DEVELOPMENT OF PHARMACEUTICALS SECTOR IN SERBIA FOLLOWING WORLD TRENDS TARIFFS ELIMINATION

RAZVOJ FARMACEUTSKOG SEKTORA U SRBIJI U SVETLU SVETSKIH TENDENCIJA UKIDANJA CARINSKE ZAŠTITA

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Abstract

This agreement known as the Pharmaceutical Zero-for-Zero Initiative took effect in 1995. Initially 22 countries agreed to eliminate tariffs on pharmaceutical products. Serbia has taken part in that agreement during 2007. Sectoral initiative in pharmaceuticals, according to the Serbian Custom Tariffs consists of 114 tariff lines and all products are included in Chemical Harmonization Agreement. The sector accounts for 3.24% of the total Serbian industry in 2006, with the value of sector's annual production is € 308 million. Annual growth of the sector in 2006 was 15%. During the period 2001 – 2006, the foreign trade of Pharmaceuticals was characterized by constant and growing trade deficit with the faster growth of imports (24.14%) than the exports (14.63%). The annual average share of those products in the total exports and imports accounted for 2.3%.

Apstakt

Sporazum koje je poznat pod nazivom „Inicijativa nula-za-nula" je stupio na snagu 1995. godine. Inicijalno su se 22 zemlje dogovorile da eliminišu carinsku zaštitu na proizvodima farmaceutske industrije. Srbija je pristupila sporazumu tokom 2007. godine. Sektorska inicijativa u farmaceutskim proizvodima u skladu sa Carinskom tarifom Srbije se sastoji od 114 tarifnih linija i proizvoda i oni su svi uključeni u sporazum o harmonizaciji Hemijske industrije. Ovaj sektor čini 3.24% ukupne proizvodnje Industrije Srbije u 2006. godini, sa vrednošću godišnje proizvodnje od 308 miliona evra. Godišnja stopa rasta u 2006. godini je bila 15%. U periodu 2001-2006 spoljnotrgovinska razmena je imala stalni trend porasta trgovinskog deficita, sa većom stopom porasta uvoza od 24.14% u odnosu na stopu rasta izvoza koja je bila 14.63%. Učešće ovog sektora u ukupnoj spoljnotrgovinskoj razmeni Srbije se kretalo na nivou od 2.3%.

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Sector initiative overview

In 1995, 22 countries[1] agreed to eliminate tariffs on pharmaceutical products, their derivatives, and certain chemical intermediates used to manufacture pharmaceuticals. This agreement is known as the Pharmaceutical Zero-for-Zero Initiative. Since the original agreement entered into force, it has been updated twice, in 1997 and 1999, to expand the list of products that can be imported free of duty. The agreement, effective January 1st, 1995, eliminated tariffs in signatory countries regarding approximately 7,000 pharmaceutical products and chemical intermediates for all World Trade Organization members on a Most Favored Nation (MFN) basis In the Uruguay Round Agreements Act (URAA).

Description of Products Covered

Pharmaceuticals are used to prevent, diagnose, treat, or cure diseases in humans and animals.[2] Products included in the pharmaceutical agreement include dosage-form pharmaceuticals, bulk pharmaceuticals, and certain chemical intermediates used in the production of pharmaceuticals. Dosage - form pharmaceuticals are formulated products in dosage forms, such as tablets or vials, which may be packaged for retail sale. Pharmaceuticals in dosage form are generally sold to the final customer as generic or brand name products, either by prescription or over-the-counter. Bulk pharmaceuticals are active ingredients that are produced or purchased by pharmaceutical firms and further processed into dosage-form products. The chemical intermediates covered, generally organic chemicals, are inputs in the production of pharmaceutical active ingredients. Chemical intermediates are produced by either pharmaceutical firms or specialty chemicals firms and usually used by pharmaceutical firms for producing bulk pharmaceutical products.

Overview of the Pharmaceutical Industries in USA and EU

Most finished pharmaceutical products and bulk active ingredients are manufactured by pharmaceutical companies. Chemical intermediates included in

[1] The 22 countries were the EU-15 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom), USA, Canada, the Czech Republic, Japan, Norway, the Slovak Republic, and Switzerland.

[2] The Pharmaceutical Zero-for-Zero Initiative applies only to pharmaceuticals for human use.

the Pharmaceutical Appendix may be produced by either pharmaceutical companies or by specialty chemicals firms. The closer the intermediate is to the final pharmaceutical product, the more likely it is to be produced by a pharmaceutical firm. Pharmaceutical companies may produce final and intermediate products by either fermentation or traditional chemical synthesis.[3] Specialty chemical companies that supply intermediates to drug companies generally use traditional chemical synthesis, but future advances in biotechnology may allow more specialty chemicals to be produced via fermentation or enzymatic processes. Both the pharmaceutical and chemical industries include large, multinational firms that often have manufacturing facilities throughout North America, Europe, and Asia.

Both the U.S. chemical industry and the U.S. pharmaceutical industry spend large amounts of money on research and development (R&D). According to the Pharmaceutical Research and Manufacturers Association (PhRMA), the pharmaceutical industry spent 39.4 billion USD on R&D in 2005. Much of that spending went to the development of new drugs. The average cost of developing one new drug is estimated to be 800 million USD over 10 to 15 years. The largest portion of the money and time is spent in clinical trials, which the U.S. Food and Drug Administration (FDA) require to ensure the safety and efficacy of the new drug. Since other chemical sectors typically do not face as stringent a regulatory system as pharmaceutical companies, product development in these sectors is generally faster and less expensive.

Patent protection is also important to the pharmaceutical industry. Usually firms receive exclusive rights to sell a pharmaceutical product for 20 years. However, depending on the length of the product approval process, the period of time during which the patent holder has the exclusive right to commercially market the product may be significantly less than 20 years. Generic drugs are increasingly being produced in developing countries, such as China and India, for internal consumption and export.

In 2002, shipments for the chemical and allied products industry totaled approximately 454 billion USD; the pharmaceutical industry accounted for 31 percent of this amount. The pharmaceutical industry also accounted for 47 percent of U.S. chemical imports and 24 percent of U.S. chemical exports in 2002. Employment in the pharmaceutical industry accounts for 30 percent of total employment in the chemical industry and 24 percent of its production workers.

When a new pharmaceutical is available for human use, it is immediately eligible for duty-free treatment if it is classified in chapter 30, defined in part as

[3] Fermentation is the cultivation of microorganisms for the enzymatically controlled production of compounds by cellular metabolism. Chemical synthesis is the formation of compounds from simpler compounds by chemical reaction

imported in dosage form and/or packaged for sale, or if it is imported as a bulk pharmaceutical under one of the four HS headings in chapter 29 mentioned above. However, if this new pharmaceutical is imported in bulk under another HS heading and is not already included in the Pharmaceutical Appendix, it may be added to the duty-free list in the appendix only after a periodic update. Most chemical intermediates used to make new pharmaceuticals that are not yet covered by the agreement would fall outside Chapter 30 and HS headings 2936, 2937, 2939, and 2941 and would have to be added to the Pharmaceutical Appendix to receive duty-free treatment.

Trade data from the period 2004 - 2005 for the products currently included in the Pharmaceutical Zero-for-Zero Initiative are presented in table 1, providing imports for consumption, domestic exports, and the trade balance for HS chapter 30 and HS headings 2936, 2937, 2939, and 2941.

Total trade in products classified under these subheadings was valued at more than 64 billion USD in 2005. Imports of these items were valued at approximately 19.2 billion USD in 2004 and 18.8 billion USD in 2005. Bulk pharmaceutical active ingredients and chemical intermediates listed in the appendix are classified under various HTS subheadings; the tariff rates for the products range from 0 to 6.5 percent ad valorem. Based on 2005 import data, the ad valorem equivalent tariff rate for the products currently in the Pharmaceutical Appendix would have been 6.0 percent if they had not received duty-free treatment.

Table 1. Trade of Pharmaceuticals in US, 2004–2005 (million dollars)

Product grouping	imports for consumption		domestic exports		trade balance	
	2004	2005	2004	2005	2004	2005
2936	644	620	424	425	-221	-195
2937	1,720	1,697	2,405	1,879	685	181
2939	644	336	17	135	-627	-201
2941	1,197	1,380	1,149	1,348	-48	-32
Chapter 30	32,245	35,574	18,934	21,059	-13,312	-14,515
Total	36,451	39,607	22,929	24,846	-13,522	-14,761

Source: *Official statistics of the U.S. Department of Commerce.*

For the proposed additions to the Pharmaceutical Appendix, it is impossible to provide official trade statistics because the 8-digit classifications of goods included in this study cover multiple products, many of which are not included in the pharmaceutical agreement.

Table 2. Pharmaceuticals industry data in EU*(million EURO, units)

Type	1990	1995	2000	2004	2005
Production	60,220	87,799	121,471	160,769	170,000
Exports	23,180	44,188	90,935	165,003	178,000
Imports	16,113	31,018	68,841	132,853	144,000
Trade balance	7,067	13,170	22,094	32,150	34,000
R&D expenditure	7,766	11,484	17,849	21,106	21,700
Employment	500,879	506,052	538,317	612,114	615,000

(*) Data relate to EU-25, Norway and Switzerland since 2004

Source: *EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-25 trade data 1995-2005)*

Production in Serbia

Generic drugs have very important role in the industry. This trend has created a tremendous business opportunity for pharmaceutical companies who serve the "bottom of the pyramid". Serbian pharmaceutical companies have strategically positioned themselves to take advantage of the mentioned trends. Many of the Serbian pharmaceutical companies have invested substantial capital into development and are capable of producing quality low-cost generic drugs. If short of in-house manufacturing capacities, want to outsource small-batch production, reduce manufacturing costs, or delay/avoid capital investments in manufacturing, one should consider manufacturing in Serbia.

Sectoral initiative in pharmaceuticals, according to the Serbian Custom Tariffs consists of 114 tariff lines. All products are included in Chemical Harmonization Agreement. 55 products are from chapter 29 - Organic chemicals and 59 products from chapter 30 - Pharmaceutical products. Comparative classification of the 4 digit HS and ISIC rev.3 is shown in table 3.

Table 3. Comparative classification of Pharmaceutical products, number of companies and employees in Serbia

HS 4 digit	ISIC3 classification	Number of active companies*	Number of employees*
3001, 3002.9	24410	5	602
2936,2937,2939,2941, all other 30	24420	27	7214

*** Source:** *Serbian Chamber of Commerce, Privatization Agency of Serbia*

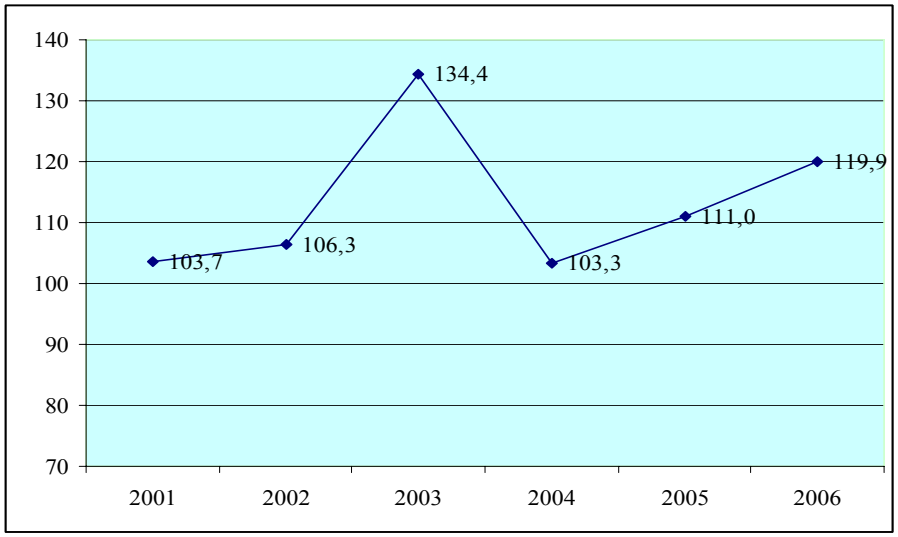
All HS 4 digit product lines are clearly divided into ISIC rev.3 classification. Its very important to notice that 129 companies registered to ISIC3 classification 24660 belonging to HS 3006, which employ over 2000 employees are taken out of consideration since 99.9% of their production belongs to Chemicals rather than to Pharmaceuticals.

The largest companies in Serbia in manufacture of Pharmaceuticals are: Galenika, Hemofarm, Zorka Pharm, Jugoremedija, employing 2700, 1700, 600 500 workers respectively. Galinka is state owned and the other three are private owned companies.

Value of production of Galenika in 2004 was 63 million EURO which in 2005 increased to 70 million EURO.[4] At the same period, Hemofarm production increased from 110 to 160 million EURO.[5]

The sector accounts for 3.24% of the total industry in 2004, with the value of sector's annual production is EURO308 million. Annual growth of the sector in 2004 was 15%.[6]

Graph 1. Index of industrial production in pharmaceuticals in Serbia (previous year =100%)



Source: *Statistical office of Serbia*

[4] Galenika a.d., Financial Statement, http://www.galenika.co.yu

[5] Belgrade Stock Exchange, www.belex.co.yu

[6] The Association of Chemists and Chemical Engineers of Serbia, http://www.shts.org.yu

Companies like Hemofarm and Galenika, which have invested substantial capital into development, are expanding the frontiers of pharmaceutical industry in the Region. Other companies like the Zdravlje Actavis (owned by Actavis company from Iceland) which is one of the leading manufacturers of generics in Serbia provide access to low cost drugs.

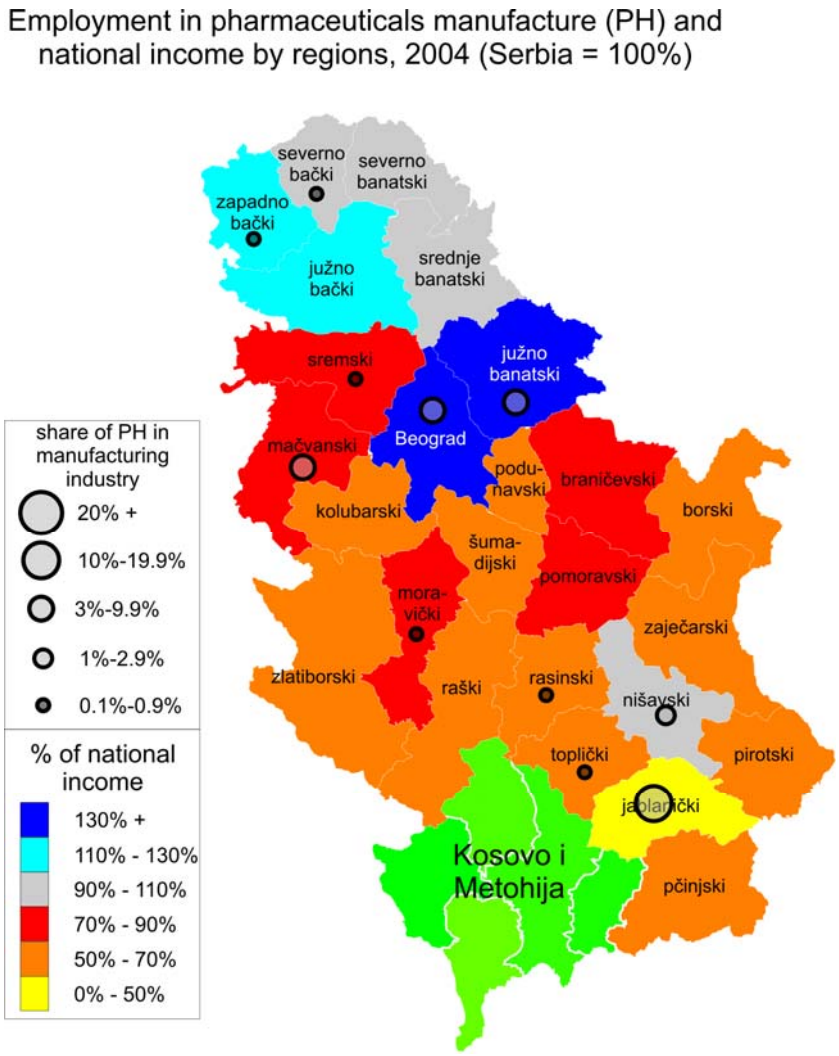
Hemofarm is a company with decades of experience in drug production. Today, the Group comprises a parent company and 21 subsidiaries, 12 in Serbia and the rest abroad. Galenika has been producing drugs for 60 years. It was established in 1945, and soon after became the fourth company in the world producing penicillin. In 1991 it has entered JV with ICN, which ended in 1999. Currently, the company accounts for 30% of the domestic market.

Regional distribution of employment and production

In Serbia there are 32 active companies employing 7816 people in pharmaceuticals production. Three of them with 2800 employees are still in state ownership. In analysis of regional distribution of companies, it is noticeable that production is concentrated in five counties: "Beograd, Južnobanatski, Mačvanski, Nišavski and Jablačnički" county, where 97%[7] of employees working in pharmaceuticals production are employed. Moreover production in Podunavski region accounts for 57% of value added in 2005[8].

[7] Serbian Chamber of Commerce, http://portal.komora.net

[8] Government of Serbia, Strategy for Regional Development of Serbia 2007-2012, p. 98



Source: *Data are taken from Table in Annex 1*

Foreign trade

During the period 2001 – 2006, the foreign trade regarding those products was characterized by constant and growing trade deficit with the faster growth of imports (24.14%) than the exports (14.63%). The annual average share of those products in the total exports and imports accounted for 2.3%.

Table 5. Trade in Pharmaceuticals 2001-2006 in Serbia, annually (000 EURO)

	2001	2002	2003	2004	2005	2006	Export growth (%)	Import growth (%)
Export	45,216	53,876	62,999	58,132	82,825	102,594	14.63	
Import	81,383	116,674	147,397	193,895	223,213	297,902		24.14
Balance	-36,167	-62,798	-84,398	-135,763	-140,388	-195,308		

Source*: Statistical Office of the Republic of Serbia*

The biggest volume of foreign trade was recorded with the products from tariff group 3004 – medicaments prepared for the retail sale. During the period under review, the import grew twice faster and the trade deficit made the half of the total trade deficit in the foreign trade of pharmaceutical products. In the same time the two products from the tariff heading 30 (3004 32 10 00 and 3004 10 10 00) are the only products from this group that recorded significant surplus in foreign trade. The tariff protection of these two products is not so significant, and also is not highly expressed in the initial offer.

After the tariff group 3004, the second place are taking the products from the tariff group 2941 (antibiotics) and 3002 (blood) even though their trade volume is much lower. These products together the products from the tariff group 3004, in six years will contribute to the realization (80%) of trade deficit in trade of pharmaceutical products. Regarding the fact that products from the tariff group 2941 are used as a row materials in the pharmaceutical industry, their current protection is 0% and in the initial offer the protection is increased only for one products (due to the harmonization with EU). Almost there is a same situation regarding the products from the tariff group 3002.

Regarding the trade volume, there is still one group of products that distinct from the other pharmaceutical products. In average, the trade volume of those products recorded 8.6 mill. EURO and 90% concern the imports. Those products belong to the tariff group 3006.

Generally speaking, the tariff protection of pharmaceutical products does not deviate significantly from the sector initiative requirement. The tariff protection expressed in the initial offer is ranging from 0% to 10% (only one product has a protection of 30% - pharmaceutical waste) and the average tariff protection accounts for 3.74% which is not so significantly different from the current level (1.7%). However, according to the Law on medicaments and medical devices, the legal persons have to fulfill the conditions prescribed and have a license for disposing the medicines for sale issued by the Ministry of Health and license

issued by the Ministry of Agriculture, Forestry and Water management in the case of veterinary medicaments. This measure regards the quality control, safety and efficiency of medicaments within aim of protecting people's health. This measure also represents the non tariff barrier in trade of pharmaceutical products and medical devices.

During the period 2001-2006, Serbia recorded high **trade deficit** in trade of pharmaceuticals. Average trade deficit during the period under review was around 109 million EUR.

Table 6. Trade in Pharmaceuticals 2001-2006, annually average (000 EURO)

Average trade 2001-2006 000 EUR	
Export	67,607.00
Import	176,744.00
Trade Balance	-109,137.00

Source: *Statistical Office of the Republic of Serbia*

Literature

1. (2007) Government of Serbia, Strategy for Regional Development of Serbia 2007-2012, p. 98
2. The Association of Chemists and Chemical Engineers of Serbia, http://www.shts.org.yu
3. Belgrade Stock Exchange, www.belex.co.yu
4. Galenika a.d., Financial Statement, http://www.galenika.co.yu
5. *EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-25 trade data 1995-2005,) http://epp.eurostat.ec.europa.eu*
6. *Official statistics of the U.S. Department of Commerce. www.census.gov/ftp/pub/foreign-trade*
7. *Privatization Agency of Serbia, www.priv.yu*
8. *Serbian Chamber of Commerce, www.pks.co.yu*
9. *Statistical office of Serbia, www.statserb.sr.gov.yu*

County (Districts)*	Size (km^2)	Population 2002	Value Added (% distribution)	National income (Serbia 2004 =100%)	Eemployment 2006		
					Total	Distribution (%)	Pharmaceuticals
SERBIA	88.361	7.498.001	100,0	100,0	2.025.922	100,0	7.816
Grad Beograd Barajevo, Voždovac, Vračar, Grocka, Zvezdara, Zemun, Lazarevac, Mladenovac, Novi Beograd, Obrenovac, Palilula, Rakovica, Savski Venac, Sopot, Stari Grad, Surčin, Čukarica	**3.224**	1.576.124	31,4	164,3	621.747	30,7	3.034
Severno-bački Bačka Topola, Mali Iđoš, Subotica	**1.784**	200.140	2,9	108,3	54.700	2,7	12
Srednje-banatski Žitište, Zrenjanin, **Nova Crnja**, Novi Bečej, **Sečanj**	**3.256**	208.456	2,3	101,6	43.311	2,1	0
Severno-banatski Ada, Kanjiža, Kikinda, Novi Kneževac, Senta, Čoka	**2.329**	165.881	2,7	109,1	36.383	1,8	0
Južno-banatski Alibunar, **Bela Crkva**, Vršac, Kovačica, Kovin, Opovo, Pančevo, Plandište	**4.245**	313.937	5,6	131,9	71.792	3,5	1.675
Zapadno-bački Apatin, Kula, Odžaci, Sombor	**2.420**	214.011	3,6	120,9	47.247	2,3	7
Južno-bački Bač, Bačka Palanka, Bački Petrovac, Beočin, Bečej, Vrbas, Žabalj, Novi Sad - grad, Srbobran, ***Sremski Karlovc*****i**, Temerin, Titel	**4.016**	593.666	12,0	125,8	212.062	10,5	5
Sremski Inđija, Irig, Pećinci, Ruma, Sremska Mitrovica, Stara Pazova, Šid	**3.486**	335.901	2,1	70,7	60.418	3,0	20
Mačvanski Bogatić, Vladimirci, Koceljeva, ***Krupanj***, Loznica, Ljubovija, ***Mali Zvornik***, Šabac	**3.268**	329.625	2,1	72,2	60.189	3,0	595

Kolubarski Valjevo, Lajkovac, Ljig, Mionica, Osečina, Ub	**2.474**	192.204	1,6	70,0	44.098	2,2	0
Podunavski Velika Plana, Smederevo, Smedervska Palanka	**1.248**	210.290	2,9	65,1	54.365	2,7	0
Braničevski Veliko Gradište, Golubac, **Žabari**, ***Žagubica***, Kučevo, **Malo Crniće**, Petrovac, Požarevac	**3.865**	200.503	1,0	82,4	39.715	2,0	0
Šumadijski Aranđelovac, Batočina, Knić, Kragujevac-grad, Lapovo, Rača, Topola	**2.387**	298.778	3,4	67,0	74.313	3,7	5
Pomoravski Despotovac, Jagodina, Paraćin, **Rekovac**, Svilajnac, Ćuprija	**2.614**	227.435	2,3	70,7	61.367	3,0	0
Borski ***Bor*****,** Kladovo, ***Majdanpek***, Negotin	**3.507**	146.551	1,0	52,3	32.972	1,6	0
Zaječarski Boljevac, Zaječar, Knjaževac, Sokobanja	**3.623**	137.561	0,8	55,1	29.420	1,5	0
Zlatiborski Arilje, Bajina Bašta, Kosjerić, Nova Varoš, Požega, ***Priboj***, ***Prijepolje***, ***Sjenica***, Užice, Čajetina	**6.140**	313.396	4,0	65,0	70.715	3.5	10
Moravički Gornji Milanovac, Ivanjica, Lučani, Čačak	**3.016**	224.772	3,6	87,1	52.829	2,6	111
Raški Vrnjačka Banja, Kraljevo, ***Novi Pazar***, Raška, *Tutin*	**3.918**	291.230	1,5	5,7	71.314	3,5	0
Rasinski Aleksandrovac, ***Brus*****,** ***Varvarin***, Kruševac, Trstenik, Ćićevac	**2.668**	259.441	3,2	64,7	53.170	2,6	57
Nišavski Aleksinac, **Gadžin Han**, ***Doljevac***, Merošina, Grad Niš, Mediana, Crveni Krst, Pantelej, Palilula, Niška Banja, ***Ražanj***, ***Svrljig***	**2.729**	381.757	4,8	95,2	97.755	4,8	521
Toplički Blace, Žitorađa, ***Kuršumlija***, Prokuplje	**2.231**	102.075	0,3	51,2	17.489	0,9	7
Pirotski Babušnica, ***Bela Palanka***, ***Dimitrovgrad***, Pirot	**2.761**	105.654	1,8	70,4	26.641	1,3	0

Jablanički ***Bojnik***, ***Vlasotince***, ***Lebane***, Leskovac, ***Medveđa***, ***Crna Trava***	**2.769**	240.923	1,3	46,2	46.240	2,3	1.757
Pčinjski ***Bosilegrad***, ***Bujanovac***, ***Vladičin Han***, Vranje, ***Preševo***, Surdulica, ***Trgovište***	**3.520**	227.690	1,9	52,4	45.670	2,3	0

* in italic and underlined are under developed districts, ie. districts where national income is less than 50% of Serbia average

Sources: Statistical office of Serbia, Serbian Chamber of Commerce, Republican Development Bureau of Serbia