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COMPETITIVENESS IN THE PHARMACEUTICAL INDUSTRY: A HISTORICAL OVERVIEW

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Abstract

The aim of the paper is to present the key periods of competitiveness dynamics in pharmaceutical industry. The historical overview covers the emergence of modern pharmaceutical industry. Given the role of pharmaceutical industry in healthcare, particular attention is paid to the impact of state supervision on dynamics.

The results of the paper determinate ten periods in the dynamics of competitiveness. Both internal factors of competitiveness and external factors are presented. Competitiveness of pharmaceutical industry marks a dynamics that is similar to that of other sciences and at each period, a new factor is added from the external environment.

Keywords: *state supervision, competitive advantage, path dependence*
JEL Codes: *D24, L65, N80*

INTRODUCTION

Modern pharmaceutical industry begun since the early 20th century by using of scientific approaches for discovery, trial, manufacturing and distribution of pharmaceutical products. Notwithstanding the fact that specialized literature determines some new pharmaceutical products as a „random discovery“ or a „lucky accident“, we can point out that scientific approaches have been used in their discovery as well as a systemic methods for treatment with new pharmaceutical products. The competitive advantages based on mysterious ingredients and secret nature of manufacturing are replaced by wide range of pharmaceutical products on synthetic basis. The society go through a cultural transformation due to substitution of obsolete pharmacists and pharmaceutical products with new ones (Nedeltchev, 2004).

Another distinguishing feature of modern pharmaceutical industry is involvement of the state in all processes of the complex value chain: discovery,

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trial, manufacture and distribution of pharmaceutical products. The first form of state regulation is in setting of standards for production of established pharmaceutical products. The adoption of the first pharmacopoeia in Florence in 1498 (*Nuovo Receptario*) and the imposition of the Latin language as a basic for the scientists provide the basis for state control over the systematization of pharmaceutical products in their unify manufacturing. Following the differentiation of pharmaceutical products, the state controls their production through the second form of state control - the patents. The last form of state control dates back to 1902, when in the USA began licensing of pharmaceutical products after clinical trials. Since 1906 it is mandatory to describe the ingredients of pharmaceutical products and the packaging, in addition to its commercial function, acquires a new one – an informational function. The packaging is first form of modern competition when Eli Lilly, a USA manufacturer, has advertised its pharmaceutical products as safe due to their reliable packaging at own plants. The safety of pharmaceutical products becomes a leading factor in determining of competitiveness.

The third feature of modern pharmaceutical industry is the contribution of other sciences to discovery of new pharmaceutical products. For a long time, pharmaceutical industry has grown on a small scale, primarily on a family basis, for a direct sale to patients (Madgerova, Kyurova, 2014). Keeping the process of manufacturing and ingredients of pharmaceutical products in secret leads to family competitiveness as well as to rumors about the effects of treatment. With the development of other sciences (chemistry, biology, genetics and computer systems), number of both the pharmacists and pharmaceutical products are expanding. The discovery of new pharmaceutical products, mostly on a synthetic basis, gives transparency about the effects of treatment as well as a new way of distribution through sales points. At the core of competitiveness is the effectiveness of pharmaceutical products.

DYNAMICS OF COMPETITIVENESS IN MODERN PHARMACEUTICAL INDUSTRY

Competitiveness is expressed in the adaptability to dynamics of external environment (Filipova, 2004). Our research on the competitiveness dynamics of pharmaceutical industry is shaped by the modern visions of humanity development:

The Great Depression. The effects of the Great Depression (1930s) have an impact on all aspects of society, including pharmaceutical industry. Limited scientific knowledge applied in pharmaceutical industry, in combination with single cases of mass production; explains the limited range and the relatively high cost of pharmaceutical products (Houbenova-Delisivkova, 2012). The established distribution practice contains delivering of pharmaceutical product by a doctor directly to a patient and the pharmaceutical companies provide to a small number of doctors with the formula for ingredients of pharmaceutical product.

The competitiveness in pharmaceutical industry is expanding and already incorporates biology, and in particular - microbiology, as a factor (Rowberg, 2001). A complementary factor is the use of biochemistry knowledge for discovery of new pharmaceutical products. Such a combination of research areas determines why pharmaceutical companies are include in their infrastructure a research unit. Since that period, a constant competition for pharmaceutical products research has been introduced in the pharmaceutical industry.

The combination with other sciences and establishment of their own research centers, identify the efforts to find synthetic substitutes for natural substances (Kettler, 2000). The first attempts to innovate in pharmaceutical products have resulted in the discovery of antibiotics, and the period has been identified as the „Golden Age of Antibiotics“ (Wernicki, 2013).

The publication of treatment effects with new pharmaceutical products gives to the society a new attitude towards a science and the pharmaceutical industry is a transparent already (Borisova, 2017). The rumors of randomize discoveries lapse and the health care culture is rising for new pharmaceutical products beyond traditional herbal therapies.

State interventionism. In the 1940s, in the society is raised the question for ethics, given the scale and profits of pharmaceutical companies. The state intervenes proactively through a patent protection and there are incentives for investments in new pharmaceutical products. Research centers are funded and protected by the state, and the first cases of oligopoly and monopoly arise. The trade brand is already a factor of competitiveness and a motive for maintaining innovation.

The pharmaceutical teams are expanded and included biotechnologists for discovery and manufacturing of therapeutics. Attention is directed towards the knowledge gained over decades about the symptoms and origin of the diseases. Government programs develop the leading part of new pharmaceutical

products. For a competitiveness begun a focus on marketing for increasing of sales.

New World Order. Since the 1950s, efforts to discover vaccines and to reduce pandemics were globalized. The need for co-ordination among countries and the accumulation of significant financial resources lead to establishment of the World Health Organization. The Marshall Plan has invested more than USD 130 billion for restoration of industry in Western Europe and created a prerequisite for outsourcing USA production abroad, including knowledge sharing among leading pharmaceutical states. While in Germany the military ban on new pharmaceutical products as a means of regulating pharmaceutical manufacturers continues, in the USA the laws are being liberalized and over-the-counter pharmaceutical products are being sold, increasing the specialization of the pharmaceutical industry and reaching higher profit levels. Another USA competitive advantage over Europe is the development of health insurance, which reduces the importance of pharmaceutical products' prices for both patients and doctors. Finally, the USA supervisory authority is authorized to approve generics without additional clinical trials, and pharmacists are allowed to advise patients when purchasing over-the-counter pharmaceutical products.

A process of harmonization of national laws is taking place, which continues to this day. The results achieved are in the field of international good practices, which reflect the ethical standards and accountability to pharmaceutical supervisory authorities (Todorova, 2019).

At the initiative of the EU, the USA and Japan, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use has been established. Its main purpose is to provide public confidence in the safety, quality and efficacy of approval and authorization of new pharmaceutical products for the three major countries (USA, Japan and the EU). For other countries, World Health Organization guidelines apply.

Competitiveness is determined at a macroeconomic level by the country of registration where international good practices have been adopted. Companies outside these countries may participate as subcontractors and lose their competitive advantages. Begun a process for offshoring in countries with „location advantages“ - a large population and lower production costs (Hymer, 1976).

Competition at a micro level is determined by human potential - establishing a link between pharmacy and life sciences (Petrova, 2014). Expectations are for cost reductions due to introduction of biotechnology and, accordingly, a higher return of pharmaceutical products. In production list a reduction of the number of pharmaceutical products derived from natural

substances and from organic compounds. The number of pharmaceutical products safety and efficacy tests is increased.

The economic situation is characterized by increasing market needs for pharmaceutical products. In response, pharmaceutical companies began to invest in research programs to discover and improve medicines. The political environment creates conditions for reduction of barriers from national borders, which facilitates the exchange of experience and the creation of opportunities for increasing the production of pharmaceutical products. As a balance of the situation, large investments in research work are being launched (Keremidchiev, 2013). Pharmaceutical manufacturers are rapidly adapting to mass production and reaching competitive prices.

The exchange of information between countries raises the need for new treatments and, above all, the effects of treatment. A competitive advantage is the access to database of information about the origin and effects of individual pharmaceutical products, which is facilitated by the development of computer equipment.

A major change has been made in marketing and, more specifically, in distribution. Country laws allow pharmaceutical products' advertisements for doctors who prescribe a treatment to patients, and patients receive pharmaceutical product from pharmacies. Pharmaceutical industry begun to become personalized and transformed into professional service for doctors and patients. The regulatory powers of the state are extended to the advertising of pharmaceutical products. Public attention is centered on pricing policies and unfair marketing practices, including huge mark-ups and generating colossal profits.

State regulation. Since the 1960s, regulatory requirements for safety of pharmaceutical products have increased. Following a series of unfair practices, the control for clinical trials to determination the efficacy of new pharmaceutical products is given to a state authority. The state began the control over pricing and reimbursement in pharmaceutical industry (Stoimenova, et al., 2014).

The supervisory authority standardized and controlled clinical trials in the USA. In Europe, a flexible marketing regime is allowed - the prescribing doctor carry out observations about side effects of pharmaceutical product.

There are significant changes in the competitiveness of pharmaceutical industry due to state regulation on pharmaceutical products:

- Reducing the number of new pharmaceutical products approved to market leads to an expanding range towards perfumery and cosmetics. The process of diversification includes optics, food products and infant products. The trade brand is a competitive advantage already and attention focuses on brand loyalty.

- Strict control gives a comparative advantage of pharmaceutical products being competitive on international markets. There is a positive relationship between the degree of state supervision and the position in international trade of pharmaceutical products.

- Differences in national regulations give reasons for new trials or repeat trials in overseas laboratories. Standing teams of scientists are emerging instead of ad hoc groups to verify results according to national requirements in imported country.

- Using of computers is introduce for creation of databases with new formulas, as well as to analyze the results of clinical trials. We can assume the computers will find new formulas themselves for next generation of pharmaceutical products.

- A new profession is established - an internal auditor. With the process of outsourcing, the internal audit is separated as an activity from the external audit (World Health Organization, 2011). Internal audit is a part of quality control of pharmaceutical products. Given the social and economic importance of pharmaceutical industry, most countries adopt national policies under which manufacturers undertake to have a quality system, including an internal audit. Manufacturers of pharmaceutical products have the right to control suppliers and distributors, with the latter creating new structural units for internal audit.

State regulation of pharmaceutical products has the following effects on competitiveness:

- Diversification of pharmaceutical products is transformed into concentration on certain therapeutic categories. Individual pharmaceutical companies specialize in standardized products such as antibiotics and vitamins (Kirilov et al., 2011).

- Competitiveness, apart researches, is characterized by a new factor – the distribution. Revenues from sales were invested in researches for new pharmaceutical products.

- Obtaining a patent on a medicinal product by a competent authority gives relative advantages to the patent holder. There is a narrowing number of pharmaceutical companies with financial opportunities for investment in researches.

- The biotech companies have a leading position due to their specialization and use of new technologies in the USA. In order to preserve competitiveness, research activities are carried out in academic laboratories. In Germany and Switzerland, pharmaceutical companies purchase the results of external researches or enter into agreements to access scientific bases. The French strategy is a merger, for example between Rhone Poulenc and Rorer, to gain access to research facilities of both companies (European Commission, 1996). The maturity of the venture capital market in the UK defines a pharmaceutical industry of small pharmaceutical companies that remain

conservative to innovation and maintain a contractual relationship with local research institutes.

- Unlike other industries, the backward integration strategy in pharmaceutical industry is successful (Georgiev, 2013). The justifications for positive results are the existence of a patent for a new pharmaceutical product and the possession of a manufacturing authorization by a competent authority.

Venture capital. Stagflation in the 1970s, along with the oil shock and the crisis of US dollar, have changed the pharmaceutical industry. The escape of state from funding research results in entry of a venture capital. The ultimate effect is a quality change in the composition of pharmaceutical companies by entering new competitors mainly outside the USA.

Genetic engineering is at the heart of competitiveness. Knowledge of man and diseases determines the level of competitiveness and the direction of „rational design“ of pharmaceutical products (Daemmrich, Bowden, 2005).

Inorganic growth. The development of enzymology in the 1980s changed both the innovation process and the composition of research teams. To preserve their competitive advantage on the research market, pharmaceutical companies focus on marketing and sales on international markets. Exhaustion of organic growth opportunities for pharmaceutical companies has led strategies to inorganic growth in horizontal (mergers and acquisitions) and vertical (strategic alliances and franchise). Additional factors for the new direction are regulatory requirements, distribution options and increased healthcare costs. Reached closed production cycle brings the pharmaceutical product to ultimate user and isolates the pharmaceutical company from the impact of the market environment, which explains the anti-monopoly authorities' measures for transparency and good practices.

The market adapts to the resulting environment through the restructuring of wholesale and retail sales. With increasing scale of pharmaceutical companies, research spending is decreasing (Congressional Budget Office, 2006). State subsidies contribute for entry in market niches of new small companies specializing in genetics and genomics which taking on research into new pharmaceutical products. A competitive advantage is automation of production.

The wave of offshoring is observed in clinical trials and production, while process with large capital investment (discovery of new pharmaceutical products) remains in home country, i.e. in the country that has made the investments. A modern look at the action taken indicates that outsourcing enhances creativity in home country and reduces innovativeness in host country.

Maintaining the competitiveness of the national economy is a leading goal, and for first time the state regulation and safety requirements are seen as

contributing factors through discovery of new pharmaceutical products and marketing for increasing sales. A new point in competition is the management of stocks, wrongly called as a „logistics".

Globalization. Since the 1990s, discovery of new pharmaceutical products has been separated from the complex value chain as a stand-alone process. Relatively small companies specializing in genomics focus on discovering new pharmaceutical products and selling the license to large companies that have resources and teams to carry out clinical trials. The contractual relations are directed at scientific achievements in university and government laboratories, which later commercialize the product for the retail chain. Competitive advantages are determined by the allocation of resources and, to large extent, the determination of patent rights. The cost of licensing agreements are increasing and the pharmaceutical industry falls in spiral of specialization.

There is a parallel process of outsourcing to subcontractors. These activities are not related to investments in the discovery of new pharmaceutical products - clinical trials, laboratory services, biostatistical analysis, clinical packaging, relations with regulators and start of bio-production (Findlay, 2007).

Competitiveness is determined by the outsourcing of processes. The benefits of globalization are related to cost reductions by carrying out part of the activities in countries with relative advantages where, in addition to cheap labor, there is a large population for clinical trials and sales (Glickman, et al., 2009). For example, China and India have begun a process of adopting international good practices as well as progress in protecting intellectual property. Additional factor for competitiveness of these countries is related to their acceptance as members of international organizations, such as the GATT, as well as a change in the policy of host state regulators.

Parallel to the integration of the Far East into international good practices and participation in the complex value chain, a new process begins - a transition to a market economy in Eastern Europe. Offshoring becomes attractive in closer countries and begins a process of nearshoring. The basis of the new form of competitiveness is the level of quality, the reduction of duplication of trials and reporting, similar supervisory policies and the protection of copyright. In addition, a new risk, a reputational risk, associated with the trademark is reduced.

Global financial crisis. The years of liberalization (2000s) increase mergers and acquisitions beyond national borders. The upturn in the economy is reflected in the standard of living. The Far Eastern countries reach the technical achievements of the leading pharmaceutical states. Strengthening the middle

class internationally leads to an increase in health care costs, including for pharmaceutical products.

The withdrawal of the state from the market is offset by a quasi-supervisory entity - the stock exchange. A large number of new companies are entering the practice, whose speculative capital strengthens the number of patent applications filed. The public status of new entrants provides an additional source of data for the development of pharmaceutical innovations. The annual reports declared in stock exchange and the participation of research staff in the boards are considered as competitive advantages. The importance of auditors for the results is growing and the first scandals with unfair practices from leading audit companies are noted. The global financial crisis begins and the attention of the whole society is on the new challenges.

Enhancing competition in the pharmaceutical industry is a consequence of reducing red tapes globally. Adopting international good practices creates a unique landscape where certain pharmaceutical companies receive additional competitive advantages for easy location and relocation of business processes. The center of gravity directed on to the discovery of new pharmaceutical products and starts hunger for investment in research activities. In order to maintain the profit level, mergers between the 20th leading pharmaceutical companies were held in response to the expiry of patents (Ministry of Health, Labor and Welfare, 2007).

New reality. At the beginning of the 21st century, the global financial crisis had an impact on the pharmaceutical industry. Pressure is mainly on R&D, the cycle of which becomes longer, more expensive and more risky. The increased requirements for reveal of data by supervisory authorities and taxpayers have obliged pharmaceutical companies to carry out more trials. The patient organizations demand greater burden of proof not only for the safety of pharmaceutical products but also for cost-effectiveness. New investments are needed to offset reduction of national health budgets. The competitiveness of a product depends on the efficiency of the processes that produce and maintain it (Filipova, 2005).

Successful offshoring strategies are being revised. The backshoring is a new strategic decision following offshoring due to changes in macroeconomic environment in host countries. Labor cost equalization in Far East reduce competitive advantages and business processes are return in the home country. Cross-border R&D, which was on a contractual basis with universities in the host country, is integrated already into the home country of pharmaceutical companies. National health insurance authorities are competent for competition in local markets. To preserve competitive positions in 2012, the European Commission adopts a re-industrialization strategy based on backshoring, reshoring and nearshoring (European Commission, 2012).

CONCLUSIONS AND RECOMMENDATIONS

Contemporary competitiveness is define by external factors and, to greater extent, involving the state as a supervisor and the contributions from other sciences. There is a path dependence in dynamics of competitiveness in pharmaceutical industry - spillover effects from each development period. We can say that the competitiveness is similar in terms of the importance of the chemical element Mercury (Hg 80), a metal in a liquid form, which is either useful or harmful, depending on the historical period of use.

The essential role of the pharmaceutical industry in health care determines its responsibility to society. The interests of pharmaceutical companies are subordinated to patients' interests. The social contract in the new reality calls for a new look at competitiveness: in the pharmaceutical industry is applicable J. B. Say's law* (producer's decision take priority over buyer's need) and not that the views of A. Smith and D. Ricardo (the buyer's demand determines manufacturer's supply). The countries' absolute advantages (A. Smith) and comparative advantages (D. Ricardo) are not appropriate for the competitiveness in modern period - *Industry 4.0*.

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* „Supply constitutes its own demand", Jean-Baptiste Say (Traité d'économie politique ou simple exposition de la manière dont se forment, se distribuent et se composent les richesses, 1803)

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