The Impact of Governmental Policy on R&D Projects in the Pharmaceutical Industry

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Abstract

Most of the countries worldwide have strong regulations on drug markets, in order to cope with the rising costs of health care. On the other hand, the regulations violate the incentives for investment in pharmaceutical R&D projects. Thus, in order to stimulate R&D activity, and at the same time to regulate pharmaceutical market, every government is obligated to create balanced reforms for pharmaceutical market. This paper presents the policies for fostering innovations and regulations in the pharmaceutical market in R. Bulgaria and R. Macedonia. The comparison with the regulations and stimulations for pharmaceutical market in USA and other EU countries will help in creating the most corresponding programme, both for the customers and pharmaceutical companies.

Keywords: government policy, pharmaceutical pricing, R&D projects, pharmaceutical industry
JEL classification: I180, L510

Introduction

Innovation activity and investments in R&D (research and development) projects are main characteristics and drivers for sustainable development of the pharmaceutical industry (Civan et. al, 2009). The time in which we live in is characterized with increased number of chronic diseases and rapid aging population, which results with constant demand of new and better drugs and medical therapies. So for, success of one pharmaceutical company is determined by R&D activities. At the same time, in order to protect the customers (patients) from monopoly prices and so called "me-too" drugs, government has responsibility to create balanced reforms for fostering innovation and limiting monopoly prices in the pharmaceutical market (Light et al., 2012).

Most countries worldwide, especially European countries employ a huge variety of regulation measures at the same time both on the demand and on the supply side (Eger & Mahlich, 2014). As both the supply and demand side of the market is strongly regulated it is difficult to evaluate the effect of a specific regulatory action. Sood et al. (2009) showed that different regulative measures have different effects on pharmaceutical revenues with direct price controls having the largest negative impact, followed by economic evaluations and budgets.Countries with strict regulation such as France or Italy exhibit lower drug prices than the less regulated market of the United States (Danzon & Chao, 2000). Lower prices in turn make it more difficult for firms to redeem the rising R&D costs. All regulatory regimes that lead to lower drug prices can distort incentives to invest in R&D, which might incur long run economic costs induced by a future absence of new drugs and consecutive lost life years.

The goal of this paper is to chart the impact of the governmental regulations on the pharmaceutical industry, as well as to show the need for effective and balanced governmental policies for the pharmaceutical market. The following four sections give a brief overview of the importance of well-developed regulations, showing positive and negative sides of the governmental policies and relationship between regulations and R&D investments in the pharmaceutical industry in R. Bulgaria and R. Macedonia.

The Importance of Well-developed Regulations of R&D Investment in the Pharmaceutical Industry

The importance of innovative activity by firms for securing economic growth and welfare is generally recognized and widely documented in the scientific literature. Lichtenberg (2005) points out the social value of innovation in the pharmaceutical industry. He finds out that pharmaceutical R&D and the introduction of new drugs have significant impact the economy through increased longevity, productivity and savings in other types of medical expenses.The estimations showed that for each extra dollar spent on prescription drugs, $4.5 is gained through productivity enhancement. Furthermore, each extra dollar spent on drugs reduces other health related expenses by almost $4. What is important is that there is a substantial rate of depreciation in the value of old drugs implying that future innovation is essential for the gains in health and wealth to be sustainable.

A common view is that investors view steady firm-level R&D investment as evidence of the firm's commitment to R&D-based innovation. However, recent research shows that R&D expenditure volatility is positively related to firm performance, suggesting that higher levels of R&D expenditure volatility indicate effective governance of the R&D function.Controlling the prices in order to restrict and remove formation of legal monopoly, but rewarding the companies that invest in R&D activities, is the key of success and achieving the benefits for the both, customers and pharmaceutical companies.The break in the link between the price of the product and the reward to the drug developer has many benefits, including the following:

- Customers (patients) who need medical treatment paid by third parties, through insurance would no longer restrict access to medicines because of high prices. Formularies for medicines should not be based upon drug prices, but rather the medical qualities of the medicines.
- By restriction and removing of the legal monopolies, companies that are efficient and have a good reputation for quality would have an edge.
- Incentives for marketing should be radically changed. Marketing of a product like vitamins, supplements, vaccines to patients who did not need that product, as is done by Merck, would not be profitable. Only evidence of benefits should generate rewards, making it less profitable to market medicines as if they are supplements and vaccines.
- Inventors would effectively use patents to make claims on the prize fund, rather than to create monopolies for products.

With the social significance of new drug discovery and development and the anticipated negative impact of pharmaceutical price controls, challenges to the noninterference and to produce reforms that will foster innovation and restrict the creation of monopoly in pharmaceutical prices, those are issues thatshould be taken more seriously.

Government Polices with Negative Influence on Pharmaceutical R&D Activities

Basic economic theory suggests that direct price controls can have disastrous effects on innovation by squeezing out R&D expenditures. Thus, price controls can lead to fewer new pharmaceutical products, products that would have improved, extended, or saved human lives.Giaccotto et al. (2003) provided empirical evidence for the contention in the context of price controls. They find that pharmaceutical R&D would be 30% lower if they were introduced price limits on drugs. Lowering R&D by 30% would result in 330 to 365 fewer new drugs within a twenty-year period. Price controls are widely believed to have hurt the competitiveness of pharmaceutical firms in Europe.

Table 1 summarizes the declines that would accompany various price controls, for example if 10 percent decline in real pharmaceutical prices in period t will cause a 5.83 percent reduction in industry research expenditures in period t+1.The present value of future R&D that is "lost" because of price controls is simply the policy-induced decline in research in period t+1 divided by r-g.

Table 1
Relationship between Decline in R&D, Life – Years Lost and Price Controls

Decline in R&D from Price Controls		Life – Years Lost from Price Controls	
Real Drug Prices	R&D Investments	Real Drug Prices	Life – Years Lost(Millions)
-10%	-5.8%	-10%	-40.1
-20%	-11.7%	-20%	-77.8
-30%	-17.5%	-30%	113.5
-40%	- 23.3%	-40%	147.1
-50%	-29.2%	-50%	178.8

Source: Vernon (2004)

Price controls lower the expected returns on investments in pharmaceutical research, which leads firm managers to divert resources away from R&D investments into other investment opportunities. Also, it leads up to the point where bio-pharmaceutical foreign direct investment is shifted into countries with less strict price controls (Koenig & McGarvie, 2011). Kyle's research (2007) confirmed those findings. In addition, she concluded that drugs invented by firms headquartered in countries that use price controls reach fewer markets and with longer delays than products that originates in countries without price controls.

Other contraines to R&D have also received some attention in the theoretical and empirical literature. Beside price control, R&D activity alsois contrained by other financing difficulties, showed the studies conducted in many countries about the effectiveness of R&D tax incentives (Mohnen, P. et al., 2008). Also, Lokshin and Mohnen (2009) concluded that the largest negative impact is in the first R&D period, after which the effect of the tax incentives declines. According to their results the effect of the tax incentives is the larger for smaller firms and is smaller for the larger firms.By loweringthe taxes of conducting R&D, the R&D incentive scheme stimulates additional R&D expenditures by private business firms.

Government Polices with Positive Influence on Pharmaceutical R&D Activities

R&D is at the core of the pharmaceutical industry in terms of generating patents and exclusive rights over time. This legal rewarding system is linked to monetary rewards, such as retention of profits and preventing competitors from catching up or copying information knowledge. But, an investment in R&D activity makes economically sense only if it leads to more drugs and medical therapies that meet an unmet medical need and make a significant difference to the patient.

Regulation with patents means that the pharmaceutical company with brand new product is usually given for 10 to 20 years of exclusive rights on selling that product, from the day the patent is accepted by the national patent office. For most innovations, holding a patent is equivalent to holding a marketing authorization and market exclusivity for a certain period of time, until a newer, better alternative is introduced.The role of patent or intellectual property rights (IPRs) in R&D activities, prove that IPR are very important in the pharmaceutical industry, much more than relative to other industries. Grabowsky and Vernon (2000) provided a compelling answer. They found out that IPRs are very significant for pharmaceutical innovation because of the high cost of innovation relative to thecost of imitation as generic products. Patent protection and data exclusivity provide innovators with a period of market exclusivity that allows them to recoup their large initial investments and earn a profit. But also, among the high selling drugs, known as blockbusters, the return to R&D has been substantial (five times greater than the return to all other drugs). But, legislative enactments that weaken IPRs and lower the price of blockbusters, without lowering their costs of development, could cause a cascading reduction in pharmaceutical innovation. On the other side, pharmaceutical and other R&D oriented companies are faced with lots of regulations, restrictions, very long and complex procedure of patent application and approval. Also, pharmaceutical R&D activity is primarily driven by gross profit expectations, high prevalence diseases of poorer countries are generally not in the focus of pharmaceutical R&D investment decisions (Kremer, 2002).

Regulations in pharmaceutical industry all over the world are often viewed as treat for R&D (Glans, 2014).R&D investments do not necessarily lead to drug innovations. So for, future research should shed more light on the quality aspects of the outcomes as regulation may not only decrease R&D spending but lead to a more efficient use. This argumentis not brand new. It has received some attention in the context of environmental regulation and its origin is known as the "Porter Hypothesis" (Porter & van der Linde,1995).A well-designed regulation can actually enhance competitiveness because it can trigger innovation. Applying this argument to the pharmaceutical industry regulation could in principle reduce the development of so called "me-too drugs" while maintaining or even increasing the number of break through innovations.Which means that the regulatory approval process can be reformed in a way that does not compromise public health and that substantially reduces the costs incurred by innovators in gaining marketing authorization for their innovative products.

This idea is supported by Love and Hubbard (2007). They believe the system for financing new drug development can be radically improved, spending less overall, aligning investment incentives more efficiently, while making drugs available to everyone at cheap generic prices.Reforming the way it's paid for R&D on new medicines involves a simple but powerful idea. Rather than give drug developers the exclusive patent rights to sell products, the government would award innovators

money: large monetary "prizes" tied to the actual impact of the invention on improvements in health care outcomes that successful products actually deliver.

In Aventis, a giant pharmaceutical firm, in 2002 was held a three-day scenario planning session. One product of that meeting involved a proposal to eliminate marketing monopolies for new pharmaceutical drugs, in return for a system of large cash prizes. In order to ensure the entire world shared the costs of drug development, there would be a global treaty that set minimum levels of support for R&D, either through similar prizes funds, or other research projects, including open source research.This new system of "prizes" for newly discovered medical therapies is important, because creates mechanisms to stimulate R&D:

- New drugs are needed to combat resistance to older drugs. It is better if the drugs are only used when the older drugs fail, to reduce the risks of resistance to the new medicines. On the other hand, companies that hold the patents on such medicines have incentives to encourage product use, in order to increase their sells (Rudholm, 2002).
- Products will be more useful if delivery systems or storage characteristics are improved, or medicines were used as co-formulated products or "cocktails," different drugs which improve the effect with each other. Often these opportunities are discouraged by restrictive licensing policies set by parties holding patents of complementary drugs.
- When system focuses on market exclusivity also suffers from over-investment in wasteful marketing activities, and often from the irrational prescribing practices that such marketing efforts promote. Company designs of clinical trials often avoid the types of comparisons between drugs that would be most useful in designing rational prescribing practices.

This system will be justified on both moral and economic grounds, because brand name products are on average twelve times more expensive than generics when purchased from manufacturers. And, price premiums for patented brand name products are taken in consideration for one reason only, to stimulate R&D for new medicines. On the other side, it is well known that most new drugs are not very important, because they don't offer significant improvements over existing medicines, but the costs of drug development for the so called "me-too" products are often more expensive. The patent system is a government intervention that makes a compromise. Inventors are given temporary legal monopolies. But, the patent system is a very expensive way to stimulate R&D, both for the companies and for the governments.

Relationship between Government Polices and Pharmaceutical R&D Activities in R. Bulgaria and R. Macedonia

The pharmaceutical industry is one of the most R&D orientedindustries in R. Bulgaria and R. Macedonia.Amid the continuous economic uncertainty worldwide and delayed growth in major economic segments,in pharmaceutical industry is registered impressive results. This industry constantly contributes to the production of products with high added value, employs highly qualified and has grown steadily in the years of uncertainty and deterioration in theeconomy.

According to IMS Health in R. Bulgaria and R. Macedonia prices of generic drugs are four times more affordable than the original. On the other side, self-payments (out of pocket cost) for drugs are 56% compared with 18% on average in other European countries.This is a signal for the need of improvement for better organization in the healthcare system, as well as fostering innovations and R&D activities in pharmaceutical industry in R. Bulgaria and R. Macedonia. Also,

governmental policy must ensure the opportunities for real competition in the pharmaceutical sector, which is currently impaired mainly from the requirement generic and biosimilar medicines have price within 80% of the original reference product inclusion in the positive drug list. If this requirement is not removed in a timely manner, in the medium and long term it will leave its deep imprint on drug production and pharmaceutical market.

An additional obstacle for encouraging R&D projects in the pharmaceutical industry in Bulgaria is that that the application of a generic drug for positive drug list, it may be included only if price is at least 20% lower than that of its referent price. This means that there is luck of fair competition in the pharmaceutical market, which is an obstacle for entry of new pharmaceutical products, whether originator or generic drug. In the R. Bulgaria and R. Macedonia, new innovative medical therapies are patent protected which means the pharmaceutical company for the brand new product is usually given for 10 to 20 years of exclusive rights on selling that product,with opportunity of 10 years extension from the day the patent is accepted by the national patent office. There is no other prize stimulation for R&D development of new medical therapies. On the other side, price regulations like referent prices where health insurance fund reimburse or pay only to the value of the referent price of the drug. Highly regulated anti monopolistic and antitrust laws, which is barrier for M&A contracts as one of the most effective ways of gaining financial support and expertise for R&D projects and highly unregulated competition are main obstacles for bigger number of R&D pharmaceutical projects.

Methodology

In this paper were used scientific methods applied in the social sciences. Under research of this topic wasused qualitative and quantitative method: deductive method, analysis of theoretical knowledge obtained by study of professional literature, method of comparison through good practices of the governmental policies toward pharmaceutical industry and the method of synthesis, that brings together the theoretical and practical knowledge ina new suggested responses. Data used in this research contains information of governmental policies for the most of EU and US countries. The observation time period(past two decades)was selected because of data availability and theneed of actual data for this subject.

Results

Most countries worldwide, especially European countries employ a huge variety of regulation measures for the pharmaceutical industry. Those regulation measures are crucial for the decision of starting with new R&D projects by pharmaceutical companies. Price controls, insufficiently regulated competition and R&D tax incentives aregovernmental regulations which are negatively correlated toR&D investment projects, while regulations with positive correlation are patent protection orIPRs, as well as monetary prizes for new and effective drugs and fairly regulated competition. R. Bulgaria as a one of the new members of EU and R. Macedonia as EU candidate, both have great opportunities for development of pharmaceutical industry, as one of most profitable and R&D oriented industry in the region. Luck of proper governmental regulations is a barrier for more productive and sustainable engagement in R&D activities for this industry.Overall, the results suggest that a system of rewards for brand new drugs, combined with price controls has a substantial impact on the pharmaceutical market.

Discussion

Pharmaceutical industry is one of the most profitable and R&D oriented industries, and also has a great social impact in a world with constantly growing older population and increasingly number of chronic diseases. This is why this research topic is of a great significance not only for the scientific forums, but also for governments and citizens all over the world. In order to stimulate production and development of new drugs, which should be completely new medical entity, not "me too" kind of drug, and also to protect the customers (patients) from monopoly prices governments are obligated to create policies which guarantee financial return of newly created drugs, stimulated with monetary prizes and/or patent protection, highly regulated competition, smaller tax incentives, shorter and easier R&D procedures and affordable prices for the customers.In R. Bulgaria and R. Macedonia, pharmaceutical market has great potential for development, based upon past experiences and global needsfrom this industry. Creating a good climate for R&D investments and better organization of the healthcare system will lead those countries to the leadership position in this region.

Conclusion

Creating policies which guarantee financial return of newly created drugs, stimulated by monetary prizes, replacing or making combination with old patent protection system, regulating competition, creating appropriate tax incentives, making shorter and easier R&D procedures, price controls satisfying both producers and customers, are strong reasons to gather experts from the Ministry of Healthcare, Ministry of Economy and pharmaceutical experts for resolving those issues. Due to limitation of this study and the need for improvement of global policies toward R&D activity in the pharmaceutical industry, this subject should be considered for further research. This further research should be empirically oriented and should produce precise measures and regulation for this issue, ready for implementation and adaptation in this global society.

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