

Objective determination of pharmaceutical product in transition countries

Abstract: The value of a pharmaceutical product is a complex category exceeding the level of physiological needs, although it stems from maintaining or re-establishing the organism's normal functions. Moreover, not only does humanity's need to keep good health and extend their own lifespan exceed the resources that an individual or society can allocate, but also the quantum of human knowledge about the 'mystery of life' does not suffice to safeguard people from biological vulnerability and impermanence. The controversial issue is that there is no price we would not pay to stay (or become) healthy, as opposed to the fact that any price a company charges for its pharmaceutical product is excessive.

Key words: pharmaceutical market, pricing regulations, the cost of pharmaceutical products

JEL Classification System - A11, D73, I11, I18 , H51, H75, K32

OBJEKTIVES

The cost of pharmaceutical products is one of the key causes of controversy related to this industry. Numerous cultures have proverbs expressing the opinion that health is priceless or that health is the greatest wealth. What if health does have a price? One of the basic premises of marketing is that price should reflect consumer value. How can one measure the value of keeping good health or gaining it back? The objective need for health does exist. 'It's not like buying a Lexus-it's not something where you have a choice. People get angry because this is something that is critical, that they need, and companies are raising the prices so much.' (Mahan in Hawthorne, 2004, p. 46). The value of a pharmaceutical product is a complex category exceeding the level of physiological needs, although it stems from maintaining or re-establishing the organism's normal functions [1][2]. Moreover, not only does humanity's need to keep good health and extend their own lifespan exceed the resources that an individual or society can allocate, but also the quantum of human knowledge about the 'mystery of life' does not suffice to safeguard people from biological vulnerability and impermanence. The controversial issue is that there is no price we would not pay to stay (or become) healthy, as opposed to the fact that any price a company charges for its pharmaceutical product is excessive. Why? Because '...particularly in the case of health-care sector, where many persons consider access to health care a right of citizenship rather than an ordinary service (health service themselves) or an ordinary commodity (pharmaceuticals and medical devices).' (Vogel, 2004, p. 1331). Golec and Vernon (2007) point to the fact that an average consumer is willing to pay for the superior quality of high-tech products such as cell phones, computers or game consoles, but circumstances tend to change drastically when comes to an innovative patented pharmaceutical. Between the objective R&D cost of

innovative pharmaceutical products and the subjective perception of their value and the company's right to make a profit on them stands the pharmaceutical product's market price. Marketing has the responsibility to capitalize on the newly discovered knowledge translated into an innovative product, enable future R&D and achieve the pharmaceutical company's business objectives, bearing in mind the availability of the pharmaceutical and the public opinion (which is not favorably disposed to pharmaceutical industry's pricing policies). 'Drug costs (and change in drug costs) are visible to naked eye; identification of drug benefits requires careful analysis of good data.' (Lichtenberg in Hensley, 2003, p. 6). Advances in the quality of life, extended life expectancy and medical/therapeutic advances are undoubtedly evidence pro industry, but there is also the evident critical attitude to '... monopolistic pricing and high profits...' (Scherer, 2004, p. 927). [3] [4].

INTRODUCTION

Pharmaceutical industry and its products are an inseparable part of the healthcare system in which they function. In the opinion of Milburn *et al.* (2006), the past few decades of discourse on healthcare system are marked by three key issues: quality, cost and availability. The price of pharmaceuticals makes a direct impact on all three. The apparent logical response is to control prices of pharmaceuticals, i.e. to lower them. However, such a response is only a part of a complex equation which is supposed to provide a wide range and adequate quantities of pharmaceuticals, which requires maintaining the economic logic in their production, and at the same time, certain advances in finding more efficient, safer (and why not more agreeable) therapies. Such a requirement is objectively feasible in encouraging R&D within pharmaceutical industry. Most authors propose the unequivocal position that the past decades have seen a rise in the share of pharmaceutical costs in the total healthcare system expenditure⁷⁴ (Abbott, 1994; Lichtenberg 1996 and 2005; Calfee, 2001; Ekelund, Persson, 2003; Golec, Mossialos *et al.*, 2006; Vernon, 2007). The rise in the total expenditure on pharmaceuticals results from the introduction of more effective (therapeutically superior) products (Lu, Comanor, 1998; Calfee, 2001) and increased use of drugs (Calfee, 2000):

- for diseases for which adequate/appropriate therapy did not exist; and
- preventive therapies.

According to Calfee (2000), even in circumstances when the product's unit price is reduced, one can expect that '...applications expand and total expenditures increase.' (*ibid.*, p. 49). [5][6]. Another problem, which suggests that cost-cutting alone will not necessarily result in healthcare expenditure reductions, is also evident in the fact that during 2007, '...in terms of overall health spending, pharmaceuticals consume on average around 17%' in OECD countries (Health at a Glance 2007 – OECD Indicators, accessed November 2008). Interest in pharmaceutical price cuts will not cease. Upon the analysis of demographic trends, it can be expected that (on the average) elderly population will need more (and better) drugs. Viewing social trends which highlight prevention as well as better informed consumers and/or patients (and available information), pressures on healthcare system, however it may be financed, will increase. The most successful pharmaceutical companies operate globally, so that it is logical to expect that they will encounter different attitudes of both regulatory bodies and the

general public to their product pricing. The analysis of various factors influencing prices and pharmaceutical companies' pricing policies must always be viewed from the aspect of seemingly conflicting positions of different stakeholders [7].

Materials and Methods

Pharmaceutical product pricing is influenced by a complex set of internal and external factors. Analyzing the available sources, one may infer that external factors in these products are more numerous than on other markets, with direct consequences for the marketers' freedom to make tactical and strategic decisions. According to PhRMA's data published in June 2005, pharmaceutical costs account for about 10% of the total healthcare costs in the pricing domain. The complexity of factor interplay on this market additionally burdens the analytic approach to individual factors, as they manifest their action in the complex interaction of the total conditions on a given market, intensified by the fact that these are products bearing a strong 'emotional charge' both from the aspect of the final users and the public. At the same time, pharmaceutical marketers try to appreciate the internal factors, notably marketing objectives, the appropriateness of pricing policies in relation to the total marketing mix, and, of course, the aspect of costs. A significant factor determining any discourse on the nature and movement of pharmaceutical prices is the issue whether they are patent protected innovative drugs or generic medicaments. The domination of external factors demands that the prime attention be paid to them, but in view of the fact that the influence of individual factors is not linear and unambiguous, we shall attempt to encompass the key aspects of the complex mutual influences [8][9].

Pricing Regulations

Pharmaceutical product pricing depends primarily on whether they are placed on markets with legislatively regulated prices in one form or another, such as the markets of the EU, including Serbia, or markets where prices are formed freely, with the US as a relatively isolated example. The basic idea of legislative bodies is to prevent the prices of pharmaceuticals growing above the rise in prices of consumption goods, the so-called zero real pharmaceutical price inflation (according to Golec, Vernon, 2006). Discussion on pricing regulations primarily refers to branded, patent protected drugs, although the impact on the generic drug market is also evident. ...where one must bear in mind that it is the most significant pharmaceutical market, consuming almost a half of the world's total sales of drugs, and the fact that the USA is a leading country in terms of pharmaceutical companies' investment in R&D [10] [11]. Attempts to control the prices of pharmaceuticals may be interpreted as efforts to substitute for monopoly, where the state (or one of its bodies) acts as the only or exclusive buyer, for the relatively monopolistic position of innovative drug manufacturers. Pricing regulations on a national market are aimed at accomplishing the social objective of availability of adequate quantities of safe and effective drugs, while, on the other hand, one finds the objectives of pharmaceutical industry (Mossialos *et al.*, 2006). Efforts to assess the efficiency of pharmaceutical pricing control systems from the aspect of accomplishing the goals of both society and industry have produced a voluminous body of research. Sources are

dominated by authors advocating the position that long-term pricing regulations are a sub-optimum strategy for accomplishing the desired goals (Lichtenberg, 1996; Lu, Comanor, 1998; Danzon, Chao, 2000; Calfee, 2001; Vogel, 2004; Scherer, 2004; Golec, Vernon, 2007). Ekelund and Persson (2003) view the difference between the two systems, free (unregulated) pricing and externally (government) regulated pricing in relation to two key determinants: the system's ability (or perhaps eligibility) to reward investment in innovative pharmaceutical R&D, and the role of pricing as a market competition tool. Vogel (2004) and Mossialos *et al.* (2006) point to the opinion that free pricing does not satisfy the social aspect, but Vogel also argues that government control can be equally unsuccessful in their accomplishment. Pharmaceutical patent protection can also be regarded as a specific form of government intervention, as the state legislation provides relative monopolistic position for a certain period, as some kind of compensation for resources invested in R&D. However, 'patents do not guarantee profits' (Ridley, 2005, p. 625) and unless consumers recognize product value, it is hard to expect that they will be willing to pay any price [12].

According to Vernon *et al.* (2006), methods of controlling public expenditure on pharmaceuticals can be divided into two basic groups:

1. Methods focused on the pharmaceutical supply side:

- directly controlled prices of individual products;
- reference prices, where prices are set based on the prices of the same or similar products on reference markets;
- average pricing;
- curbing the margins of wholesale and retail pharmacies; and
- positive and negative drug lists (where the payer, i.e. the state, defines which drugs are to be dispensed at the cost of the healthcare system).

2. Methods focused on the pharmaceutical demand side:

- patient co-payment levels when purchasing drugs;
- advice and guidelines for prescribing physicians and limited budgets; and
- even
- parallel imports; and
- moving drugs from the ethical to the OTC product category.

The normal practice is to regulate markets with a combination of the above methods rather than just one measure. Reviewing pharmaceutical prices in Europe, Mossialos *et al.* (2006) give an overview of approaches to their formation. The regulatory body in Serbia provides that the reference markets are those of Croatia, Slovenia and Italy [13] [14]. In the case of markets without external price level control, price levels are practically defined by the supply/demand ratio on the given market. According to Calfee (2000), the dominant factor for setting pharmaceutical price levels is '... consumer willingness to pay for the potential benefits of new product.' (*ibid.*, p. 47). Discussing pharmaceutical pricing, a considerable number of US authors predominantly highlight the importance of demand-side factors (Lu, Comanor, 1998; Chumney, Simpson, 2002;

Scherer, 2004), defined by the product's therapeutic value and market structure in terms of the available number of alternative therapies. Calfee highlights the specific nature of drug supply and demand. According to Smith *et al.* (2002), nothing happens on the ethical drug market before the consumer and/or patient initiates contact. Initiating contact is the problematic part of the concept, as it is hard to estimate the size of the potential market segment that is '... untreated, undertreated or even undiagnosed.' (Calfee, 2000, p. 50). Demand for pharmaceuticals stems from the consumer's/patient's deeply subjective judgment that there is a change in the health condition disabling his/her daily activities and causing pain above his/her, once again subjective, pain tolerance threshold. On the other hand, pharmaceutical supply is also a category with high uncertainty levels, accompanied by the nature of discovery of new knowledge in the entire scientific nexus surrounding the industry. In the case of pharmaceuticals, the above mentioned consumers' willingness to pay for an innovative product refers to attempts to predict consumers' willingness to pay for a product that will appear on the market following at least eight to ten years of clinical studies [15][16]. As public pressure has turned healthcare costs, and therefore pharmaceutical costs, into a political issue, there is a permanent dilemma whether it is better to regulate drug prices or let them form freely on the market. Practically, it is about social welfare on the one and the issue of pharmaceutical industry development on the other side. The advocates of pharmaceutical pricing control system highlight the issue of drug availability and criticize the industry for high profits, often assailing marketing budgets as well. Opponents of price control argue that pharmaceutical pricing control systems are short-term strategies. 'Lower drug prices today will unequivocally improve access to currently developed medicines and this will improve public health.' (Vernon *et al.*, 2006, p. 181). Of course, no less important is the question how much these lower drug prices will cost society. According to most authors, price control makes a detrimental impact on future R&D investment (Abbott, 1995; Scherer, 2004; Vernon *et al.*, 2006; Golec, 2007). Golec and Vernon (2006) argue that, due to the existence of external pharmaceutical price controls, consumers in the EU have limited access to new pharmaceutical products, plus the estimated five billion US dollars of missed R&D investment opportunities between 1986 and 2004, which would have resulted in 46 innovative products that may have resulted from potential, but unrealized research. Calfee (2001) and Chapman (2003) present an argument in favor of Golec and Vernon's opinion, which is that large pharmaceutical companies are relocating their R&D activities to the USA. Of course, price regulations have enabled Europeans to have cheaper medicaments on the average [17] [18]. In the short run, customers will pay lower prices, and the amount of taxes they pay is still lower than the amount of money needed to cover expenses for pharmaceuticals if their prices were determined freely on the market. Lower revenues for pharmaceutical companies will lead to reduction of R&D investments (reducing profit in same amount as expansion of consumer surplus). Considering this simplified model in which only monopoly or full competition exists, any intervention by the government in a market mechanism would result in welfare loss. In case of pharmaceutical products, three theoretical assumptions can be made:

- Any form of monopoly pricing, as opposed to competitive pricing, will result in a reduction of output, at a higher price, and will engender a loss in consumer surplus, and thus a welfare loss.

- Society grants a monopoly to the inventor of a pharmaceutical for a limited amount of time, willingly sacrificing short run welfare, expecting that, after patent expires, new knowledge will contribute to greater welfare gain (above experienced short time loss).
- Price controls generate welfare losses in the short run as well as the long run.
- Taxes (income, sales, or property) that are used to pay for publicly financed health care (acute care, long-term care, or pharmaceutical care) generate welfare losses in the short run as well as the long run, through detrimental distortions in economic activity [12][14].

CONCLUSION

Led by economic logic and in the absence of imposed pricing limitations, pharmaceutical companies allocate their resources to projects with the 'highest risk-adjusted expected rate of return'. According to Vernon *et al.* (2006), imposing external pricing controls is a direct threat to R&D investment in pharmaceutical industry, on at least three grounds:

- External pricing control reduces the expected rate of return on investment, which also means that projects become less attractive, and there is a real threat of losing funding sources.
- External pricing control and the need to negotiate the inclusion of drugs into drug formularies with various government bodies, and also negotiations on drug prices, may delay market launch of drugs.
- Reduced pharmaceutical prices impact on reductions in future cash flow, and long pharmaceutical development periods and high risk levels result in the fact that pharmaceutical companies are especially sensitive to funding sources, as their own funds have lower capital costs than external ones.

A number of authors (Danzon, 1998; Scherer, 2004; Vernon *et al.*, 2006) point out that R&D expenditure in pharmaceutical industry is regarded as sunk cost, or unrecoverable past expenditure. According to these authors, it is a misconception that high prices of pharmaceuticals can be justified by the manufacturers' effort to recover invested funds. The decision to invest in R&D is the outcome of future expected profits from investments, and the products will be priced in accordance with objective market conditions – the demand curve and variable production and distribution costs. Vogel (2004) and Scherer (2004) also dispute the criticism leveled at above-average profits made by pharmaceutical companies. They argue that there is a significant difference between the accounting and economic rate of return on invested funds. Know-how or R&D are significant corporate assets in pharmaceutical industry; however, accounting standards do not allow for depreciation of intangible resources, which means that investment in R&D is regarded as expenditure and thus expressed in accounting. This leads to a distorted image in which the rate of return on investment during the R&D period is negative, and subsequently moves high above the average rate of return on invested capital during the sales period. The authors point out that, if the long term nature of investment in knowledge in pharmaceutical industry and the value of this knowledge were depreciated like the value of fixed assets, the rate of return on invested capital in

pharmaceutical industry would be similar to the rate normally found in high-risk industries. One of the central ideas of marketing is channeling resources into the production of products in demand on the market. The prices of given products are formed on the market. The price should reflect the value comprised in the given product, and a market with freely formed prices also provides feedback on the price that consumers are willing to pay for the given product. Calfee (2001) deems it unfeasible to make an analysis that would enable an objective determination of pharmaceutical product prices by third parties (such as regulatory bodies, governments *etc.*):

Acknowledgments

1. Application of value-based principle is impossible due to the fact that the regulatory body's interest is to keep prices down, and assessing the value of medicaments is left to the regulatory body itself, with the assumption that it is capable of assessing product value more objectively than users or prescribing physicians.
2. Pharmaceutical R&D costs are incurred much earlier than the product's utility appears, and the real 'medical and economic benefits' of the drug can only be viewed in post-launch studies, when the drug has been on the market for a period of time.

Authors who dispute pricing controls argue that without free formation of market prices resources will not be employed appropriately, which will primarily threaten future R&D, and the consumers will be deprived of innovative therapies. Pricing control positions, on the other hand, are defended with the accomplishment of the social goal – availability of therapies to a wide circle of users [3][8].

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