention on the identification of certain long-term strategies for the pharmaceutical business.

Over recent years the Romanian pharmaceutical market has gone through a period of growth, following the general trend of the country economy. The Romania’s accession to the European Union in January 2007 has set the tone for economic development of all sectors, not just

of the pharmaceutical one. All legislative changes on the market focused on the harmonisation with the European Union directives and the authorities' attitude focused on transparency and openness. The accession to the European Union has eliminated customs duties and generated the intensification of competitiveness and the increase of imported generic drugs in terms of volume. Moreover, the number of registered drugs has increased as a result of simplifying the registration procedure for new drugs in the European Union.<sup>1</sup>

The health care reform in Romania has been slow over the past few years due to political obstacles. However, it is expected that the pharmaceutical market in Romania will become the fifth market in Central and East Europe by the year 2016. This growth is mostly due to increased imports of drugs.

The generic drug market in Romania has been stimulated by the privatisation processes. The increasing number of foreign companies that manufacture generic drugs has strengthened the average of pharmaceutical products available on the market, has allowed the access of certain new exporting markets and has increased the sales value.<sup>2</sup>

Thus, it should be noted that the pharmaceutical market is very important for the Romanian economy and society. Notwithstanding the drugs business and manufacturing, the Romanian generic drug manufacturers significantly contribute to the increase of the gross domestic product and they are an essential factor of economic growth.

Among the factors that have influenced favourably the pharmaceutical market and that have led it in this direction there are: the launch of new products under the conditions of increased market attractiveness, the passage to the prescription by brand which favours the sales of expensive drugs, „The Health condition assessment programs” by which new patients enter into new treatment schemes and the appearance of free and subsidised drug lists which brought new products on the market. Another positive factor for the Romanian pharmaceutical market is the population's aging process which helps the drug manufacturers, and also the high rate of rural population.

However, in Romania we need a systematic approach of this field in order to gain functionality and, at pharmaceutical level, the customer orientation and a scrupulous control of costs are imposed.<sup>3</sup>

In general, the drug life cycle model corresponds to the life cycle of any other products and at the same time, it has certain particularities.

There are three distinctive stages in the life cycle of a new drug: (1) the research and development stage, up to its launch to the market, (2) the period of time between its launch and the loss of exclusivity (for instance the patent expiry date) and (3) the period after the loss of exclusivity, when generic drugs can enter the market.

During the first stage, the companies identify possible new drugs and submit them to certain intensive clinical and pre-clinical tests. Innovative companies are mostly based (namely for more than a third of all new drugs in approval stage for marketing) on innovations acquired from third parties.

During the second stage, innovative companies market the drugs they have developed in order to offset the direct investments and to make profit. The assurance of an effective protection of the patent is essential for the support of this commercial pattern which guarantees the existence of certain stimuli for the continuation of this innovation process.

The last stage is the one in which exclusivity is lost, and at this moment generic drugs can enter the market. Once the expiry of the patent, a drug can be copied and manufactured by other pharmaceutical companies under a different trade name. This process is legally possible only if the license is acquired from the original manufacturer. The approval of a generic drug takes on average between 1 and 3 years, compared to 10 to 15 years required for the approval of an original drug, the costs of generic companies also being considerably lower than the costs of the pharmaceutical companies that developed the original product. In 2005, important amendments of the regulatory framework in the pharmaceutical field have become applicable aiming at facilitating the entry of generic drugs into the market, for instance the introduction of the Bolar provision. Within the European Union, this one entitles generic drug manufacturers to prepare the documentation for

approval before the expiry of the patent so that the generic drug to be available on the market immediately or shortly after the original product is no longer protected by patent.

Some of the advantages and disadvantages associated to the production and use of generic drugs are listed below.

#### **Advantages:**

- The cost of a generic drug is 20-80% lower than that of an original product, as the company that produced the generic drug does not have to recover the investment costs of clinical and pre-clinical research that a company manufacturing original drugs has paid for, which could reach 2 billion dollars; furthermore, the companies testing new drugs lose their investment for about 2 of 5 substances studied.
- The prescription of generic drugs by doctors, through the subsidised prescription system instead of original ones leads to savings for both the patients and the sanitary systems.
- Having a lower price, the generic drugs are available to a large number of patients
- Generic drugs are manufactured according to the GMP (Good Manufacturing Practice) and the GLP (Good Laboratory Practice)
- The presence of generic drugs stimulates the competition between companies in terms of price

#### **Disadvantages:**

- Generic drug manufacturing companies are required to include the same active substance in their product, but not the same excipients; the presence of other excipients (which provides a different form of conservation: colour, shelf life, stability) than those of the original product could generate adverse reactions
- Generic products have only bioequivalence studies attesting that they are similar from pharmacokinetic point of view (absorption, distribution, transformation and disposal) and from pharmacodynamic point of view, but they are not supported by therapeutic clinical studies like the original products. The restrictions in terms of bioavailability (absorption rate and concentration) for which 2 products are reported bioequivalent are between 80-125% (according to the EMEA and FDA regulations).
- Generic drugs are mostly manufactured in laboratories located in developing countries, compared to the original ones that are synthesized in top laboratories in developed countries – thus there is risk of using different technologies in the drug manufacturing process.

A preliminary report of the European Commission DG Competition „Investigation in the pharmaceutical sector” conducted in 2008 indicates that for 40% of the drugs which were part of the sample selected for a thorough analysis and which have lost their exclusivity during the period 2000-2013, the innovative companies have launched the so-called second generation drugs/continuation drugs. On average, the launch took place one year and 5 months before the loss of exclusivity for the first generation product.

In certain cases, the first drug was withdrawn from the market a few months after the launch of the second generation drug. Almost 60% of the litigations related to patents between innovative companies and generic companies analysed in the context of this investigation refer to the drugs which were subject to the transfer from first generation products to second generation products.

In order to successfully launch a second generation drug, innovative companies have paid sustained marketing efforts in order to attract an important number of patients who would use the new drug before the launch into the market of the generic version of the first generation product. In case this strategy is successful, the probability for generic companies to win an important market share significantly decreases. If, on the other hand, the generic companies enter the market before patients use the second generation products, the innovative companies face difficulties in

convincing doctors to prescribe their second generation products and/or to obtain a high price for these ones.<sup>4</sup>

Often, the launch of the second generation products is carefully prepared in terms of patents in order to make sure that the first generation product is properly protected until the completion of the transfer. It also requires the submission of new patent applications for the second generation products. While it is generally recognised that innovation is done progressively, sometimes patents related to the second generation products are criticised for lack of consistency by other stakeholders who argue that these ones have only minimum improvements or additional benefits (if any) for the patients.

Due to the specific particularities, to the demand level, one product or another can be present on the market for a different period of time: from a few months, up to several years. This period of time is called „the product life cycle” (hereinafter referred to as PLC) and it represents the period time between the moment of its appearance on the market as new product and up to its disappearance from the market. Therefore one should not mistake the notions of „product life cycle” and „the product shelf life”.

The research of the period of time for the presence on the market of the range of products of certain pharmaceutical company can be done by studying the products life cycle. The concept taken from biology and applied for the first time in 1950 by Joel Dean in marketing, represents both an interesting pedagogical concept and a management tool in the product policy.

The drug represents a product of the human life, with social character and it will be studied through different perspectives. Given that any drug is characterised by pharmaceutical form, packaging, price, use properties, information flow, level of demand on the market, etc. – it should be seen first as a product, as an economic good.

According to the classical definition, the product is an essential element of the market category capable, due to its features, to satisfy the consumers’ needs.<sup>5</sup>

The patient, by purchasing a drug, sees it first as a healing hope, an improvement of his/her health as a result of its use and then as a product as such.

## **DRUGS LIFE CYCLE AND CORRESPONDING STRATEGIC PLANS**

The PLC pattern of the drug is done taking into account the macro- and micro-environmental factors of the company, the participation of doctors in the creation of the demand, the particularities of the market share, the elasticity of the demand compared to the price, etc.

When elaboration the marketing plans for each stage of the PLC, the changes in the competition environment, the strategic purpose of the company, the product competitiveness, the dynamics of sales and the structure of expenses, the reaction of the consumers, etc. will be taken into account, following the propriety purposes.

Determining the drugs life cycle represents another important practical aspect in the activity of manufacturing or distribution companies, and also of the centres for the study and testing of pharmaceutical market. The analysis of the product sales volume dynamics, taking into account the main factors for the creation of the market demand for each drug, the competition level and not at last the consumer’s requirements offer the possibility of manufacturing companies to position the given product and to select the target markets for a productive activity.<sup>6</sup>

**Table 1: Priorities in the marketing activities related to the life cycle of a pharmaceutical product**

Stage of the life cycle	Priorities	
	Strategic purposes	Marketing program
<b>Placing on the market</b>	Creation of the demand	Information of current and potential consumers, of doctors and pharmacists on the new product placed on the market
<b>Increase</b>	Maximising the market share	Activation of sales and increase of turnover
<b>Maturity</b>	Maintenance of the market share	Consolidation of the company on the market segments gained
<b>Decline</b>	Minimisation of expenses	Concentration of the activities on the remained market

Thus, the drug life cycle represents an important indicator necessary for the pharmaceutical company in its marketing and research-development activities. This is where resides the practical importance of the discussed issue – determining the drug life cycle.<sup>7</sup>

For domestic drug producers, the issue of determining the PLC represents an important and responsible moment. This opportunity is conditioned by the following aspects:

- the high level of market competition of the pharmaceutical companies;
- the extremely low parity of the population's purchasing capacity;
- low budget funds for the procurement of drugs by the medical and sanitary institutions;
- the harsh competition on the market between the products of the overseas producers and the domestic ones;
- the particularities of the drug supply system

Taking into account the above mentioned, for the domestic manufacturer the issue of determining the life cycle of each product becomes a current issue for the fundamental argument of its research-development strategies.

The introduction of new products involves a high risk dose for the company and it is a much more difficult and expensive process than the administration of the existing products.

The new product is a product that, by its features, is different from the ones already existing on the market. The concept of new product has a quite large sense. Thus, Booz, Allen and Hamilton have identified the following categories of new products according to their novelty for the company and for the market:<sup>8</sup>

- global innovative products;
- lines of new products;
- improvements of the lines of existing products;
- improvements of existing products;

- repositioning ;
- cost reductions.

The newly introduced drug must, as far as possible, be subject to the following criteria:

- be part of the modern therapeutics (not obsolete)
- include, if applicable, the pharmaceutically active drug, not its metabolic precursor;
- be able to be administered on the less traumatic and dangerous route for the patient (preferably on oral administration);
- manifest its therapeutic effect in as small dose as possible;
- have as less side effects as possible;
- not have acute and chronic toxicity;
- not have teratogenic and carcinogen effects;
- possess good pharmacokinetics;
- its concentration to be consistent with the therapeutic dose;
- have a cheap or affordable price for the patient.

The options formulated by the pharmaceutical company concerning the sizes, structure and dynamics of its range of products or of the traded range of product are reflected in the product strategy adopted.

The objectives of the product strategy are set depending on the resources of the pharmaceutical company and on the environmental conditions. They are related to:

- strengthening its position within the existing segments of consumers
- increase of the consumption degree of a certain product it manufactures and/or sells;
- increase of the distribution degree of a certain product on the market for the attraction of new segments of consumers;<sup>9</sup>
- differentiation from similar products of the competition;
- a better positioning within the range a product is part of and thus increase of its market share.

Considering the objective followed by the company as criterion for setting the sizes, structure and dynamics of its range of products and services, the company can formulate more strategic alternatives for its product strategy. For instance:

*1. Concerning the range size:*

- the selection strategy – with reference to the restriction of the range sizes, thus efforts being concentrated on a small number of products;
- the product stability strategy—either by the preservation of the quantitative proportions between products, or by the modification of these proportions in favour of items with higher demand;
- the product diversification strategy—for the increase of product variety within the range.

*2. Concerning the quality level:*

- the adaptation strategy – depending on the requirements of each segment of potential buyers;
- the differentiation strategy – depending on the similar offer of other competitors on the target market;
- the stability strategy – consolidating the clearly shaped position of the company on the market.

*3. Concerning the product renewal degree*

- the strategy of assimilating new products for the segments of potential consumers;
- the strategy of improving the products existing in the manufacturing range structure;
- the strategy of maintaining the novelty degree within the already existing range of products.

Each strategic variant has advantages, but also limitations, being indicated only in certain concrete situations. For instance, the selection strategy is recommended in case of exaggerated diversification or when the efficiency indicator related to some products within the range reaches certain unacceptable levels for the company.

The most dynamic and the most complex product strategy is the product renewal strategy. This one leads to the creation of new lines of products within the already existing range, mobilising the entire human, material and financial potential of the company. It is recommended in the maturity phase of a product line, aiming at replacing the „obsolete” products with new, more efficient ones. Thus the consumers of the eliminated product are taken by the new one to be launched on the market.

The company can permanently search for „ideas” of new products: but there are multiple factors accelerating/ slowing down the research-development activity.

The pharmaceutical market is unique due to the importance of the decision factor on the purchasing act. This one is not free, it does not belong to the patient, it is directed by the doctor. Therefore the drug target market is represented by the prescribing doctors. Since the decision power belongs mainly to the doctor, it is necessary to classify both doctors and patients.

Another particularity of the pharmaceutical market is represented by the importance of the disease. With few exceptions, the incidence of diseases is an important criterion for classification, for the identification and quantity evaluation of the market share for a prescribed pharmaceutical product. The value of the disease incidence is decisive for the drug manufacturers' efforts. However it is possible that the relation between the disease statistics and the marketing decision making related to the marketing research to be less obvious. Due to the almost unlimited possibilities to identify different pharmaceutical markets, the most frequent approach of the studies refers to the market of medical prescriptions. In order to identify the consumers' needs for concentrating the marketing effort, the pharmaceutical market presents this aspect; unfortunately for the patient, he is only a patient.

This one cannot choose his/her treatment. The mortality rate is important in making decisions on the importance of this feature as market factor. Statistics highlight important modifications of the main death causes nowadays, one of these being influenced by the use of certain drugs which have led to the eradication of certain diseases or to the increase of the populations' life expectancy. By combining this information to other data, such as the sales of certain competitive products, the effectiveness of a new product, the success of new products in the past, one could create the basis for granting the success of new products on the market.

The pharmaceutical industry is characterised not only by the highest added value per employee, the most intensive use of research and development and the greatest trade surplus in all high tech sectors, but it also contributes in a unique way, in the largest sense, to the economic growth by products contributing to the population's health. The sector is composed not only by great companies with a large number of employees, but also by small and medium companies whose margin is different, usually depending on their size. Partnerships with universities and other institutions around the world form a true „integrated system” of the life sciences.

In the context of intensified global competition, the European Committee considers that now is the appropriate time for a new strategy in the field of life sciences, which could ensure a coordinated approach of industry, guaranteeing that all stakeholder groups will continue to benefit from this unique sector.

The pharmaceutical industry brings a major contribution to the European Union, not just from economical point of view, but also in terms of highly qualified human resources, scientific investments and public health. Europe has made great efforts in terms of life expectancy and the results in the health field in the last 60 years. The use of innovative drugs has played a major role in these recent developments. Europe is currently facing a series of new challenges.

There are still certain inequalities in terms of access to medical assistance and the impact of chronic and degenerative diseases has led to the situation in which life expectancy of the persons

with a certain form of medical disability or disease has increased. This has a negative influence on the costs for medical assistance and productivity.

Providing a sure and effective supply chain of pharmaceutical products for European consumers represents an important priority. Theoretically, the European regulatory framework grants high quality standards to the patients, regardless the place where pharmaceutical products are manufactured. However, the on-going strengthening of the supply chain safety, eliminating the risk of marketing counterfeit products, will be an important step forward that will include the allocation of a code and a serial number to each package of drugs in Europe, improving the essential element of identifying and tracing the counterfeit products.

## CONCLUSIONS

The pharmaceutical sector is one of the sectors with the greatest strategic importance for the European future. Europe holds a rich patrimony, being one of the main global centres for pharmaceutical innovation, complying with the necessary conditions in order to remain a successful sector. However, future success depends on the political environment and on its support in terms of appropriate use of innovation in the European health systems.

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