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PHARMACEUTICAL SECTOR IN SERBIA IN THE PERIOD 1990-2013⁴

Abstract

In this paper authors give an overview of the development of the pharmaceutical industry in former Yugoslavia and Serbia in the period 1990-2013. The aim is to examine whether pharmaceutical industry, which was largely fragmented at the beginning of 90's, after a decade of privatization and restructuring had come to consolidation. In this paper we review the essentials of the pharmaceutical industry as well as key trends in that industry. In addition, there has been analyzed the privatization process in the pharmaceutical sector, as well as the outcomes of these privatizations. There was also presented the market distribution with market shares of the largest manufacturers of drugs and medical products, and trends that have shaped the market structure of the pharmaceutical industry in the analyzed period. In conclusion we can say that foreign owned pharmaceutical companies, as compared to domestic companies record higher and above average levels of profitability indicators. This indicates that there is a need for another round of restructuring in public owned companies in Serbia.

Key words: *Pharmaceutical sector, Serbia, Economic trends*

JEL Classification: L650

ФАРМАЦЕУТСКИ СЕКТОР У СРБИЈИ ОД 1990. ДО 2013. ГОДИНЕ

Апстракт

У раду је дат преглед развоја фармацеутске индустрије у периоду од 1990. до 2013. године у тадашњој Југославији и данашњој Републици Србији. Циљ рада је да се провери да ли је у фармацеутској индустрији која је била у великој мери фрагментирана, након деценије приватизације дошло до консолидације. У раду је дат посебан осврт на специфичности фармацеутске индустрије и као и на кључне трендове у фармацеутској индустрији уопште. Додатно се посебно анализира процес приватизације у фармацеутском сектору, као и исхода тих приватизација. Такође дат је детаљан приказ

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тржишног учешћа највећих произвођача лекова и медицинских препарата и дата су појашњења о основним трендовима која су обликовала тржишну структуру фармацеутске индустрије у анализираном периоду. Као закључак се може рећи да фармацеутске компаније које су у страном власништву у поређењу са компанијама у домаћем власништву бележе веће и изнад просечне вредности индикатора профитабилности. То указује на потребу још једног круга реструктурирања.

Кључне речи: Фармацеутски сектор, Србија, Привредни трендови

Introduction

Pharmaceutical industry has its own peculiarities like any other industry. They are arising from the peculiarities of the production process, the basic characteristics of the products of this industry and the legislation regulating the release of drugs and other medical preparations in the market.

The pharmaceutical industry belongs to high technology industries. It is necessary to comply with strict industrial and health standards that make up the production process extremely complex. In order to create new products, the pharmaceutical industry applies newly acquired knowledge from two fields of science, namely medicine and pharmacy. Taking into account nature of scientific multidisciplinary of pharmaceutical industry, the nature and importance of pharmaceutical products, it is not surprising that development and production of new drugs and other medical products require substantially high levels of resources and investments in new technologies and development of human resources. The average period for introduction of a new original drug takes in average of 10 to 15 years, out of which up to 10 years is spent on their development.

A drug that is under patent protection for its drug substance has an absolute protection and represents the original drug. Upon expiration of a patent drug becomes generic. Generic drugs⁵ are pharmaceutical products under the expired basic patent protection (patent protection on the drug substance). On the market they are sold under the non-proprietary name (commodity generics) or under the brand name-stamp (brand generics). The key criteria that need to be fulfilled in order for a generic drug to be allowed for free market sale is bioequivalence. Bioequivalence means that the generic drug must have substantially the same speed and duration of action in the body, if consumed in the same dosage as the original drug. The major difference between generic and innovative drugs is the selling price. For that reason in many countries generic drugs are being used to a greater extent. In recent years, generic companies are paying increasing importance on innovation, thus creating innovative generic drugs. These innovations in the production of generic drugs, pharmaceutical companies may also be protected as a patent (Jovanovic, Dragutinovic & Matović; 2009). Considering the potential for innovation in generic production of medicines, according to Jovanovic et al. (2009) all generic drugs can be divided into:

⁵ Under the Law on Medicines and Medical Devices (Government of Serbia, 2010) definition of generic drugs is as follows: "Generic or substantially similar drug, is a drug that has the same qualitative and quantitative composition of the active substance in the same pharmaceutical form as the reference medicinal product, with proven bioequivalence compared to the reference drug derived through appropriate bioavailability studies". A reference drug is a drug that was first given permission for release on the basis of its own data on quality, safety and efficacy.

- Conventional generics - after the expiry of the basic patent protection they may be marketed under the international non-proprietary name (INN) or the brand name;
- Specialties - preparations in common forms (tablets, injections) which are innovated, such as a system with sustained release of the drug. They represent bioequivalent products with high barriers and have higher rates of commodity generics;
- Biogenerics - bioequivalent and clinically equivalent versions of biological products. Their introduction to the market is more complex compared to conventional generics;
- Supergenerics - products with high added value, obtained by the reformulation of drugs varying degrees. They have an enhanced therapeutic effect based on some change in the structure of molecules or new salts, esters, or a new form of the drug. They require clinical trials and new complete registration documentation.

According to some authors (Adžić & Adžić, 2013; Ciceli et al 2008; Wrzochalska, 2009) patent protection of original drugs (up to 20 years) is an essential element in the development of original drugs, because it allows the manufacturer a monopoly position in the market during the period of patent protection. In contrast to the development of original drugs, the development and marketing of generics, biogenerics and supergenerics drugs requires significantly lower costs. In recent years, apart from negative impact of the global economic crisis, global drugs sales of innovative companies had been influenced by termination of the basic patent protection for valuable products, the introduction of generic drugs and marketing of innovative generic drugs. At the end of 2004, about 35% of best-selling drugs in the world have lost patent protection (Simoens & Coster, 2006). As of 2010 the pharmaceutical industry has been faced with the largest recorded wave of expiration of patent protection for original drugs (patent cliff). In the period 2010-2015 a high number of best-selling drugs in history will lose patent protection which will result in a significant expansion of cheaper generic copies of original drugs (Jovanovic, Matović, Brown, 2010). In November 2011 four drugs with highest recorded sales volumes have lost patent protection. They include: Lipitor (atorvastatin), Caduet (amlodipine/atorvastatin), Combivir (lami vudine/zidovudine), and Solodyn (minocycline - tablet with extended range). Combined, on a global level they generated sales revenue in the amount of approximately 7 billion US\$. It was expected that by the end of 2012 patent protection would expire for drugs whose total sales at the global level were estimated at about 30 billion US\$. It is estimated that generic companies will overtake part of sales of companies which own the patents on the original drugs for the estimated value of approximately \$ 67 billion. It is expected that in the period 2012-2015 due to the expiration of patent protection on best-selling original drugs (blockbuster drugs) there will be offered generic drugs in the estimated value of 250 billion US\$ (DeRuiter & Holson, 2012).

Drugs and other medical preparations significantly differ from other consumer products. Examples of their specificities are: drugs are treated as products of great importance; their demand is often influenced by psychological and emotional effects; end users often do not have adequate knowledge and information about the utility and quality of the drug; fear of diseases may create an unreasonable growth in demand for drugs; price rarely plays important role in prescribing drugs. Because of these characteristics circulation of drugs and other medical products is specifically regulated by law. Issuing permits drugs and medical devices sale is under jurisdiction of an appropriate executive authority, most often it comes to the Agency for Medicinal Products and Medical Devices. For a drug

to be allowed for sale it must be pharmaceutically, pharmacological-toxicologically and clinically tested. In addition, when approving drugs for free sale, the competent agency shall take into account the provisions of international agreements on compulsory marketing of high quality, safe and effective medicines, the flow of fake drugs and illegal traffic of unregistered medicines.

In Republic of Serbia there exist a total of five lists of drugs that are issued to the mandatory health insurance: A, A1, B, C and D. Their range depends on the degree of development of their pharmaceutical industries as well as the economic potential of the country. A large part of the revenue of pharmaceutical companies is coming from the sale of drugs that are on the positive list of the National Health Insurance.

Methodology

In this paper we have mainly used secondary data sources. They were used as a source for conducting longitudinal comparative study in Serbian pharmaceutical industry. Initially there has been conducted a historical review of the process of ownership transformation in pharmaceutical industry. The trends were monitored with a goal to test the level of sustainability of this industry in rapidly changing conditions in the environment. At the same time it was possible to monitor the degree of fragmentation of the market as well as the susceptibility to changes that occurred after the entry of new global competitors in Serbian market. Finally by the means of comparison of income and gross value added levels we have monitored the level of profitability of the industry.

Market structure and competitors analysis pharmaceutical industry

Twelve major drug producers for human use in FR of Yugoslavia in 1998 were: „Hemofarm Koncern“ Vršac, „Galenika AD“, Beograd, „Zdravlje“ Leskovac, „Jugoremedija“ Zrenjanin, „Zorka – Pharma“ Šabac, „Panfarma“ Belgrade, „Fampharm“ Kruševac, „Farmakos“ Prizren, „Hemoved“ Vršac, „Hemomont“ Podgorica, „Sanitarija“ Novi Sad and „Slavijamed“ Belgrade. Six out of 12 companies had a status of large companies, five were medium and only one was small sized. In 1998 all companies employed 7.926 workers which accounted for 85% out of total employment in the drugs and pharmaceuticals industry. Sales volume of drugs for human consumption was equal to approximately €60 million (Government of Yugoslavia, 1999).

The dominant ownership form for those companies in 1998 was a mixed ownership. In fact ten out of twelve listed companies were in joint ownership, and the other two were publicly owned. In mixed ownership companies share of private ownership in average was equal to 20% of total value, while the rest referred to public property (Government of Yugoslavia, 1999). Those companies have been transformed according to prior Laws on ownership transformation (on the model of internal shareholding). Only in company Galenika AD there was an exception to the rule and in that company 75% of total capital was state owned by the National Health Insurance Company. At that time there existed a plan by which 4 mixed owned companies and one public owned company should have been privatized under the Law on Ownership Transformation Act from 1997.

Companies in the pharmaceutical industry belonged to a group of 1,500 companies that began the process of ownership transformation in early stages. About two-thirds of all pharmaceutical companies began a process of privatization by a model of internal

shareholding, which was the only legally allowed process of privatization at that time (Law on Social Capital in 1990 and the Law on Ownership Transformation Act of 1991). This resulted with majority ownership of companies being given to workers of these enterprises.

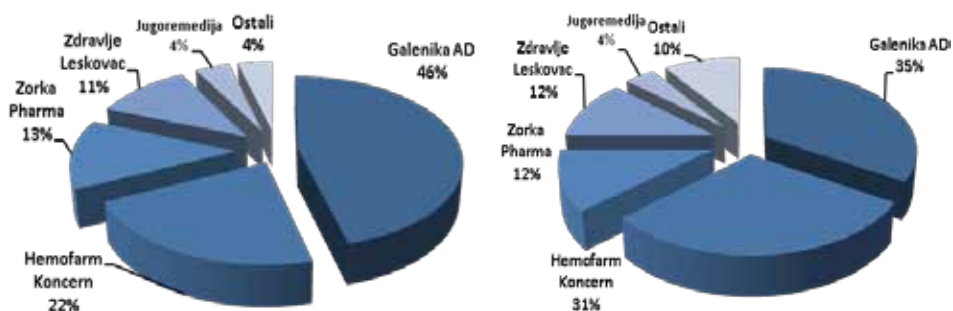
Companies which have entered the process of ownership transformation according to laws of 1990 and 1991 as a rule have been successful enterprises. To that group of successful companies all pharmaceutical companies were included, although according to official financial statements they should not have been classified as such. One of the main factors that generated poor business results of pharmaceutical companies was the high degree of government regulations in the drugs market. State control regulating prices of pharmaceutical products usually resulted with depressed or below actual market prices. The state aimed to provide sufficient quantities of medicines to health institutions. At the same time those institutions did not regularly fulfill their financial obligations to suppliers despite subsidized prices.

The pace of privatization in pharmaceutical (along with all other) companies has significantly accelerated during 1993 due to hyperinflation and devaluation of the debts which was caused by the sale of shares on installments. In the absence of provisions on revaluation of debt for inflation, many enterprises in the former Federal Republic of Yugoslavia have been fully privatized. After stabilization of prices in early 1994 and due to changes in legal regulations which declared void all inflationary gains and by which all ownership changes were due to conduct revaluation, almost all privatizations were canceled (Government of Serbia, 1994).

As a result of changed legislations there has been recorded a reduction in the share of private ownership from 43% to only few percent (Government of Yugoslavia, 1999). Among pharmaceutical companies participation of private capital has been reduced to 20.4% (Government of Yugoslavia, 1999). Apart from good intentions to terminate hyperinflationary profit in privatization, revaluation proved to be very harmful. It caused resistance to privatization in successful companies that have first started the process of privatization, among which belonged the pharmaceutical companies.

By the end of 1997 Galenika became the most important manufacturer whose production of medicines for human use accounted for 40% of total production in Federal Republic of Yugoslavia (Government of Yugoslavia, 1999). After Galenika has been removed from the “positive list” in the second half of 1998 there have been significant changes in market shares of pharmaceutical products in Yugoslavia. Market share in almost all pharmacological groups of drugs for Galenika were reduced from an average of 59.7% in 1997 to 34.7% in 1998. The largest part of the market was taken over by Hemofarm Concern from Vrsac, whose market share increased from 20.9% in 1997 up to 31.3% in 1998. After these changes in market distribution Galenika and Hemofarm Concern jointly held 66% of the market for medicines for human use.

Figure 1 - Market share by value of production in medicines for human use
1994-1997 1998.



Source: Government of Yugoslavia (1999)

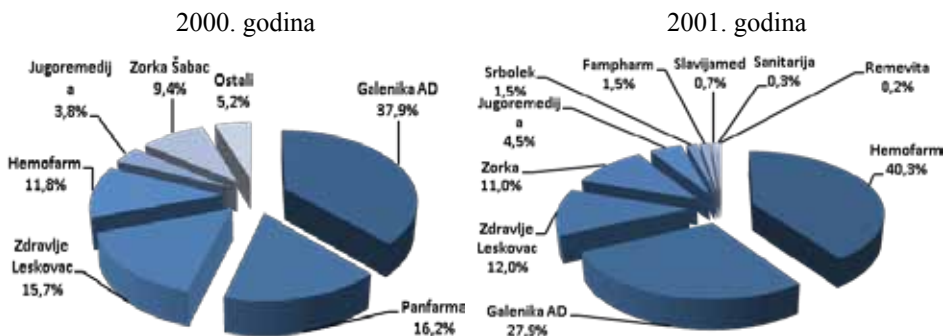
Deset najprodavanijih proizvoda „Zdravlja“ AD Leskovac u svojim tržišnim nišama u 2001. godini zauzimali su udeo između 40% i 60% (Zdravlje, 2002). Pozicija „Zdravlja“ AD Leskovac je posebno bila jaka u tržišnim nišama gastrointestinalnih i respiratornih lekova gde su imali udele od 50% odnosno 34% respektivno. „Zdravlje“ AD značajna tržišna učešća je ostvarivalo i na tržišnim nišama lekova za trudnice (26%), bolesti krvi i bolesti organa koji učestvuju u krvnoj genezi (23%) i metabolizma i regulisanja ishrane (18%)(Zdravlje, 2002). „Jugoremedija“ je u periodu od 2000. do 2004. godine uspela da podigne svoje tržišno učešće sa prosečno 4% na 8% tržišnog učešća. Imajući u obzir veličinu tržišta farmaceutskih proizvoda SRJ i broj učesnika na njemu, tržište farmaceutskih proizvoda je bilo značajno fragmentirano.

Pharmaceutical market in the period from 2000-2004 was significantly fragmented. This period was also marked by very low levels of investment in research and development.

In the pharmaceuticals' market in Yugoslavia during the period 2000-2004 operated twelve pharmaceutical companies. Galenika and Hemofarm kept the first two positions by the volume of sales. Yugoslavian pharmaceutical market in 2001 was dominated by four pharmaceutical companies with a common share of around 80%. Hemofarm significantly increased its market share after acquisition of the pharmaceutical company Zorka from Sabac during 2002.

If we take a look at company Zdravlje Leskova we may note that their ten best-selling products in 2001 generated market share up to 60% in respective market niches (Zdravlje, 2002). Zdravlje Leskovac was particularly strong in the niche markets of gastrointestinal and respiratory drugs where they had share of 50% and 34% respectively. They exercised significant market shares in drugs for pregnant women (26%), blood disorders and diseases of the organs involved in the genesis of blood (23%) and metabolic regulation of feeding (18%) (Zdravlje, 2002). Company Jugoremedia in the period 2000-2004, managed to raise its market share with from 4% to 8%. Taking into account the size of the market of pharmaceutical products FRY and the number of participants on it, the pharmaceutical products was significantly fragmented.

Figure 2 – Market share of domestic pharmaceutical companies in Yugoslavia



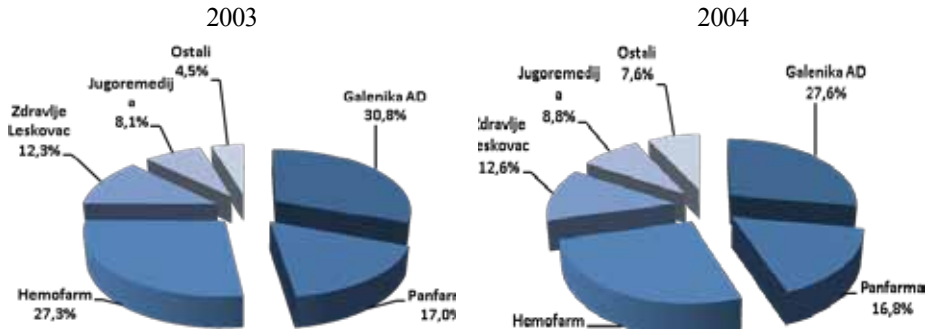
Source: Authors' calculations

The period after 2000 was characterized by gradual increase in market share of imported pharmaceutical products. Prior to year 2000, the value of imports of drugs and other pharmaceutical products was relatively small. For that reason domestic producers have had dominant position in the market of pharmaceutical products. However, in subsequent years, domestic producers had been losing dominant position for several reasons. At first company ICN the owner of Galenika has stopped supplying the market after a dispute with the state

over the contractual rights and obligations. Moreover, other pharmaceutical companies have not been able to import enough raw materials of the desired quality in order to produce sufficient quantity of the final product. This has resulted with faster growth of imports of pharmaceutical products in the following years and gradually growth of market share of imported pharmaceutical products.

According to Zubovic (2008) in the period 2001-2006 foreign trade has had a steady upward trend in the trade deficit, with a higher rate of increase in imports by 24.14% compared to the growth rate of exports which equaled 14.63%.

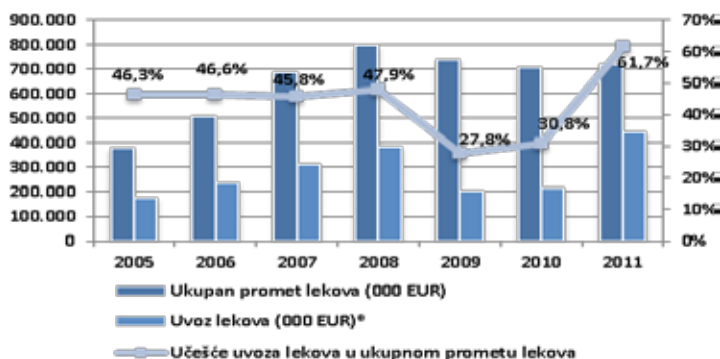
Figure 3 - Market shares in drugs sales in 2003 and 2004



Source: Authors' calculations

High levels of market fragmentation lead to weak bargaining position of domestic pharmaceutical enterprises in domestic and foreign suppliers and vendors. That further contributed to increased costs of production and distribution as well as the overall increase of inefficiencies in the business. High market fragmentation, pressure from foreign competition and inefficiencies in production pointed to the need for consolidation of the pharmaceutical industry in the coming years, which eventually did happen.

Figure 4 – Total sales and imports of drugs in Serbia in the period 2005-2011



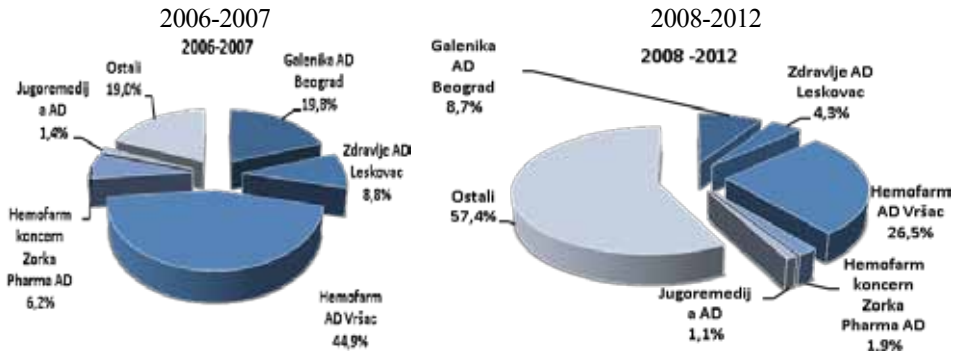
* Custom tariffs 3003 i 3004;

Source: Trademap

Looking at the relative share of individual producers, pharmaceutical market indicated the existence of oligopolistic market structures during 2006. Broken down by individual

producers, dominant share had Galenika and Hemofarm (the largest domestic exporter of drugs). Bearing in mind the link between legal entities Hemofarm with Zorka, Panfarm and Hemomont, domestic drug market in this period could be characterized as a pure oligopoly.

Figure 5 - Average market shares by sales volume in pharmaceutical industry



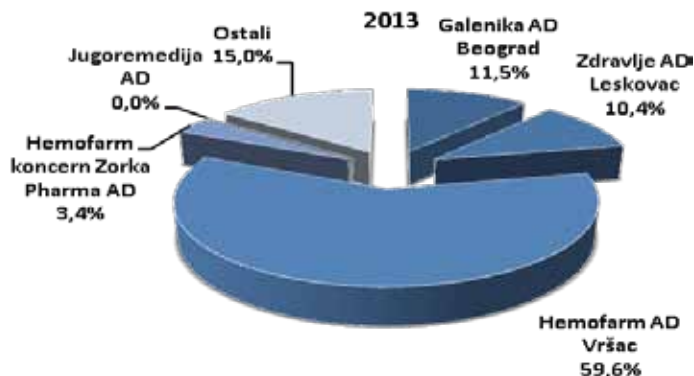
Source: Authors' calculations based on Serbian Company Register

The period 2008-2013 was characterized by negative market conjuncture, which was result of global economic crisis and significant illiquidity of the pharmaceutical sector in the Republic of Serbia.

The most significant factor contributing to the sharp rise in insolvency of pharmaceutical company was delay in payment for medicines supplied by government institutions (Republic Institute for Health Insurance and other health institutions) to wholesalers and drug manufacturers. In support of previous statements goes the fact that at the end of 2010 debt of National Health Insurance Fund to pharmacies has grown to over 14 billion RSD (€140 million), which had seriously eroded stability of the health system in the country. In addition National Health Insurance Fund in February 2011 signed a protocol with drug manufacturers stipulating pharmaceutical companies to reduce claims for drugs to the Fund by 10%, thus ensuring security of supply markets. Protocol was signed by leading pharmaceutical companies in Serbian market. The agreement in the Protocol applies to drugs in List A and A1, while for medicines from List B will be applied using the same principle, but through procurement procedures that will be implemented by healthcare facilities.

The aforementioned crisis of insolvency, and bad business decisions led the drugs companies (Velefarm, Vetfarm, Unifarm) to insolvency and drugmakers such as Habitfarm and Srbolek to bankruptcy and liquidation. At the same time position of Galenika as the largest drug manufacturer in Serbia was threatened. Changes in the market were best used by Hemofarm which managed to retain its market, despite the decline in total turnover in the market. Company Jugoremedija had significantly lost its market share in this period due to cease in production, repair of existing production facilities and liquidity problems. Those circumstances finally led to the complete collapse of the company.

Figure 6 – Market share by sales volume in pharmaceutical industry in 2013

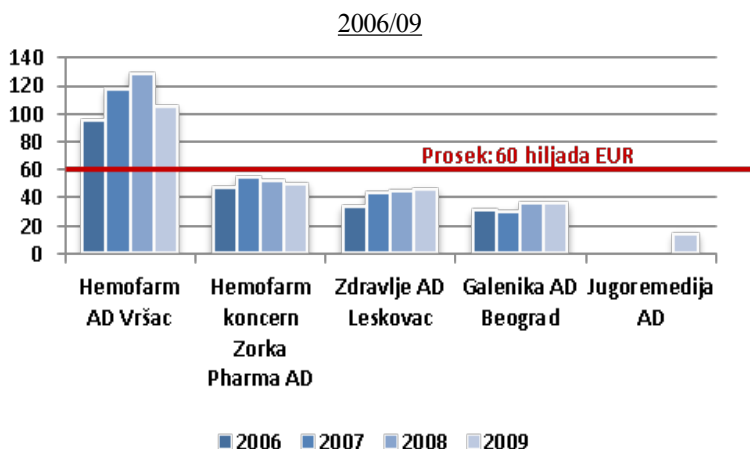


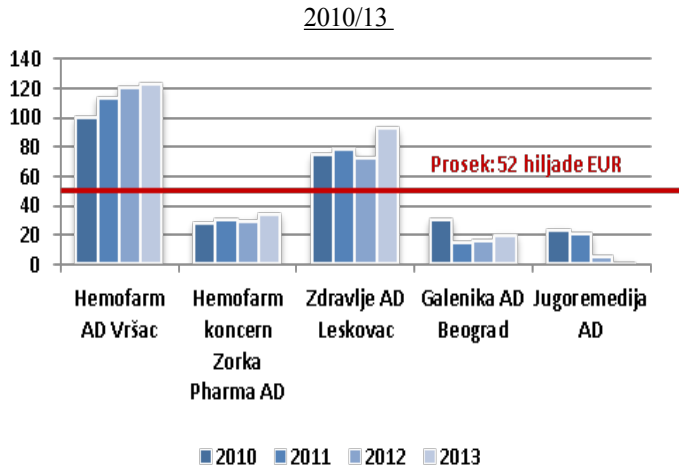
Source: Authors' calculations based on Serbian Company Register

Profitability and Gross Value Added Indicators

Observing the sales revenue per employee in largest drug producers in Serbia during the period 2010-2013, above the average values were recorded in company Zdravlje (average of € 52,000). Jugoremedija had recorded the lowest values according to this indicator. At the same time foreign owned companies (Hemofarm and Zdravlje) have recorded higher and above average values of observed indicator, compared to companies that were 100% owned by domestic capital (Galenika and Jugoremedija).

Figure 7 - Sales revenues per employee in selected companies and total average in the period 2006/09 and 2010/13

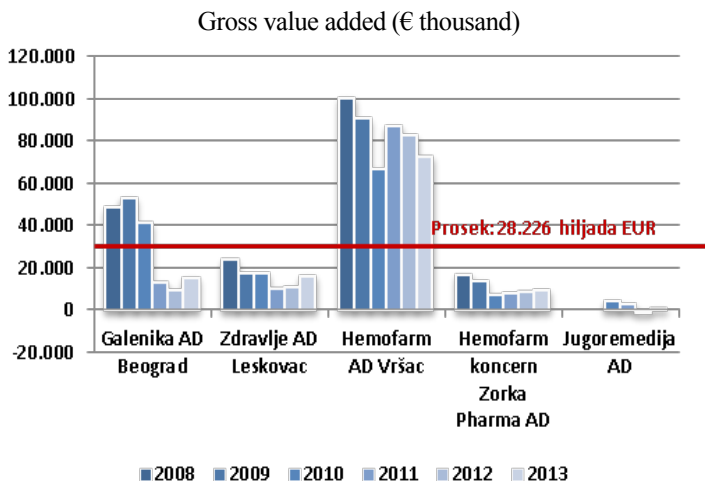


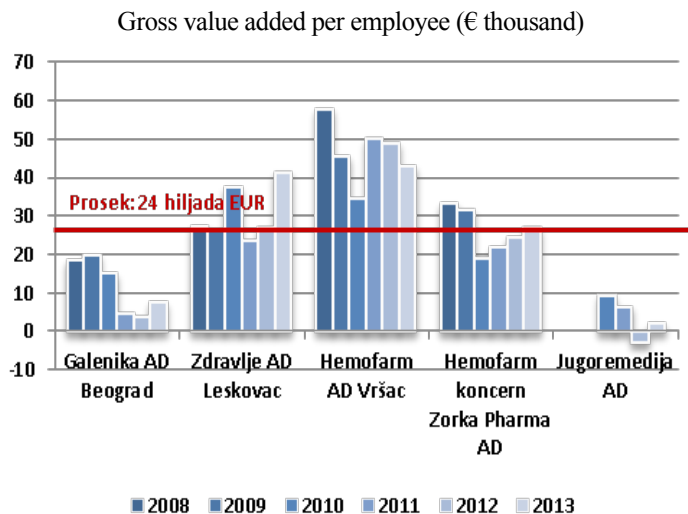


Source: Authors calculations based on data of Serbian Business Registers Agency

In the period 2008-2013 Zdravlje has generated gross value added that was under the average value in pharmaceutical branch. There was also recorded a negative trend in created value added in the observed period, caused by poor business results that characterized the period 2009-2012. In same period, below average values of GVA was also recorded by Jugoremedija. Gross value added of largest companies in production of pharmaceutical preparations was in average approximately €28.2 million, while GVA per employee in same period amounted to €24,000.

Figure 8 - Gross value added and gross value added per employee in selected companies in pharmaceutical preparations, in the period 2008. - 2013.





Source: Authors calculations based on data of Serbian Business Registers Agency

Conclusion

In the period 1990–2013 besides wars and disintegration of country, decisive impact on pharmaceutical industry in Yugoslavia/Serbia had a processes of privatization and market liberalization. Structure of the pharmaceutical industry in pre-war Yugoslavia was designed so that there was competition between pharmaceutical companies from different republics, but not within the one republic. This illusion of market economy and competition had ceased to exist with the breakdown of former Yugoslavia, when started a true market competition between national producers of pharmaceutical and medical products. After former Yugoslavia had fallen apart, there was an attempt of pharmaceutical companies' privatization by the model of internal share ownership, although certain pharmaceutical companies have not gained all preconditions to initiate privatization. Privatization process in former Federal Republic of Yugoslavia was accelerated during the 1993 due to hyperinflation, but after price stabilization and change in legislation in 1994 privatization processes were almost annulled.

Until 1997 Galenika dominated pharmaceutical market with market share of about 40% in the total volume of sales of drugs for human. However, after Galenika was removed from the positive list of the National Health Insurance Fund, in the second half of 1998, there came significant changes in market shares on the market of pharmaceutical products of the former Federal Republic of Yugoslavia. In the following years, national pharmaceutical market had become more fragmented. That period was characterised by small volume of investments in research and development. The process of privatization of pharmaceutical companies continued after 2000. Successful privatizations were led by foreign owned companies. However there did not significantly increase production, but they made a significant investment and considerably increased a profitability margin through the reduction of number of employees. After 2000 there had been gradual increase of market share for imported pharmaceutical products.

High market fragmentation, pressure of foreign competition and production inefficiency resulted with the need for consolidation of the pharmaceutical industry in upcoming period. Excluding drug wholesalers that had significant share within the total turnover of drugs and medical devices in Serbia, relative shares of certain drug producers indicated the existence

of oligopolistic market structure. It is indicative that the pharmaceutical companies owned by foreign capital recorded higher and above average values of the profitability indicators compared to companies that were majority owned by domestic shareholders. That indicates the need for domestic owned pharmaceutical companies to impend another round of restructuring

References

- Adžić, S., & Adžić, J. (2013). Transition of the Health Care System and Sustainable Economy-Case Study for Serbia. *American Journal of Public Health*, 1(1), 1-9.
- Cicea, C., Cvijanović, D. V., & Subić, J. (2008). The health care systems in European Union and international comparison. *Ekonomika*, 54(1-2), 9-19.
- Government of Serbia (2010), *Law on Drugs and Medical Devices*, Belgrade, Službeni glasnik 30/2010
- DeRuiter J, Holson P (2012) Drug Patent Expirations and the „Patent Cliff“, retrieved from <http://www.uspharmacist.com/content/s/216/c/35249>
- Jovanović, S., Dragutinović S i Matović D (2009), Specificnosti regulative u oblasti lekova, *Pravni život*, no.9, Volume 1, Book 529, pp 1025-035, Udruženje pravnika Srbije, Belgrade, Serbia
- Jovanović, S., Matović, D., & Petrović, S. (2010). Innovative and generic pharmaceuticals industry and drugs market. *Industrija*, 38(1), 105-119.
- Simoens, S., & De Coster, S. (2006). Sustaining generic medicines markets in Europe. *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector*, 3(4), 257-268.
- Government of Serbia (1994) Pravilnik o načinu revalorizacije vrednosti društvenog kapitala koja je utvrđena u postupku pretvaranja društvene svojine u druge oblike svojine i vrednosti upisanih deonica. *Službeni glasnik Republike Srbije*, br. 62/1994
- Government of Yugoslavia (1999) Pharmaceutical development strategy of FRY, Belgrade, Economics Institute
- Study on Consolidation of the Pharmaceutical Industry in Yugoslavia, 2001. godine
- Wrzochalska A (2009): Selected aspects of life and health condition of the rural population in Poland, *Ekonomika poljoprivrede, IEP Beograd*, vol. 56, br. 2, str. 245-254
- Zdravlje (2012) Information Memorandum, Leskovac, July 2012
- Zubović J (2008) Development of pharmaceuticals sector in Serbia following world trends tariffelimination in ed. Drašković B, Vuković V, Belgrade, Institut ekonomskih nauka, pp 266-277.