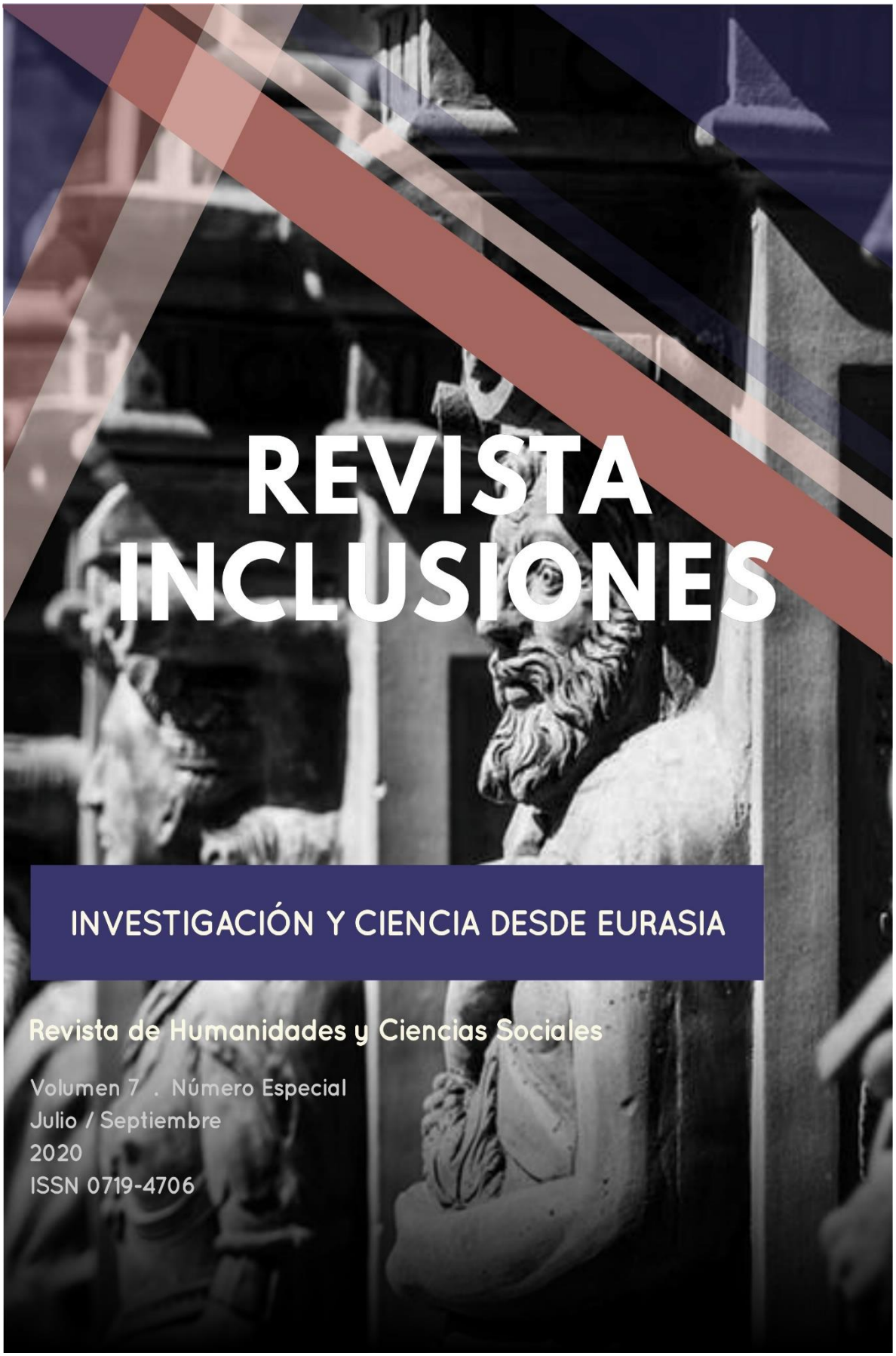

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COMPETITIVENESS IN PHARMACEUTICAL INDUSTRY: PARTICIPANTS IN SUPPLY SIDE AND DEMAND SIDE

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Abstract

The objective of the article is to explore the competitiveness of the pharmaceutical industry through supply and demand participants. We establish that the state policy for prioritizing the interests of the participants creates a temporary situation (a quasi-balance) called competitiveness. The regulatory authority plays a leading role in competitiveness by seeking the center of gravity of participants' interests. The results of the article indicate that participants have multiple roles. Particular attention has been paid to the State and its involvement in both the supply side and demand side of pharmaceutical products. The State's participation in competition in the pharmaceutical industry must be reduced and directed at the competitiveness of the State.

Keywords

Pharmaceutical products – Welfare economics – Market structure

Para Citar este Artículo:

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Introduction

The functioning of market principles involves a variety of stakeholders whose interests are often not aligned[1]. Therefore, when considering competitiveness, the structure of supply and demand must be taken into account[2]. In the pharmaceutical industry, for example, stakeholder behavior not only determines their differing interests in terms of costs and prices, but also determines the convergence of interests related to innovative and effective pharmaceutical products. A characteristic feature of pharmaceutical industry is that considerable attention is paid to the demand for pharmaceutical products due to their co-payment by the patient and the health insurance system[3] and relatively little attention to the supply of such products[4]. One of the reasonable explanation is that, unlike other healthcare markets, globally, pharmaceutical supply is primarily a private activity[5].

Supply side of pharmaceutical products

The scientific literature indicates that, in connection with the supply of pharmaceutical products, it is important to reflect two factors that are more important:

- the peak of research and development (R&D), as well as the associated costs and the need to protect the intellectual property;
- the impact of state regulation on competition between original and generic pharmaceuticals, as well as the difference in their prices. It should be noted that more attention is paid to generic pharmaceuticals due to their positive impact on the health budget.

Manufacturers

In terms of supply, two groups of manufacturers can be identified according to the business models used:

- Original pharmaceutical products. Their focus is on research into developing new pharmaceutical products, conducting clinical trials, and patenting pharmaceutical products and brands. Their strategy is to create new pharmaceutical products or compete with pharmaceutical substitute products, taking advantage of patent protection that offsets development costs while making innovations public[6] (for competition before and after the

[1] Miroslav Nedelchev, “Remuneration of Executive Directors: Stages of Development”, Economics and Management Vol: XIII num 2 (2017).

[2] European Commission, Competition Enforcement in the Pharmaceutical Sector (2009-2017). Brussels, COM (2019) 17 final. Brussels. 2019. (26.03.2020) https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf

[3] Nigel Gregson, Keiron Sparrowhawk, Josephine Mauskopf and John Paul, “Pricing Medicines: Theory and Practice, Challenges and Opportunities”, Nature Reviews Drug Discovery Vol: 4 num 2 (2005).

[4] Panos Kanavos, Joan Costa-Font and Alistair McGuire, “Product Differentiation, Competition and Regulation of New Drugs: The Case of Statins in Four European Countries”, Managerial and Decision Economics Vol: 28 No 4-5 (2007): 455.

[5] Livio Garattini and Anna Padula, “Competition in Pharmaceuticals: More Product Than Price-Oriented?”, European Journal of Health Economics Vol: 19 num 3 (2018).

[6] European Commission, Communication from the Commission Executive Summary of the Pharmaceutical Sector Inquiry Report. SEC (2009) 952. Brussels. 2009. (26.03.2020) https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

patent expires[7]). Thus, intellectual property protection creates interest for manufacturers to remain in the market segment, i.e. existing competition is increasing and new competitors are being attracted.

- Generic pharmaceutical products. They offer a generic version of the original product at a lower price after its patent expires. Their strategy is to compete in a market already created by the original pharmaceutical product. It is common practice for manufacturers of original pharmaceuticals to set up their own generic businesses to diversify their risk structure and benefit from new geographic markets[8]. The main stakeholders in the manufacturing of generic pharmaceutical products are patient organizations, budgetary authorities and health insurance systems.

In some cases, manufacturers combine the two business models and integrate forward to create their own marketing, advertising and distribution businesses.

Unlike other commercial sectors, integration forward into the pharmaceutical industry aims to establish strong positions for the first stage of production - R&D, which involves developing a separate business strategy for each type of product - both original and generic.

Depending on production methods, competition can be between:

- traditional pharmaceutical products (original and generic). The competition between them is mainly driven by the path dependence of the first-in-first-out principle. In this case, mergers and acquisitions reduce the importance of the individual manufacturer and only the brand is important.

- biological (biosimilar) pharmaceutical products. Due to their innovative nature and distinctive characteristics, biosimilar pharmaceuticals have their own areas of competition, specific marketing and a separate price structure. Their production diminishes the importance of resources and experience in determining competition. Their production diminishes the importance of resources and experience in determining competition. Characteristic of biological pharmaceutical products compared to generic pharmaceutical products are the more complex process of developing a molecule, the higher R&D costs, the significant risks of obtaining a marketing authorization and the specific requirement for launch by a competent authority. The main advantages of biological pharmaceutical products over original pharmaceutical products are lower R&D costs, shorter time to develop and test new products, and lower prices. Unlike generic pharmaceutical products, they are patented and their intellectual property is protected, and in some countries, it is mandatory for them to carry out clinical trials prior to launch. The main stakeholders in the manufacturing of such products are health insurance systems, given their lower prices, as well as patient organizations, due to the possibility of quick access to new pharmaceutical products.

These advantages, combined with the innovativeness of biosimilar pharmaceutical products, increase competition in the pharmaceutical industry. Progress in economic thought in terms of adding value to the product goes beyond production strategies of the

[7] Fabio Pammolli; Laura Magazzini and Luigi Orsenigo, “The Intensity of Competition after Patent Expiry in Pharmaceuticals. A Cross-Country Analysis”, Revue d'économie industrielle num 99 (2002).
[8] European Commission, Communication from... (26.03.2020) https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

past.[9] That is why, in some cases, government measures are even envisaged to support their launch[10]. A number of national competitiveness policies in this area, including those aimed at overcoming the effects of the global financial crisis[11], are based on biosimilar pharmaceutical products. A good practice in this respect is the adoption of the Lisbon strategy for economic, social and environmental renewal in the European Union (2000), based on the knowledge economy[12].

Nowadays, the actions of pharmaceutical companies are strongly influenced by the so-called Icarus' paradox, which is mainly reflected in the following directions[13]:

- Very often, a biotechnology company is acquired by a manufacturer of original pharmaceuticals for risk diversification[14].
- In limited cases, the manufacturer reduces internal competition by creating separate subsidiaries for both traditional and biosimilar pharmaceuticals.

Following the effects of global financial crisis, there is increased competition among manufacturers for supply[15]:

- personalization of pharmaceutical products according to the patient's health profile[16];
- innovations in molecular biology, genetics and genomics;
- creation of vaccines caused by globalization and the increased movement of human resources between different countries and continents[17];
- raising public funds for the development of enzymology[18].

The state and its institutions now play a significant role in competition, prioritizing the interests of individual participants. However, the new reality requires that this involvement

[9] Raya Madgerova; Vyara Kyurova and Anny Atanasova, “Application of the Lean Concept as a Prerequisite for a Tourist Business Development”, Economic processes management: International Scientifil E-journal Vol: VII num 4 (2016).

[10] European Parliament, Options for Improving Access to Medicines. European Parliament resolution of 2 March 2017 on EU options for improving access to medicines, 2016/2057(INI). Brussels. 2017. (26.03.2020) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017IP0061

[11] Radostina Yuleva, “Competitive Advantages and Competitive Strategies of Small and Medium-Sized Enterprises”, Economics and Management Vol: XVI num 1 (2019).

[12] European Medicines Agency, The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future. Doc. Ref: EMEA/H/34163/03/Final. London: European Medicines Agency. 2005. (26.03.2020) https://www.ema.europa.eu/en/documents/report/european-medicines-agency-road-map-2010-preparing-ground-future_en.pdf

[13] Danny Miller, “The Icarus Paradox: How Exceptional Companies Bring About Their Own Downfall”, Business Horizons Vol: 35 No 1 (1992): 24.

[14] European Commission. Communication from... (26.03.2020) https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

[15] Raya Madgerova, “Economic Growth and Competitiveness of Small and Medium-Sized Enterprises”, Economic Thought num 5 (2003).

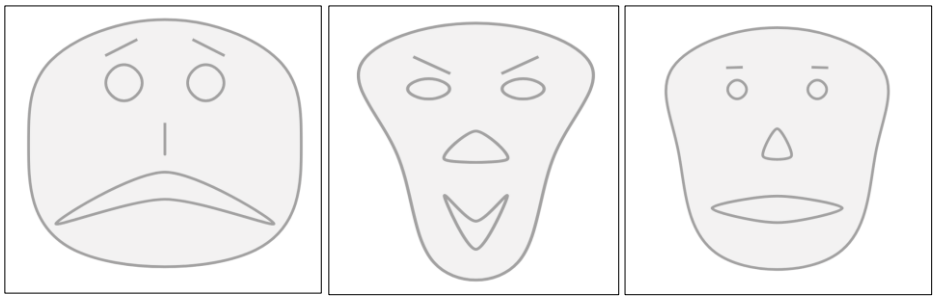
[16] European Commission, Pharmaceutical Sector Inquiry. Preliminary Report DG Competition Staff Working Paper. Brussels. 2008. (26.03.2020) https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

[17] Dragomir Nedeltchev, Sotsiologiya na evropeĭskata integratsiya (Sofia: Academic Publishing “M. Drinov”, 2001).

[18] Elina Petrova, “Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development”, In Innovation and Marketing in the Pharmaceutical Industry, eds. Min Ding, Jehoshua Eliashberg and Stefan Stremersch (New York: Springer, 2014).

be reduced at the expense of non-governmental organizations, and regulation should not be seen as a mirror of competition. In the pharmaceutical industry, the new role of the state should include determining the trajectory of competitiveness depending on the different types of pharmaceutical products. In this regard, it is very important for the state to maintain its image of targeting to high R&D costs or to low pharmaceutical prices, and this should become part of the overall government policy.

Each country builds an image according to its policy of prioritizing the interests of participants in the demand and supply of pharmaceutical products. The difference in individual policies is shown at Figure 1 by using of the Chernoff's faces[19]. This technique has advantages in the comparative analysis of multidimensional competitors (Figure 1).



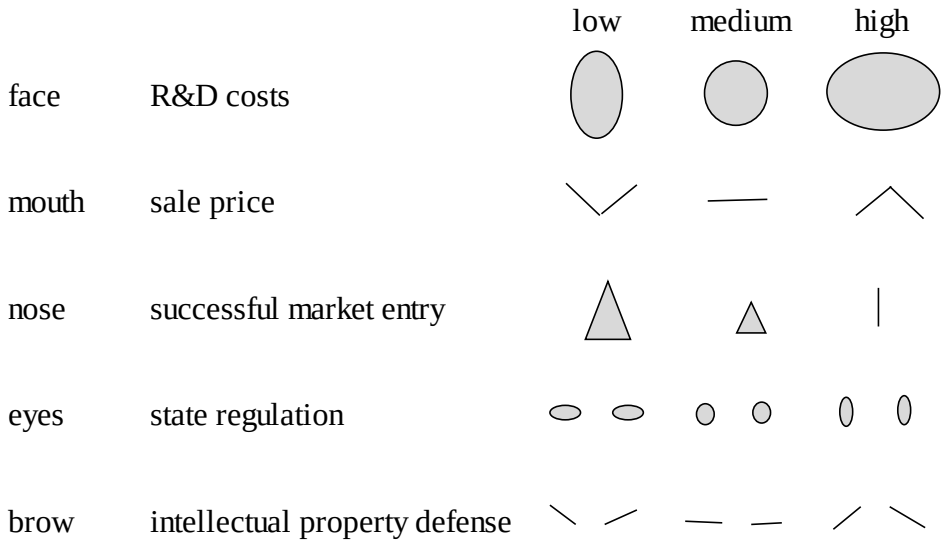
original pharmaceuticals generic pharmaceuticals biological pharmaceuticals

Source: Author's own construct by using of https://gramener.com/faces

Figure 1

Competitiveness of countries, based on different pharmaceutical products

Legend:



[19] Herman Chernoff, “The Use of Faces to Represent Points in K-Dimensional Space Graphically”, Journal of the American Statistical Association Vol: 68 num 342 (1973).

'Friendly faces' depict countries that have chosen a competitive policy based on low R&D costs and low sales prices. For example, Canada and its social focus on the distribution of taxes may be attributed to this group of countries. At the other extreme are countries that focus on competitiveness based on high R&D costs and high sales prices. One example is the United States of America, one of the leading countries in innovative activities related to large investments and risk and therefore high returns[20]. Given the differences in costs and prices of pharmaceutical products, the two countries have different competitive policies, including on the movement of resources across borders.

Physicians

In the course of treatment, physicians offer a particular pharmaceutical product, depending on a number of factors: degree of education, access to information, availability of a health insurance system and patient organizations. They are involved only in the supply of prescription pharmaceutical products and those listed in the health insurance system reimburse list. Physicians are unrelated to price competition and their behavior is determined by the efficacy and availability of the pharmaceutical product, i.e. by competition between manufacturers or between brands.

Like all health professionals, the activity and number of physicians are subject to regulation by a competent authority, and their number is defined as a "collective monopoly"[21]. State control covers access to the profession and the guarantee of minimum quality[22]. At the same time, restrictions on the practice of the medical profession, as well as the need to follow established procedures when prescribing a pharmaceutical product, narrows the choice for physicians, and their personal preferences and tastes remain in the background.

Distributors

Through their status of negotiating prices and terms of sale, wholesale distributors largely determine sales volume. These distributors also include the hospital market, with the remark that it offers only prescription pharmaceutical products or products listed in the health insurance system reimburse list[23].

Retailers (pharmacies) are involved in the supply by selling a variety of pharmaceutical products and advising consumers on differences in prices and effects. At the same time, the development of the IT industry is creating new channels for the direct and online distribution of pharmaceutical products such as online pharmacies and mail order pharmacies. An example is the joint venture between Sanofi and Google, which provides medical services and pharmaceutical products through the Google platform[24].

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[20] United States House of Representatives, Prescription Drug Prices. Congressional Record, H2701–H2702, 6 May 2004. (26.03.2020) https://www.govinfo.gov/content/pkg/CREC-2004-05-06/pdf/CREC-2004-05-06.pdf

[21] Reuben Kessel, “Price Discrimination in Medicine”, Journal of Law & Economics num 1 (1958).

[22] Kenneth Arrow, “Uncertainty and the Welfare Economics of Medical Care”, American Economic Review Vol: 53 num 5 (1963).

[23] Lalka Borisova, “Balanced Scorecard in the Organization”, Entrepreneurship Vol: V No 1 (2017): 66.

[24] Commission Decision of 23/02/2016 declaring a concentration to be compatible with the common market (Case No COMP/M.7813 - SANOFI/GOOGLE/DMI JV) according to Council Regulation (EC)

Due to their numerous variations in different countries, distributors have not yet been sufficiently studied as participants in the supply process. Nowadays, pharmacies are increasingly playing a role in enhancing the competitiveness of the pharmaceutical industry, largely due to their direct relationship with the patient, consumer traditions and loyalty to a particular pharmacy chain and brand as well as the choice of price, taking into account the capabilities and taste preferences of customers. Last but not least, patients often perceive pharmacists as having easy and free access to professional medical services and advice.

State regulation

State regulation of pharmaceutical products has a short history, but it has sufficient experience to strike a balance between the goals of state policies and the interests of participants in supply side. It is widely believed that there are conflicts and contradictions between the different goals of state regulation, but there are cases where all the goals are achieved. Although limited, these cases reflect the state's leading role in improving the competitiveness of the pharmaceutical industry and are evidence of its ability to shift the center of gravity either to controlling R&D costs or to controlling prices for patients and health insurance systems.

In addition to protecting patients, state regulation aims to guarantee high quality and maintain optimal prices in the pharmaceutical industry. These objectives apply to both pharmaceutical products and participants in the supply process:

- Achieving good quality in the pharmaceutical industry is of paramount importance for the development of statehood and is focused mainly on pharmaceutical products.
- The transition to mass production of pharmaceutical products extends the scope of state regulation - it also covers the quality of supply participants.
- A new objective related to state regulation - price control - has been added to the introduction of health insurance systems and the use of other public funds to guarantee affordable prices for pharmaceutical products[25].
- The globalization of the pharmaceutical industry adapts state regulation to control costs, retain manufacturers, and attract R&D investors.

State regulation is primarily aimed at protecting citizens[26]. In addition to granting product quality approval to be launch, the state also regulates consumer information. In this regard, steps should be taken to reduce information asymmetry, introduce strictly established reimburse rules and mandatory insurance that will balance the patent monopoly granted. The main problem with this type of control is to determine the optimum levels of R&D and product diversity so that the wealth of the community is achieved[27]).

In this context, it may be recommended to complement the role of state regulation by controlling the direction of innovation. Putting such control in the hands of pharmaceutical companies, can lead to artificial use of innovation for the sake of return on investments and

No 139/2004. 2004. (26.03.2020) https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016M7813

[25] Tatyana Hubenova. “Trends in Declining Profit Margins”, Economic Thought No 9 (1987): 23.

[26] Vyara Kyurova, “Assessment of the Innovation Activity of the Entrepreneurial Business”, Economics and Management Vol: IX num 3 (2013).

[27] Peter Younkin, Making the Market: How the American Pharmaceutical Industry Transformed Itself During the 1940s. (Berkeley: University of California, 2008).

will have little effect on healthcare. That is why not only public resources but also private investments must focus on innovation that is of greatest benefit to society.

A common feature of all state control systems is their focus on quality, and the main instruments of state regulation are compliance with good practices[28] and the introduction of quality management systems[29]. The globalization of the pharmaceutical industry requires countries to transform their control policies - the largest initiative in this regard is the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Since 1989, the European Union, Japan and the United States of America have begun to unify their requirements for the launch of a new pharmaceutical product, but although some progress has been made, issues regarding the mutual recognition of approval remain to be addressed.

The new approach to state control is leading to radical transformations in the pharmaceutical industry. In parallel with the increase in costs and the extension of time limits for the development of new pharmaceutical products, there is no increase in the number of new patents. Increased oversight requirements create new professions - experts for regulatory affairs and compliance officers. Specialization of the competent authorities in accordance with the practices in the pharmaceutical industry begins - manufacturing and distribution remain at national level, while the development of new pharmaceutical products and clinical trials are internationalized. Responsibility between the competent authorities of both the home country and the host country has already been shared.

The wave of mergers and acquisitions in the 1980s has diminished the importance of national policies, and globalization has led some scholars to argue that the supply of pharmaceuticals is oligopolistic[30]. Contemporary competition involves new strategies, such as horizontal pricing agreements and monopoly profits[31] that radically change competition rules and adapt supervisory practices to changes in the external environment. It is from here that arguments can be drawn in support of the process of convergence of national policies[32]. The main difficulty in exercising state regulation is because one or more mega-structured authorities combine several roles. This situation leads to low efficiency and creates a negative perception of the state's ability to compete with other countries and to create wealth.

[28] Assena Stoimenova; Bogdan Kirilov and Krassimira Zaykova, “Analysis of Good Distribution Practice Inspection Deficiency Data of Pharmaceutical Wholesalers in Bulgaria”, Pharmacia Vol: 66 num 3 (2019).

[29] Sauwakon Ratanawijitrasin and Eshetu Wondemagegnehu. Effective Drug Regulation. A Multicountry Study (Geneva: World Health Organization, 2002).

[30] Álvaro Zerda; Germán Velásquez, Federico Tobar and Jorge Vargas, Health Insurance Systems and Access to Medicines. Case studies from: Argentina, Chile, Colombia, Costa Rica, Guatemala and the United States of America (Washington: Pan American Health Organization, 2001). (26.03.2020) https://apps.who.int/medicinedocs/en/d/Jh3012e/

[31] UNCTAD, The Role Of Competition In The Pharmaceutical Sector And Its Benefits For Consumers. Seventh United Nations Conference to Review. All Aspects of the Set of Multilaterally Agreed. Equitable Principles and Rules for the Control of Restrictive Business Practices. Geneva, 6–10 July 2015. 2015. (26.03.2020) https://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf

[32] Eduard Marinov, “Economic Determinants of Regional Integration in Developing Countries”, International Journal of Business and Management Vol: III num 3 (2015).

Demand side of pharmaceutical products

Demand for pharmaceuticals is part of the healthcare system and, like other health products, stems from the demand for health itself[33]. On the health market, incl. in the pharmaceutical market, the patient is not independent in the choice, payment and consumption of the product.

The uniqueness of demand in the pharmaceutical industry is due to the role of each participant in the treatment process[34]. The patient is the ultimate user of the pharmaceutical product and is different from the prescribing physician who decides on the choice of pharmaceutical product and from the health insurance system that pays for it. Each participant's interests and functions lead to low price sensitivity of the product for patients and prescribing physicians, and participation of the health insurance system reduces the difference between the purchasing power of patients and the prices of individual pharmaceutical products.

The relationships in this "unique constellation"[35] are compounded by market imperfection caused by the asymmetric distribution of information between the patient and other participants. The end effect is price inelasticity, even when the overall size of market is growing, enabling the recovery of R&D costs and maintaining the interest of manufacturers in the market segment, incl. attracting investments to develop new products. The price inelasticity of pharmaceutical products, the possibility of their replacement and the need for large resources for the development of new products are the leading motives behind the argument that "competitiveness" in its traditional form cannot be applied to the pharmaceutical industry.

Each participant in the complex pharmaceutical chain for product demand takes into account the opinion of the previous participant and tries to guess the course of the next[36].

Patient

The main generator of demand for pharmaceutical products is the patient. He is both a start and a final participant, paying the cost of treatment alone or sharing the cost with the health insurance system. The patient entitle the right to the treating physician to decide on the choice of pharmaceutical product - this delegation is justified by the expertise and ethics of the medical profession.

Depending on the presence or absence of a health insurance system, two situations are possible:

- In the first case, the prescribing physician does not consider price as a factor in the process of choosing a pharmaceutical product. In such situations, competition between original and generic pharmaceutical products arises.

[33] Stuart Schweitzer, Pharmaceutical Economics and Policy (Oxford: Oxford University Press, 1997).
[34] European Commission, Pharmaceutical Sector Inquiry... (26.03.2020) https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf
[35] Rafael Bauschke, “The Effectiveness of European Regulatory Governance: The Case of Pharmaceutical Regulation” (PhD thesis in Ruprecht-Karls-Universität Heidelberg, 2010).
[36] Nigel Gregson; Keiron Sparrowhawk; Josephine Mauskopf and John Paul, “Pricing Medicines...

- In the absence of a health insurance system, the pharmacist may substitute the prescribing physician and to change his choice with another pharmaceutical product, taking into account the availability of the products and the current promotions. Then a competition between retailers comes to the fore as well as between prescription-only pharmaceutical products and over-the-counter pharmaceutical products. The price of an over-the-counter pharmaceutical product is not reimbursed by the health insurance system, i.e. the patient pays in full, and competitiveness is viewed similarly to that of the branded goods market[37] (unlike the branded goods, 90% of pharmaceutical products have a substitute[38]).

The treatment process is determined by the information the patient has about the efficacy of the pharmaceutical product. The key to proper treatment is the patient's health literacy[39] and his awareness of his rights in the healthcare system. A major factor in awareness is the packaging of the pharmaceutical product, as it enables physicians, patients and pharmacists to benefit from the experience and the established public image of a brand, and last but not least - because of the possibility of reimbursement of medical expenses from the health insurance system for specific packaging only. The packaging contributes to the formation of brand loyalty and is a leading factor in the conduct of advertising and marketing campaigns.

For the accuracy and relevance of our study, in addition to patients, patient organizations should be considered. The legal regulation of these organizations also determines their involvement in the demand for pharmaceutical products - non-governmental organizations that are independent of the budget and the economic situation in the pharmaceutical industry. Largely, the improvement of transparency and accountability in the pharmaceutical industry is due to the existence of patient organizations. In most cases, they balance government regulation and, from that point of view, has been reduced their importance throughout the healthcare system, including in the pharmaceutical industry.

Prescribing physician

The physician's motive in choosing a pharmaceutical product defines him as a supplier of pharmaceutical products, and the relationship with the patient based on trust characterizes pharmaceutical products as 'credence goods'[40]. The physician, along with other healthcare providers, determine the competitiveness of the pharmaceutical industry by demand of pharmaceutical products. Professional skills and ethical responsibility define the prescribing physician as a participant who choose the pharmaceutical product. Because the patient relies on the expertise of the physician, there is an information asymmetry between them. Hence the practice of pharmaceutical companies to keep in touch with physicians. In most cases, this relationship has a form of financial incentives for the prescribing physician, so criticisms of a conflict of interest between the pharmaceutical industry's financial goals and the physician's professional obligation to prescribe the most effective among competing products/manufacturers are often well founded.

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[37] OECD, Competition and Regulation… (26.03.2020) https://www.oecd.org/daf/competition/sectors/1920540.pdf

[38] John Lu and William Comanor, “Strategic Pricing of New Pharmaceuticals”, The Review of Economics and Statistics Vol: 80 num 1 (1998).

[39] Lorena Balili, “Analyzing Competition in Pharmaceutical Sector – With a Case Study of Albania”, European Scientific Journal Vol: 12 num 15 (2016).

[40] Aditya Bhattacharjea and Fiyanshu Sindhwani, Competition Issues in the Indian Pharmaceuticals Sector (Delhi: Delhi School of Economics, 2014).

Physicians are an important factor in the demand for pharmaceutical products, especially in countries where health insurance systems have wide cover. In such situations, when prescribing a pharmaceutical product, the physician is guided by his experience[41]. Peter Temin presents another point of view: in the choice of an appropriate pharmaceutical product, the physician is guided by the custom in the peer community of prescribers due to a lack of ready and well-organized information on the comparative effectiveness and riskiness of substitute pharmaceutical products[42].

Pharmacist

The pharmacist directly affects the financial effects of the treatment. Unlike the other participants in the demand for pharmaceutical products, he performs more than one role - acting both as salesperson and as consultant on the effects and duration of treatment. In some countries, the pharmacist has additional functions - to decide on the choice of pharmaceutical product or to switch the decision of the prescribing physician, as well as to inform the competent authorities about the side effects of the pharmaceutical product. These functions are often contradictory, with trade motives being preferred in some cases.

The pharmacist has a strong influence on both the patient's health and the formation and spending of the public budget. He can have a serious impact on the demand for pharmaceutical products, since he has the potential to switch a pharmaceutical product with another or original pharmaceutical product with a generic one, i.e. to offer a cheaper pharmaceutical product of the same quality or a pharmaceutical product from the insurance system reimburse list[43]. At the same time, the pharmacist may also influence the physician's decision, causing him to switch the prescribed pharmaceutical product to another one.

In specific cases, demand in the pharmaceutical industry is assessed as an indicator of two complementary markets - pharmaceutical products provided by a pharmaceutical manufacturer and pharmacy services provided by a pharmacist, the second being more dynamic than the first because it is closer and recognizable to the patient.

Health insurance system

Demand for pharmaceutical products is also influenced by the availability of a health insurance system[44] (regulation, competition and system for health insurance define the incentives and constraints on choice for optimal patient's health and wealth[45]). Regardless of national specifics, each health insurance system is an insurer that takes on some or all of the cost of a pharmaceutical product purchased. After the introduction of health insurance systems, the issue arises of their effectiveness, with the prevailing view being that they should only bear part of the cost. Given the transparency and accountability of health insurance systems, they are often the subject of political and public debate regarding the

[41] Judith Hellerstein, "The Importance of the Physician in the Generic versus Trade-Name Prescription Decision", The RAND Journal of Economics Vol: 29 num 1 (1998).

[42] Peter Temin, Taking Your Medicine: Drug Regulation in the United States (Harvard: Harvard University Press, 1980).

[43] ECORYS Nederland BV, Competitiveness of the EU Market and Industry for Pharmaceuticals. Volume I: Welfare Implications of Regulation. Rotterdam. 2009. (26.03.2020) https://op.europa.eu/en/publication-detail/-/publication/2c28ce31-3630-40e6-9743-006864229bf4

[44] OECD, Competition and Regulation… (26.03.2020) https://www.oecd.org/daf/competition/sectors/1920540.pdf

[45] Patricia Danzon and Li-Wei Chao, "Does Regulation Drive out …

financial system and the tax burden on society. In some cases, in addition to the state, the employer has contracts with private health funds, which is a major advantage for competitiveness in the labor market and a factor for improving employees' social packages. Competition in pharmaceutical prices is driven, in particular, by differences in health insurance systems across countries, including methodologies for admission to the national market and for obtaining authorization to be included in the reimburse list. It is the health insurance system that may lead to the emergence of parallel trade and re-export of pharmaceutical products to other countries, which will not only distort the competitive picture at macro level, but also will lead to temporarily migrate patients and know-how. The end effect is the polarization of the world and its division into countries aimed at achieving competitiveness based on the cost of R&D and pharmaceutical manufacturing, and countries pursuing a policy of import dependency and pharmaceutical price regulation.

Hospital market

Hospital market determines the wholesale prices for pharmaceutical products. It takes advantage of its scale by auctioning and negotiating the prices of pharmaceutical products. This market has a great impact on competition not only between original and generic pharmaceutical products, but also between brands and manufacturers. Due to the scale of consumption, manufacturers pay particular attention to the hospital market when developing new pharmaceutical products and conducting clinical trials. The hospital market is also a leader in educating physicians and conducting research on the effects of treatment. The main difficulty in analyzing the competitiveness of the pharmaceutical industry is the limited freedom to choose a prescription pharmaceutical product, as well as the removal of the pharmacist from the demand chain, including its trade, consultancy and marketing functions. Another difficulty is the marketing of only prescription-only pharmaceutical products and those on the health insurance system reimburse list. To limit these effects, transparency and accountability to patient organizations and the health insurance system must be increased. At the same time, government intervention in the hospital market is needed to reduce its impact on the public budget by introducing preferences for cheaper pharmaceutical products. However, such interference poses risks because it may distort competition between original and generic pharmaceutical products[46].

State regulation

State regulation affects all participators and performs several roles, the ultimate goal being to comply with the framework set by the government, including financial goals[47]. It is made visible to society, in particular, by retail prices of pharmaceutical products, which maximum levels are set by the State by imposing or negotiating prices[48]. The existence of state regulation of pharmaceutical prices is justified in terms of consumer protection and the imposition of fair prices[49]. However, compliance with fiscal discipline through price controls

[46] OECD, Competition and Regulation… (26.03.2020) https://www.oecd.org/daf/competition/sectors/1920540.pdf

[47] Spartak Keremidchiev, “Local Production Network and Governance: A Comparative Study of the Footwear Industry in Bulgaria and Poland”, Problems of Geography num 1 (2009).

[48] Álvaro Zerda, Germán Velásquez, Federico Tobar and Jorge Vargas, Health Insurance Systems… (26.03.2020) https://apps.who.int/medicinedocs/en/d/Jh3012e/

[49] Copenhagen Economics, Study on the Economic Impact... (26.03.2020). https://op.europa.eu/en/publication-detail/-/publication/8ffeb206-b65c-11e8-99ee-01aa75ed71a1/language-en/format-PDF

has a short-term effect, but in the long run, it can lead to new market niches and forms of competition.

State regulation affects public health care and the health insurance budget. Often, government policies contain goals that overlap and compete[50]. Finding a balance between different goals affects not only the final prices, respectively the interests of patients, but also the cost of manufacturing pharmaceutical products, i.e. it is important to stimulate the motivation for developing new pharmaceutical products. Through regulation, the state can attract but also discourage investors and researchers, as well as manufacturers and patients. A compromise between the interests and behavior of participants in the demand for pharmaceutical products shapes competition in the pharmaceutical industry and is of great importance to the image and competitiveness of the state. Significant in this respect is that countries that devote a significant share of GDP to R&D and intellectual property protection have built the image of leading in developing pharmaceutical products and countries with strong social policies aimed at maintaining low prices through budget subsidies.

One form of balance between the various goals of state regulation is the control of access to the market for safe, quality and effective pharmaceutical products. This form of balance is intended to balance the costs of both participants in the initial stage of the demand process (research centers for new pharmaceutical product development and clinical trials) and end-users (manufacturers, distributors, patients and health insurance systems).

Another form of government regulation is that only persons with specialized knowledge or needs are allowed to enter the market, and control of participants can be preliminary, current and final. *Ex-ante* control takes into account the resources of the participant, for example: the number of patents for research centers when developing new pharmaceutical products; training and specialization of physicians; the patient's purchasing power or participation in the health insurance system. The purpose of the on-going control is to monitor the actions of participants in the process of demand of pharmaceutical products and compliance with the budgetary framework. The task of *ex-post* control is to protect the interests of the individual participants and to coordinate the incentives for each of them regardless of their opposite views, especially regarding the price of pharmaceutical products.

The demand process for the pharmaceutical market is distorted[51]. The multiplicity of participants, as well as the fundamental differences in their interests, determine the uniqueness of competitiveness in the pharmaceutical industry. Unlike other industries, state regulation here does not completely solve the puzzle of participants, since each of them has a different influence in competition and forms its own part of the competitiveness of the industry. In most cases, however, the biggest non-compliance of opinion is related to the pricing of pharmaceuticals.

Participants and their interests in the search process create a "combined effect"[52] that shapes the competitiveness of the pharmaceutical industry. The "vagaries" (the

[50] Claudia Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade (Rotterdam: Erasmus Universiteit, 2010).
[51] Panos Kanavos; Joan Costa-Font and Alistair McGuire, "Product Differentiation…
[52] OECD, Competition and Regulation… (26.03.2020) https://www.oecd.org/daf/competition/sectors/1920540.pdf

uncertainty of the R&D process when developing new pharmaceutical products) and the high costs of R&D assigns a subordinate role to the opinion and involvement of the primary stakeholder in the demand for the pharmaceutical market - the patient. However, it should be emphasized that conducting a study by eliminating one of the participants in the demand process cannot determine whether wealth and prosperity are improving overall - the analysis can only cover individual interests for costs, prices and profits.

Conclusion

As a contrast to competition, competitiveness emerges as jargon in the political vocabulary and seeks its place in the economics. Its implementation in the pharmaceutical industry depends on sound decisions regarding the use of state resources - whether they are directed to R&D and manufacturing costs, or to prices for the import and distribution of pharmaceutical products. By using social instruments such as the health insurance system and macroeconomic indicators (employment and standard of living), the State is able to balance the interests of participants for a certain period, but this balance can be disturbed by a change in policy of another state or by innovation in the pharmaceutical industry. It is from the place of the center of gravity of this balance whether priority will be given to the interests of new product developers and manufacturers, or to the distributors and patients.

Competitiveness in the pharmaceutical industry is judged on its impact on society and especially on the creation of wealth and health for the society, but unfortunately, its spillover effects are difficult to measure and are therefore poorly studied (for example, clinical trials create a new insurance service, and innovation provides equal access to health care and knowledge). Due to the spillover effects, competitiveness is more commonly used in politics and to a lesser extent in the economics. However, despite political promises, research and clinical research continue to be international and manufacturing, distribution and regulation remain national.

Last but not least, competitiveness in the pharmaceutical industry contributes to the growth of macroeconomic indicators such as employment and life expectancy. Thus defined, it alters traditions and tastes in many countries in line with good practices in the few countries with high competitiveness in the pharmaceutical industry.

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