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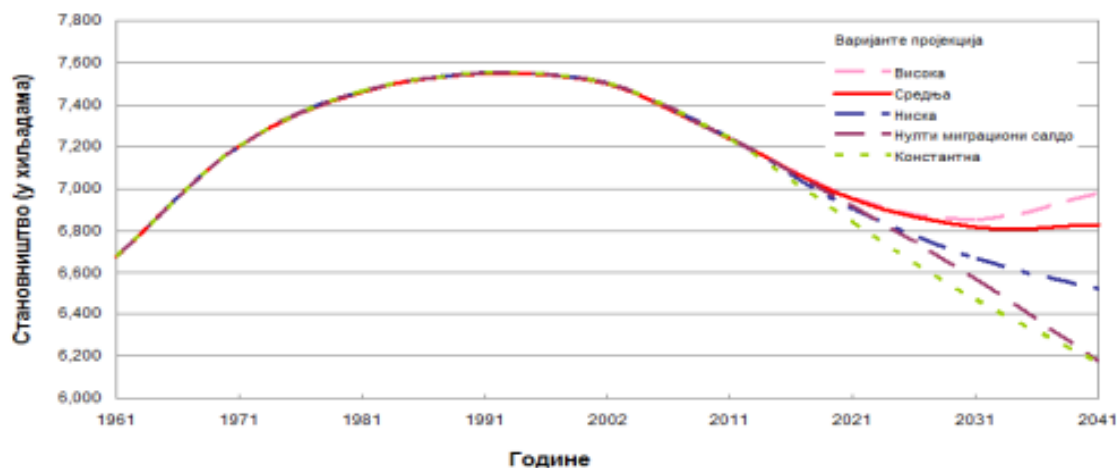
# Proposal for sustainable development of pharmaceutical sector in Serbia with necessary insurance system savings

## Introduction – Challenges for Serbian health system

With the aim to perceive the place and role of industry with regards to improvement, as well as securing the health system stability and sustainability, I have analysed macroeconomic and health statistics relevant for this topic. For the sustainability analysis of a health system it is, above all, necessary to perceive the population tendencies, employment and age structure of the population.

Recently issued publication of the Statistical Office of the Republic of Serbia<sup>1</sup>, states the following:

*“Results of the forecast for the 2011-2041 period show that in the next 30 years the population of the Republic of Serbia will still be exposed to the process of population ageing. The share of the young is low and with a decreasing tendency while the share of the old is high and it keeps growing. According to the low version, where the ageing process is the most intense, the share of inhabitants younger than 15 would drop from 14.4% to 11.7%, whereas the share of the ones older than 65 would increase from 17.3% to 25.2%. As per the same version, the share of the oldest inhabitants (over 80) within the entire population would increase from 3.5% to 7.8%, and the average age of the population would rise from 42.1 to 46.5 years of age.”*



(Data for the Republic of Serbia without Kosovo and Metohija)

<sup>1</sup> <http://webzrs.stat.gov.rs/WebSite/public/PublicationView.aspx?pKey=41&pLevel=1&pubType=2&pubKey=2208>  
Population forecast of the Republic of Serbia 2011–2041, SO of RS, Belgrade, January 2014

November Statistical Bulletin of the Statistical Office of the Republic of Serbia<sup>2</sup> highlights a further drop in the number of employees (0.1% less than in October 2013 and 1.2% less than in November 2012) to around 1.7 million according to the current estimate. Similarly, data of the Retirement and Disability Insurance Fund<sup>3</sup> for December 2013 show that the total number of retired people is 1.438.016, which is 1.2% more than in the same month in 2012.

A clear implication of the stated tendencies is a threefold pressure on the health insurance system by means of:

- 1) Constant reduction of fund inflow to the Republic Health Insurance Fund by employees
- 2) Increased number of retired people as users of the budget and the health system
- 3) Tendency of population ageing enhances the incidence and prevalence of illnesses related to the old age – cardiovascular problems, diabetes, malignancies, central nervous system problems, rheumatoid arthritis, osteoporosis, autoimmune diseases and so on.

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<sup>2</sup> <http://webrzs.stat.gov.rs/WebSite/repository/documents/00/01/30/31/MSB-11-2013.pdf>

**Monthly Statistical Bulletin XI 2013**, , ISSN 2217-2092, SO of RS, Belgrade, p. 25

<sup>3</sup> <http://www.pio.rs/images/dokumenta/statistike/2014/MESECNI%20BILTEN%20-%20DECEMBAR%202013.pdf>

**Monthly Statistical Bulletin XII 2013**, RDI fund, Belgrade

## What is the situation like in Europe?

This tendency (drop in number of employees synched with the increased number of retired citizens) is not unique for Serbia. Health systems in Europe are facing problems related to financing health care, triggered by the same causes and with same effects.

Analysis of Birgli Consulting House, contained in the text "**An Evaluation of Medicines shortages in Europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom**", Birge AG, Zug, Switzerland, July 2013, shows that the reactions of EU member states were directed towards the reduction of medicine costs or state expenses through different mechanisms:

- 1) Reduction of regulated prices
- 2) Discounts, rebates, clawback, other ways of price reduction
- 3) Reference pricing system
- 4) VAT change for medicines
- 5) Planned changes of distribution costs
- 6) Tender supply of medicines (esp. in Germany, Denmark, The Netherlands)

Data from the report shows that these mechanisms have led to the cost reduction, but at the same time they have pressured the manufacturers, so, according to the aforementioned report, national tendering procedures in, for example, Germany, Denmark and The Netherlands have led to fewer and fewer companies applying to tenders, and the process led to periodic shortages of medicines caused by the companies' impossibility to fulfil their tendering obligations. Birgli analysis states the cases where the manufacturers had simply decided not to supply the market after the tender being won, while others had not been able to fulfil their obligations as per the tenders won<sup>4</sup>.

The aforementioned Birgli report also states that the abovementioned mechanisms have made the manufacturers shift towards markets with higher prices, which leads to shortage on low-price markets. The example of this can be seen in Serbia as well (there are multiple examples of a medicines which are now on D list and supplied at higher prices than back when they were regularly produced in Serbia). Similarly, the procurement of medicines via tenders has led to global crisis in the supply of older-generation cytostatics (e.g. 5-FU) – the number of suppliers interested in producing the medicine by newly-acquired, extremely low prices has dropped drastically.

Research by the London School of Economics<sup>5</sup> also covers tender systems for prescription medicines in Germany and The Netherlands. These two countries have several years of experience in this way of supply and are an excellent sample for research of negative and positive sides of INN tenders. The

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<sup>4</sup> <http://static.correofarmaceutico.com/docs/2013/10/21/evaluation.pdf>, **An Evaluation of Medicines Shortages in Europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom**, Birgli AG, Zug, Switzerland, July 2013, p. 22

<sup>5</sup> Kanavos Panos et al, **Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands and Germany**, October 2012

research refers to a Dutch report on the shortage of 80 products (30 molecules)<sup>6</sup> chosen on tenders. Possible causes as per the research are: too short a period between the contract signing and first deliveries (manufacturers state they need around six months to produce the amount won on a tender). In order to avoid these problems, manufacturers make supplies even before the tender, which eliminates small and middle-sized companies from the market, which cannot afford goods write-off in case of losing the tender, which basically reduces the competition in the tendering procedure, and with it, the possibility to solve the shortage in shorter period of time. As a second possible reason for medicines shortage, LSE report states limited production capacities of manufacturers or simply bad calculation by manufacturers in the planning process.

Both reports point out the risks of INN tender system – shortages are a big risk even in the countries with vast experience in the field, and the competition during the process comes down only to big companies who can bear the risk of goods write-off in case of the tender loss. LSE report refers to the manufacturers who have to spend about six months (or more in case of problems in production) for new production (as per tender won and large tender amounts). In case of INN tender, all the other manufacturers have no reason to keep supplies if they lost the tender. Thus, if the tender-winning manufacturer is not able to deliver the medicine, the state may have to resort to emergency imports, which eventually can result in higher costs than if INN had not happened.

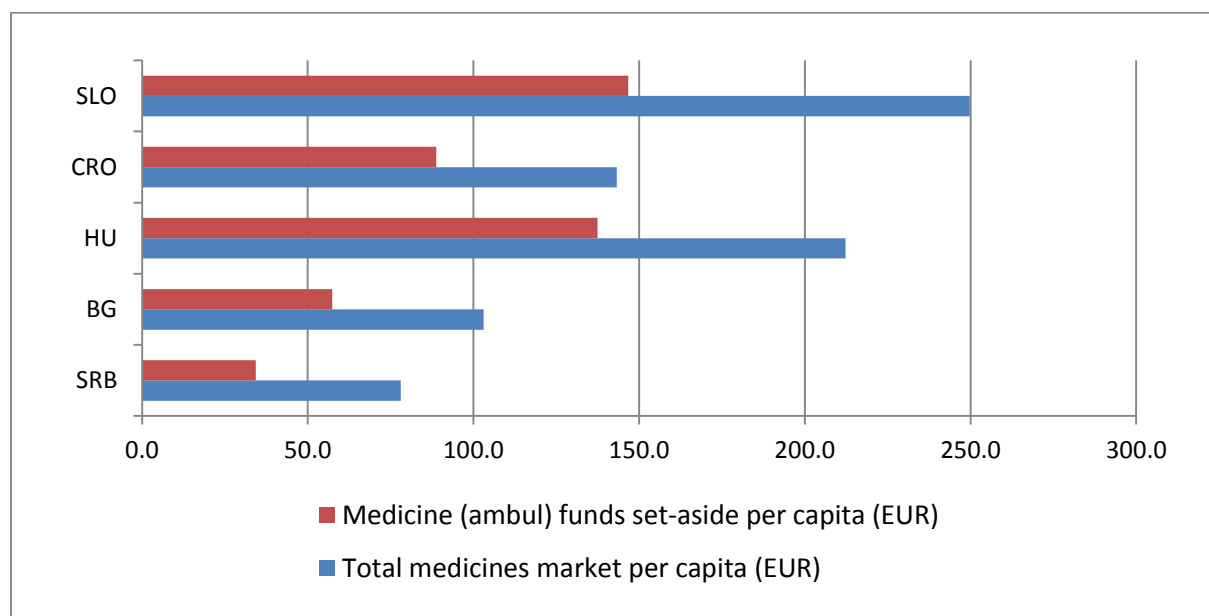
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<sup>6</sup> Kanavos Panos et al, **Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands and Germany**, October 2012, p. 31-32

### Role of generic and local production in sustention of health system stability.

Even with the fact that Serbia spends the least resources per capita in comparison to the neighbouring countries (see Table below), we can say that it has a stable medicines supply system without any major shortages in the past period. *Red: Medicine (ambulatory) funds set-aside per capita; Blue: Total medicines market per capita*

**Graph. Reimbursement funds expenditure for ambulatory medicines and total medicines market per capita**



Source: Derived from EFPIA data<sup>7</sup>

The reason for the good situation when it comes to supplies is clear when you look at the Serbian market where generic companies are present, with local production that production- and logistics-wise can react fast to shortages.

A recent example is the shortage of aminophylline by Jugoremedija, where the whole market went on to being supplied by theophylline by another domestic company. This shows that the market stability is possible to reach with low medicine prices, without the risks related to INN tenders, with the help of the strong local production which guarantees stability, and the export increase potential of the Republic of Serbia.

The best illustration for this is the Table below showing the Serbian medicine market in 2013 and comparing the share of generic and original products by volume and in Euro.

<sup>7</sup> Source: EFPIA: **The Pharmaceutical Industry in Figures**, p. 15 and 23, available at [http://www.efpia.eu/uploads/Figures\\_Key\\_Data\\_2013.pdf](http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf)

**Table. Share of generic and original products in the Serbian market by volume and value**

2013	Standard Units	Standard Units - Share of Product (Parent) %	Sales WHS [EUR]	Sales WHS - Share of Product (Parent) %
<i>SUM ORIGINAL/GENERIC</i>	5,548,809,577	100.00	624,031,930	100.00
<i>GENERIC</i>	3,902,248,339	70.33	295,375,207	47.33
<i>ORIGINAL</i>	1,646,561,238	29.67	328,656,723	52.67

Source: IMS Health, Serbia: IMS Market Viewer, report generated: 01/2014

From the table we can see that generic products make up over 70% in volume, but also less than 50% in value of medicines sold in 2013.

From the last two tables and the example of aminophylline, we may conclude that the strong local generic industry with local production is the pillar of stability of the health system, as it supplies the health system with acceptably-priced medicines in large volumes. This is a feature of other countries as well, where there is a strong generic pharmaceutical industry with local production. Below are the examples of Bulgaria, Czech Republic, Poland, Turkey, Slovenia and Croatia:

- 1) Czech Republic – Zentiva is leading, as a local generic manufacturer with production capacities in Prague.<sup>8</sup>
- 2) Poland – Polpharma is leading, as a local generic manufacturer<sup>9</sup>
- 3) Bulgaria – Actavis has a leading position in Bulgaria, as a local generic company with significant production capacities in accordance with the latest standards of good production practices in the town of Dupnitsa, with capacities of more than 5 billion pills per year, and the town of Troyan. Sopharma is also among the leading companies in the market, as another generic company with several production capacities in Bulgaria, out of which the newest is of 4 billion pills per year.<sup>10</sup>
- 4) Turkey – The first and third place as per sales is held by local generic companies with large production capacities. Abdi Ibrahim Pharmaceuticals, a leading company in Turkey, has production plants with capacity of 7.5 billion pills, 40.8 million tubes for semi-liquid forms, 82.5 million of liquid preparation vials and 800 million capsules.<sup>11</sup> Bilim Pharmaceuticals is taking the third place, with the 4.9% market share (money-wise) and 17% (volume-wise) and the sales of 109.9 million medicine packs in 2012.<sup>12</sup>

<sup>8</sup> <http://referaty.atlas.sk/cudzie-jazyky/anglictina/32845/?print=1>

<sup>9</sup> <http://www.polpharma.pl/en/company/who-we-are/>

<sup>10</sup> **Sopharma Q1 2014 Report,**

<http://www.sopharma.us/DOCS/docs/2014/01/Management%20report%20%20Q1%202014%20ENG.pdf>, page 1

<sup>11</sup> <http://www.trpharmaexporters.org/en/members/12/abdi-ibrahim-pharmaceuticals>

<sup>12</sup> <http://www.bilimilac.com.tr/en/bilimilac.html>

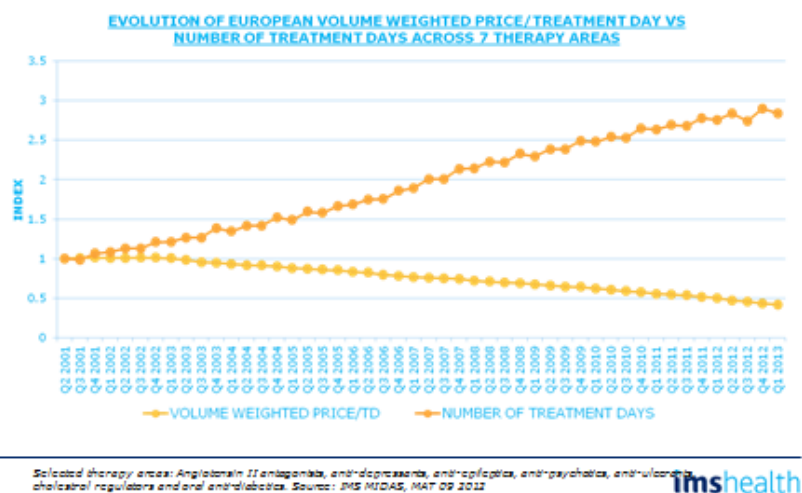


- 5) Slovenia – Krka, as a generic manufacturer with production capacities in Slovenia, is holding the first place in sales within Slovenia. Moreover, Krka has a significant market position in Poland, where they have their production plants.<sup>13</sup>
- 6) Croatia – Pliva<sup>14</sup> and Belupo are leading, as generic manufacturers with local production. Belupo has recently announced the expansion of their production capacities in Croatia.<sup>15</sup>

None of these countries has resorted to radical changes in the medicine supply system because, like Serbia, they have strong small companies with local production as a guarantee of stability, with prices that are acceptable for their health systems. In times when Serbia is facing financial difficulties, none of the local manufacturers has threatened to leave the market or withdraw products.

IMS Health analysis of the role of generic industry in sustainability and stability of health systems<sup>16</sup> has come to similar conclusions. The essence is that the need for medicines is growing, and is satisfied by generic industry, making the medicines and therapy more available - hereafter we show two graphs from IMS report to illustrate this:

In Europe, the average price per treatment day has declined 60%, while number of treatment days has increased nearly 200% over 12 years (7 key therapy areas)



Source: IMS MIDAS, MAT 09 2012. IMS Health. Copyright 2012. All rights reserved.

<sup>13</sup> KRKA Annual Report 2013,

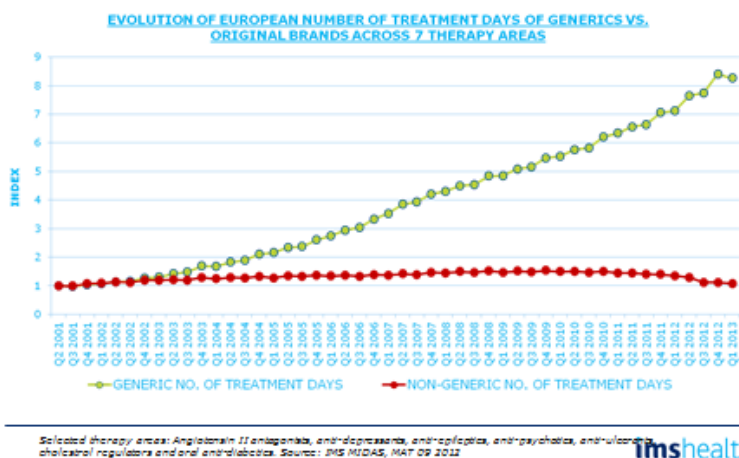
[http://www.krka.biz/media/doc/en/for\\_investors/2014/Audited%20consolidated%20and%20unconsolidated%20annual%20report%20for%20the%20year%202013.pdf](http://www.krka.biz/media/doc/en/for_investors/2014/Audited%20consolidated%20and%20unconsolidated%20annual%20report%20for%20the%20year%202013.pdf), Krka d.d., Novo Mesto, page 14

<sup>14</sup> <http://www.pliva.com/pliva/company-info>

<sup>15</sup> <http://www.belupo.hr/Default.aspx?sid=12783>

<sup>16</sup> The role generic medicines can play in controlling healthcare costs and providing investments, IMS Health, 2013

This trend has been entirely driven by generics, providing increased access to medicines



**Source: IMS MIDAS, MAT 09 2012. IMS Health. Copyright 2012. All rights reserved.**

The table with the Serbian data shows us that generic manufacturers in Serbia in 2013 represented 70,33% of the volume in the market, and account for less than 50% of market value. Thus, I conclude that the role of generic manufacturers, especially those with production capacities in the country, represent a guarantee of sustainability of the health care system.

Manufacturers with local production, employees and current investments in Serbia are naturally interested in staying in the market and having a dialogue with the participants in the health care system. They are often put in a position to solve marketing issues of non-profitable products (whose production practically brings losses), as well as liquidity issues.

### **Role of local generic industry in improvement of the health care system**

#### **A) Generic industry as a source of big savings by means of earlier introduction of new therapies thanks to the regulatory and legal framework in the Republic of Serbia**

In addition to the crucial role of the local generic industry in maintaining the stability of the health care system, we should draw attention to the regulatory framework, which, through the engagement of local industry, allows patients in Serbia access to modern therapies cheaper than the current prices in EU countries.

Until the date of entry into the EU, Serbia has the opportunity to, with the earlier launch of generic medicines, improve health care and simultaneously reduce the costs of treatment for patients and the state. This is possible because of:

- a) Level of patent protection in Serbia; and

- b) Regulations related to the issuance of permit for medicine - Our Law on Medicines, Article 230, enables the local generic manufacturers to receive a permit for medicine after the expiration of a period of 6 years (with the exception of biological medicines) from the date of registration of reference medicine in the EU until the accession of Serbia to the European Union. In EU territory, this term is 10 to 11 years, which gives Serbia an advantage of 4-5 years. Such or similar articles of the law were also enforced in Croatia until the date of entry of the same in the EU on 1 July 2013, as well as other countries that are currently not in the EU.

In addition, with the earlier launch of the medicine in Serbia in relation to the EU, a possibility arises for Serbia to become a country that would allow other countries that have similar regulations and benefits (including, for example, Russia) to launch modern medicines earlier. Serbia would thus become the exporter for such “early-launch” medicines. This has been already proven in a pilot project with Imatinib, which was, after its launching in Serbia, also launched in Bosnia and Herzegovina and Macedonia, based on the registration in Serbia and export to these countries.

Therefore, Serbia can, not only reach the EU levels of health care, if it uses local generic resources, but at the same time to also become a major exporter of modern therapies, in line with realistic goals and within the legal framework.

To my knowledge, Serbia did not properly use these benefits until 2012, when the first generic Imatinib (a medicine for chronic myeloid leukaemia) was launched in Serbia, the price of which, per box, prior to the launch of a generic parallel, amounted to 2,000 EUR in RSD, and RHIF would have, in 2012, were it not for introduction of generics - set aside over 6 million euros for this product. With the introduction of generics, price of the medicine declined 4 times, so the savings for the health care system since August 2012 to date are over 6 million euros. This was possible because Imatinib was due to lack of patent protection for Imatinib in Serbia, while in most EU countries this medicine is patent protected until 2015 for the main indications. The table below provides information on public procurement that illustrates the savings enabled by generic market penetration:

### Imatinib – Illustration of savings for the Health System in Serbia for the period Aug 2012 – Jan 2014

Period	08.08.2012.-31.01.2014.
JN	404-3-110/12-104 404-1-113/12-1 404-1-110/13-37 404-1-19/13-1 404-1-11/13-37 404-1-110/13-110
Amount in mg	58.860.000
Amount in RSD that RHIF would pay if only the originator was in the market	999.645.867,00
Amount in RSD paid by RHIF	268.769.760,00
<b>SAVINGS IN RSD</b>	<b>730.876.107,00</b>
SAVINGS IN EUR	6.355.444

Sources: *Public Procurement Portal (<http://portal.ujn.gov.rs/>) and internal sales data Actavis*

In addition to assisting in rationalisation of the health care system funds, generic industry should assist in the modernisation of the health care system. Resources acquired from these savings can be redirected towards the introduction of innovative medicines to the List, towards budget creation for rare disease medicines, as well as for the expansion of therapeutical categories through increased application of new/modern generified medicines at acceptable prices.

For instance, one third of the mentioned savings from Imatinib could treat 100.000 patients a year suffering from hypertension! It is known that about 700.000 people in Serbia uses high blood pressure medication, but that are also another 700.000 people who are aware of their hypertension but receive no therapy, which brings classifies them to the zone of high cardiovascular risk.

(Calculation explanation – This builds on an assumed savings of 2 million EUR, which I divide into 12 months, and further compare with the price of monthly basic ACE inhibitor therapy)

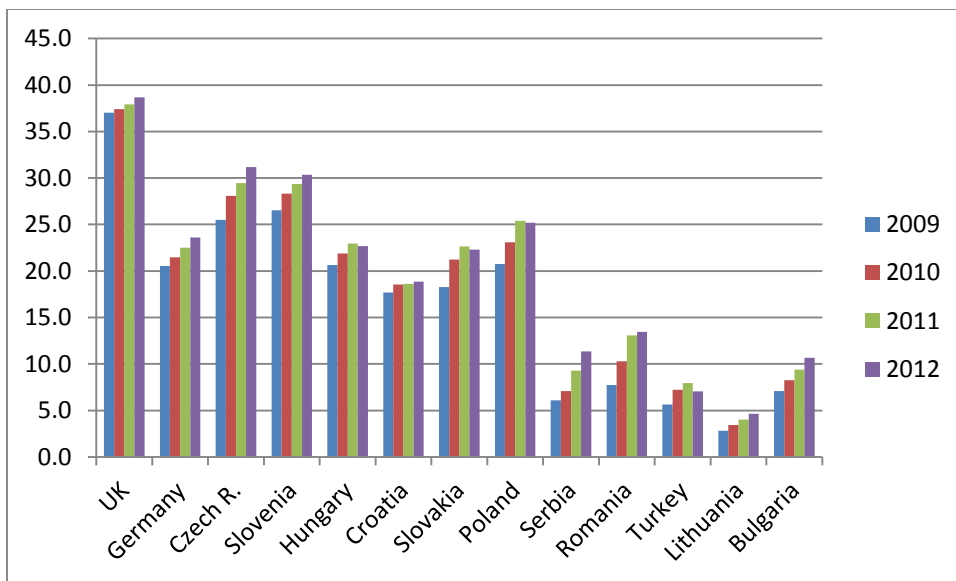
## B) Generic industry as a partner in the expansion of therapeutical categories by means of modern therapies

### **B1) Statins**

As an example of the expansion of therapeutical categories, we can look at the use of **statins**, medicines whose role is to lower the level of harmful cholesterol in the blood. Statins are very important in the prevention and delay of the occurrence of cardiovascular diseases.

The use of statins in Serbia is almost the lowest in Europe, as can be seen from the graph below that shows the use of statins per capita in several European countries:

**Graph. Use of statins per capita in several European countries**



Source: Author, analysis based on IMS Health data. Copyright 2013. All rights reserved. <sup>17</sup>

In the Czech Republic, statins are used by 1.4 million people, while in Serbia this number is just over 200 thousand due to its insufficient usage in the prevention of cardiovascular diseases.

In Croatia, the following indications are also reimbursed: Primary prevention of cardiovascular events in patients with type 2 diabetes mellitus and another risk factor, in Serbia only secondary prevention.

Adding the prevention of CVS events in patients with type 2 DM and another risk factor in accordance with the National Guide for the diagnosis and treatment of lipid disorders<sup>18</sup> would lead to cost savings for the treatment of CVS events and their consequences.

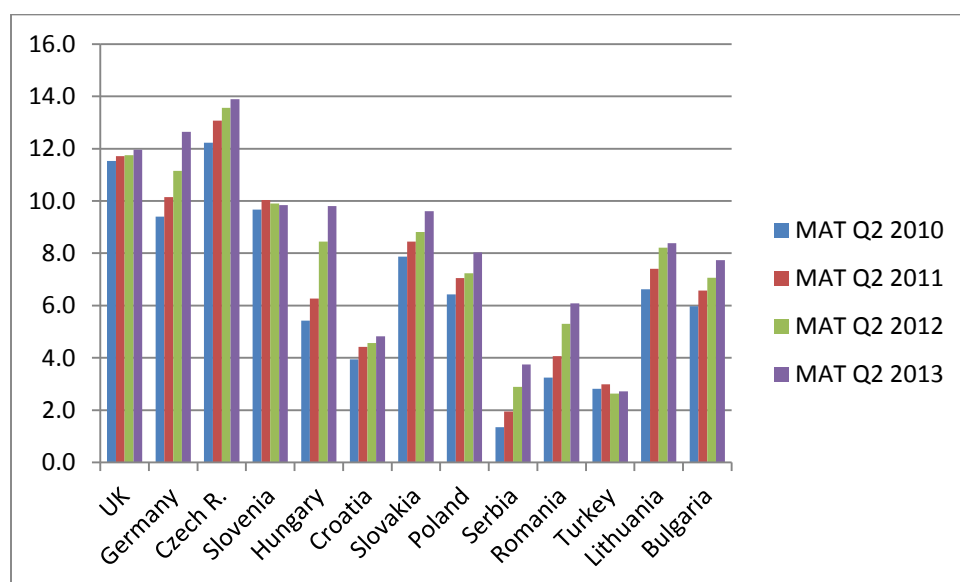
<sup>17</sup> Source of information for Serbia: IMS Market Viewer, data published on Jan 2013. Source of information for other countries: IMS, MIDAS, data published on Q1 2013

## **B2) Sartans**

Sartans are an important part of antihypertensive therapy. According to data from the National Guide of Good Clinical Practice for the diagnosis and treatment of arterial hypertension (pages 9 and 10)<sup>19</sup>, and as per the research carried out in 2006 by the Institute of Public Health of Serbia “Dr Milan Jovanović Batut”, “**46.5% of adult inhabitants had elevated systolic or diastolic blood pressure or was taking medication to lower the blood pressure**”. At the same time, the report points out that only half of that number (24.1%) was taking antihypertensive medicines.

A similar example are medicines from the group of **sartans**, for lowering blood pressure, where Serbia also lags behind Europe, as can be seen in the table below:

**Graph. Use of sartans per capita in several European countries**



Source: Author, analysis based on IMS Health data. Copyright 2013. All rights reserved.<sup>20</sup>

One of the reasons for such data is the fact that sartans are limited only to prescription by interns or cardiologists. The expansion of prescription rights to general practitioners (as is currently the case with ACE inhibitors), along with the status of sartans on the A list, would bring Serbia to join to the countries who have already introduced this way of prescribing and thus made this significant group of medicines more available to a wider scope of patients.

<sup>18</sup> Available at:

<http://www.zdravlje.gov.rs/downloads/2011/Decembar/Vodici/Vodic%20za%20dijagnostikovanje%20i%20lecenje%20lipidskih%20poremecaja.pdf>

<sup>19</sup> Dostupno na:

<http://www.zdravlje.gov.rs/downloads/2011/Decembar/Vodici/Vodic%20za%20dijagnostikovanje%20i%20lecenje%20arterijske%20hipertenzije.pdf>

<sup>20</sup> Source of information for Serbia: IMS Market Viewer, data published on Q3 2013. “Source of information for other countries: IMS, MIDAS, data published on Q3 2013.

Having the insight in the positive lists in Croatia<sup>21</sup> and Slovenia<sup>22</sup>, we can see that there prescription rights are not limited to medical specialists.

### **B3) Modern antidepressants**

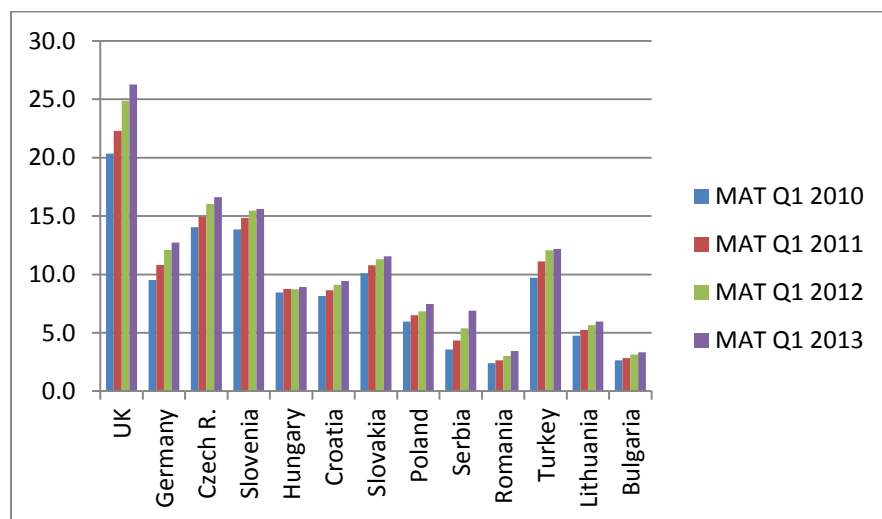
In its report from 2012<sup>23</sup>, ‘Depression, A Global Public Health Concern’, World Health Organisation recognises (WHO) depression as a heavy burden for the world health system and one of the most common diseases on the 21st century. WHO research estimates that the depression affects about 250 million people worldwide, highlighting the fact that , in the countries included in the survey, 1 out of 20 respondents had at least one depressive episode within the past year.

Analysing of the use of **modern antidepressants** in Serbia, in comparison to other European countries, including the following groups:

- **SSRI** (sertraline, citalopram, escitalopram, paroxetine, fluoxetine, and other medicines)
- **SNRI** (duloxetine, venlafaxine, desvenlafaxine, and more)
- **Other atypical modern antidepressants** (bupropion, mianserin, trazodone, agomelatine, mirtazapine, and more)

we come to the conclusion that modern therapy, which brings along better efficiency and less side effects, still has not been expanded enough in Serbia, as seen in the graph below:

**Graph. Use of modern antidepressants per capita in several European countries**



Source: Actavis, analysis based on IMS Health data. Copyright 2013. All rights reserved<sup>24</sup>

<sup>21</sup> [hzzo.hr/zdravstveni-sustav-rh/trazilica-za-lijekove-s-vazecih-lista](http://hzzo.hr/zdravstveni-sustav-rh/trazilica-za-lijekove-s-vazecih-lista)

<sup>22</sup> [www.cbz.si](http://www.cbz.si)

<sup>23</sup> [http://www.who.int/mental\\_health/management/depression/who\\_paper\\_depression\\_wfmh\\_2012.pdf?ua=1](http://www.who.int/mental_health/management/depression/who_paper_depression_wfmh_2012.pdf?ua=1)

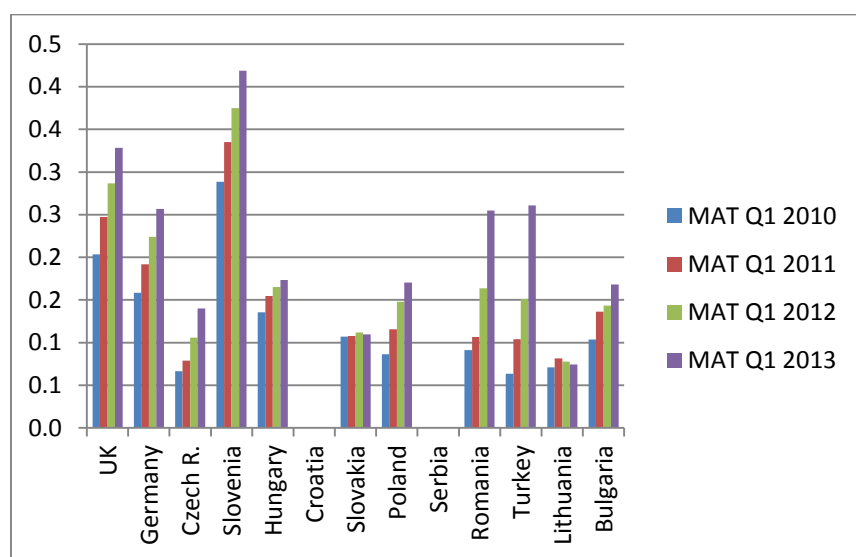
<sup>24</sup> Source of information for Serbia: IMS Market Viewer, data published on Q1 2013. “Source of information for other countries: IMS, MIDAS, data published on Q2 2013”

Having the insight in the positive lists in Croatia<sup>25</sup> and Slovenia<sup>26</sup>, we can see that there prescription rights are not limited only to medical specialists.

#### **B4) Modern antipsychotics**

The use of modern antipsychotics in Serbia still lags behind the standard of therapy in developed countries because typical antipsychotics with many more side effects and poorer quality of life for patients compared with modern antipsychotics still have a major role in therapy. One example of a modern antipsychotic widely used in the world is aripiprazole, which makes it one of the best-selling medicines in the world<sup>27</sup>, while it is not present in Serbia. The graph below illustrates the use of this medicine in Europe per capita:

**Graph. Use of Aripiprazole per capita in several European countries**



Source: Actavis, analysis based on IMS Health data. Copyright 2013. All rights reserved.<sup>28</sup>

Serbia can launch this medicine as a generic cheap version before Europe as well (European generic launch is expected only in 2015/2016) – already this year we can expect at least two generic medicines in the domestic market.

The given examples actually depict that new therapies, which have already become the gold standard in therapy of patients in Europe, are still not present in Serbia in satisfactory volume. The reason is that new therapies have been mostly too expensive for the resources we dispose of, and our system simply could not afford them.

<sup>25</sup> [hzzo.hr/zdravstveni-sustav-rh/trazilica-za-lijekove-s-vazecih-lista](http://hzzo.hr/zdravstveni-sustav-rh/trazilica-za-lijekove-s-vazecih-lista)

<sup>26</sup> [www.cbz.si](http://www.cbz.si)

<sup>27</sup> <http://www.medscape.com/viewarticle/803986>, 100 Top-Selling Drugs Report Released, May 2013

<sup>28</sup> Source of information for Serbia: IMS Market Viewer, data published on Q2 2013. Source of information for other countries: IMS, MIDAS, data published on Q2 2013.



Nonetheless, the local generic industry, through the already mentioned regulatory framework, offers more modern molecules (examples of Losartan, Olanzapine, Pioglitazone) at the prices affordable for the system. These medicines are often developed in our market by generic companies because originators do not launch them in the countries with lower purchasing power.

## **Conclusion**

Each and every reform of the pharmaceutical sector has to start at the basic postulate “Primum non nocere”, which implies that the medicines will be on the shelves even after the reform. It is also important for the reform to take care of its interested parties – patients, fund, medical community, participants in the distribution chain and pharmaceutical industry.

In my opinion, every price decline should necessarily be followed by the improvement of patients’ position, i.e. the possibility of more and more patients getting access to the medicine. The methods to achieve there are explained in this text and include removal of prescription limitations in terms of indications or prescribing rights, transferring medicines from A1 to A list, and more.

During the economic crisis, most of the countries of Eastern Europe recognise the strategic importance of local industry as a stability factor for medicines supply.

There is no magic formula for the reform of the health care system applicable in every country. The model which works well in Germany or the Netherlands could have negative implications in Serbia (different market size, shares of generic industry, different regulatory framework, health insurance system).

A partner dialogue among all the participants in the system is the only thing that can bring a sustainable solution, with the aim of:

- Preserving the system and supply stability (which we already have and should not be disrupted)
- System improvement in all aspects through savings (introduction of new therapies at prices affordable for the system...). Quick win savings:
  - o Creation of regulatory framework which recognizes the benefit of generification, removes obstacles and speeds up the process of arrival of generic medicines in the market
  - o Costs control
- Enhancing the pharmaceutical industry export, as a healthy segment of the Serbian industry, and keeping jobs for the workers in the industry.