

SeeNews

Research on demand

Pharmaceuticals Manufacturers in Slovenia in 2012

Table of Contents

1. Methodology.....	4
2. Overview	4
Chart 1 – Global pharmaceuticals sales in 2012	5
2.1 Macroeconomic background.....	5
Table 1 – Macroeconomic indicators	6
Chart 2 – SEE Countries Main Macroeconomic Indicators	6
Chart 3 – Slovenia’s Population.....	7
2.2 Total revenue of top 20 pharmaceutical companies in SEE region.....	7
Table 2 – Pharmaceuticals Manufacturers in SEE	8
Chart 4 – Total Revenue per Capita of top 20 SEE pharmaceutical companies in 2012	9
3. Legislation.....	9
4. Stakeholders in Slovenian pharmaceutical market.....	10
5. Manufacturing of pharmaceuticals in Slovenia	10
5.1 Market size	10
Chart 5 - Number of Manufacturers of Basic Pharmaceutical Products and Preparations	11
Chart 6 - Number of Companies that Held Licences for Manufacture of Medicinal Products as of Sept 30, 2013	12
Table 3 - Slovenian Pharmaceuticals Manufacture Market.....	12
5.2 Main players	13
Chart 7 – Market Share of Krka d.d. and Lek d.d.....	13
Chart 8 - Manufacture of Finished Pharmaceutical Products (in billion units) by Krka d.d.....	14
Table 4 – KRKA d.d. Profile.....	15
Table 5 – Lek d.d. Profile	16
6. Prices	18
Chart 9 – CPI change of pharmaceuticals	Error! Bookmark not defined.
7. Exports and imports	19

Chart 10 – Slovenia’s Exports and Imports of Pharmaceuticals.....	19
8. Number of employees.....	19
Table 6 - Number of Employees in Slovenian Pharmaceuticals Manufacturing Companies in 2012.....	20
9. Investments	20
10. Future trends	21
Chart 11 – Total World Pharmaceutical Market.....	21
11. References and information sources	23

The market research aims to:

- Determine the size of Slovenian pharmaceuticals manufacture market
- Outline the main players in the sector
- Evaluate the potential for growth
- Indicate the future trends

1. Methodology

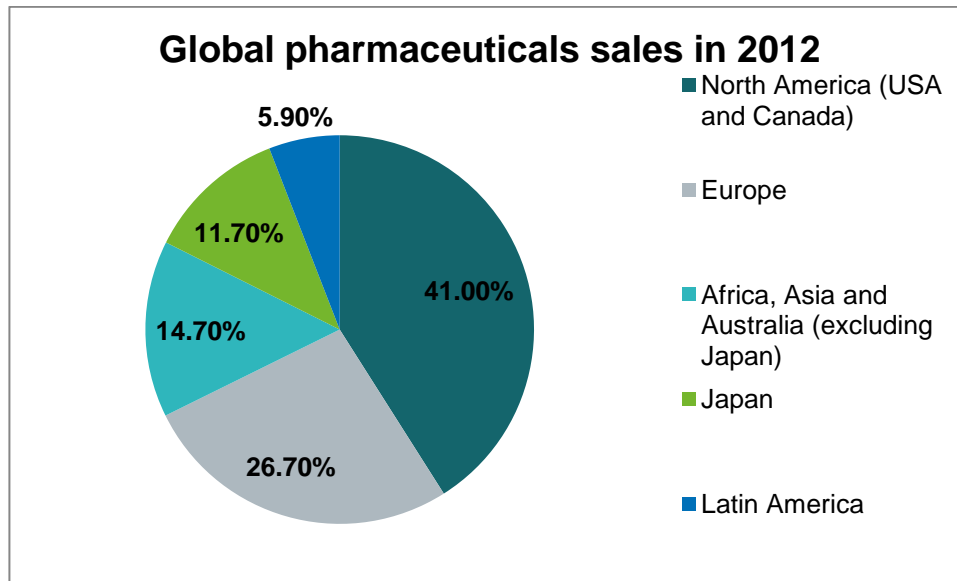
The market research followed a methodology based on desktop research. We looked through official sources including World Health Organization, International Federation of Pharmaceutical Manufacturers & Associations, European Federation of Pharmaceutical Industries and Associations, research firm IMS Health, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), Ministry of Health of Slovenia, Slovenian Pharmaceutical Society and Slovene Chamber of Pharmacy.

We have gathered and analysed data from the companies' annual reports and monitored latest news in the pharmaceutical sector in Slovenia. The manufacturers of natural products and food additives are not included in the research.

2. Overview

The majority of global pharmaceuticals sales in 2012 were realised in North America (USA and Canada) with 41%, followed by Europe with 26.7%, Africa, Asia and Australia (excluding Japan) with 14.7%, Japan with 11.7% and Latin America with 5.9%.

Chart 1 – Global pharmaceuticals sales in 2012



Source: European Federation of Pharmaceutical Industries and Associations

Although Slovenia's population stood at two million people in 2012, its pharmaceutical market is one of the most developed in Central and Eastern Europe according to market intelligence company Business Monitor International (BMI). This is due to the well-established tradition of pharmaceuticals manufacturing in the country and its tight relations with European Union (EU). Slovenian pharmaceutical market size was EUR 738 mln in 2012, of which generic medicines accounted for 32.5%.

2.1 Macroeconomic background

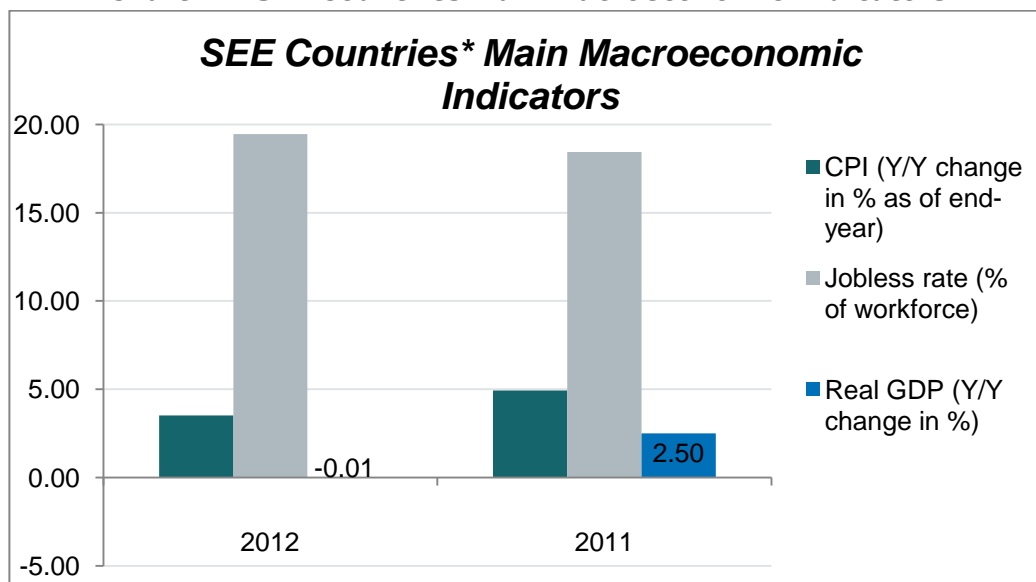
Slowdown in economic activity and soaring unemployment rates put a mark on the year in Slovenia and all over in Southeastern Europe (SEE). The recession in the Eurozone had unfavourable influence upon SEE countries' foreign direct investment and external demand.

Table 1 – Macroeconomic indicators

Country	CPI (Y/Y change in % as of end-year) in 2012	CPI (Y/Y change in % as of end-year) in 2011	Real GDP (Y/Y change in % in 2012)	Real GDP (Y/Y change in % in 2011)	Jobless rate (% of workforce) in 2012	Jobless rate (% of workforce) in 2011
Albania	2.0	3.5	1.7	3.0	13.0	13.3
Bosnia and Herzegovina	2.1	3.7	-0.5	1.0	31.7	27.6
Bulgaria	3.0	4.2	0.8	1.8	11.4	10.4
Croatia	3.4	2.3	-2.0	0.0	15.8	13.5
Kosovo	2.5	7.3	3.8	4.5	44.8	39.4
Macedonia	3.3	3.9	-0.3	2.8	31.0	31.4
Moldova	4.6	7.6	-0.8	6.8	5.6	6.7
Montenegro	4.1	3.1	0.5	3.2	19.7	19.7
Romania	3.3	5.8	0.7	2.2	5.6	5.1
Serbia	7.8	11.0	-1.7	1.6	23.9	23.0
Slovenia	2.6	1.8	-2.3	0.6	13.0	12.1

Source: SeeNews

Chart 2 – SEE Countries Main Macroeconomic Indicators

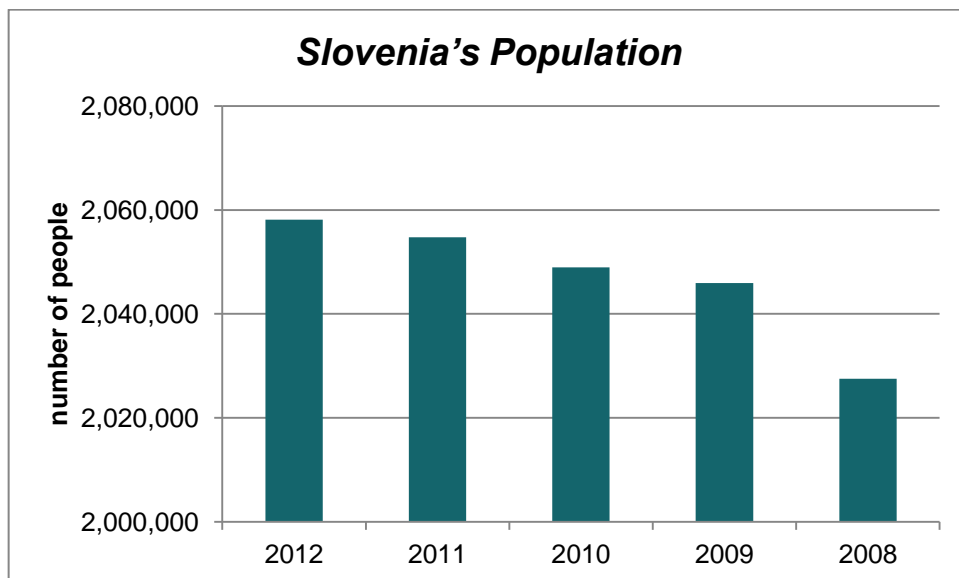


*SEE countries include: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Kosovo, Macedonia, Moldova, Montenegro, Romania, Serbia and Slovenia
Source: SeeNews

In 2012 Slovenia suffered the most severe recession in the region with minus 2.3% on the year. It resulted from a considerable reduction in domestic investment spending, insufficient government and household consumption and a negative trade balance. Slovenia's GDP is expected to further go down in 2013.

The number of people living in Slovenia in 2012 was 2,058,123, up by more than 30,000 people compared to 2008. Population is expected to grow further which means that the volume of pharmaceuticals production and sales will also increase.

Chart 3 – Slovenia's Population



Source: Statistical Office of the Republic of Slovenia

2.2 Total revenue of top 20 pharmaceutical manufacturers in SEE region

In 2012 Slovenia's drug companies Krka d.d. and Lek d.d. registered the highest total revenue out of the 20 biggest pharmaceutical manufacturers in SEE region in terms of total revenue and they captured a 52% market share.

Table 2 – Pharmaceuticals Manufacturers in SEE

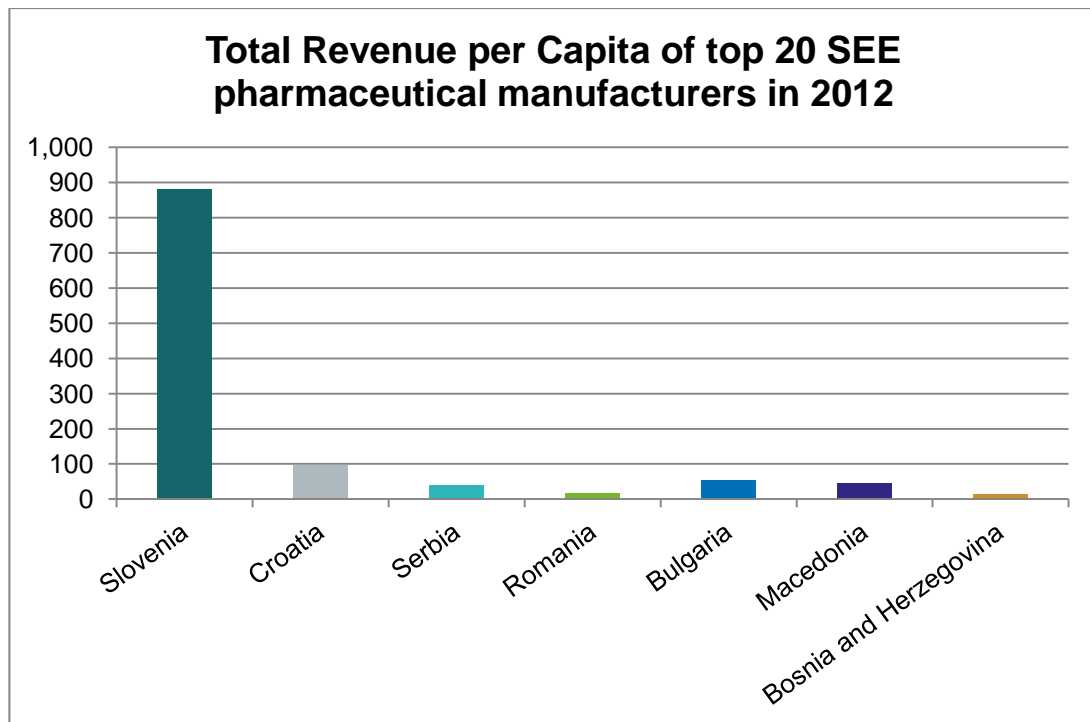
Company name	Country	Total revenue 2012 (EUR)
Krka d.d.	Slovenia	1,060,027,000
Lek d.d.	Slovenia	697,910,862
Pliva Hrvatska d.o.o.	Croatia	439,549,966
Hemofarm AD	Serbia	220,990,923
Europharm SA	Romania	119,025,687
Terapia SA	Romania	109,257,878
Balkanpharma Dupnitsa AD	Bulgaria	108,314,629
Sopharma AD	Bulgaria	107,520,081
Alkaloid AD	Macedonia	94,058,504
Biovet AD	Bulgaria	91,636,287
Antibiotice SA	Romania	72,894,748
Galenika AD	Serbia	59,322,085
Zentiva SA	Romania	59,187,383
Bosnalijek d.d.	Bosnia and Herzegovina	58,219,908
Biofarm SA	Romania	25,152,168
Balkanpharma Troyan AD	Bulgaria	22,944,223
Balkanpharma Razgrad AD	Bulgaria	17,239,228
Balgarska Roza - Sevtopolis A	Bulgaria	11,180,931
Actavis Operations EOOD *	Bulgaria	8,897,501
Unipharm AD	Bulgaria	8,667,420

* Actavis Operations EOOD manages two pharmaceutical plants operated by Balkanpharma Dupnitsa AD and Balkanpharma Troyan AD

Source: SeeNews Top 100 SEE (www.top100.seenews.com)

Slovenian Krka and Lek's total revenue per capita in 2012 also was the highest compared to the other pharmaceutical manufacturers from top 20 in SEE.

Chart 4 – Total Revenue per Capita of top 20 SEE pharmaceutical manufacturers in 2012



*population – as of mid 2012

Source: SeeNews

3. Legislation

The main legislation documents dealing with medicinal products manufacturing in Slovenia are:

- Medicinal Products Act (Official gazette of RS No 31/2006) - The act regulates medicinal products for human and veterinary use, settles conditions and measures for quality assurance, safety and efficaciousness. It also stipulates conditions and procedures for medicinal products' testing, manufacture, pricing, sales, control and supervision aiming at protecting public health. The act defines the founding of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) and its tasks as well. In May

2008, Act amending the Medicinal Products Act (Official gazette of RS No 45/2008) became effective.

- Rules on specific conditions for pharmaceuticals manufacture and on policy of issuing and revoking GMP (Good Manufacturing Practice) certificates (Official Gazette of RS, No 91/2008)
- Rules on conditions that must be fulfilled by individuals for analytical testing of pharmaceuticals and the procedure for checking whether the conditions are met (Official Gazette of RS, No 16/2010)

4. Stakeholders in Slovenian pharmaceutical market

JAZMP is the agency responsible for regulating the medicinal products market in Slovenia. It was established as a result of merger between the Agency of the Republic of Slovenia for Medicines and Medical Devices (ARSZMP) and the Institute for Pharmacy and Drug Research, Ljubljana (ZAF) in January 2007. Since then JAZMP has all rights and obligations of ARZSMP and ZAF.

Another main stakeholder in the sector is the Ministry of Health of Slovenia. Its work is related to healthcare and health insurance including manufacture, trade and supply of drugs and medical products. The safety of products for general use is also in the scope of the Ministry's duties.

It is required by law that every pharmacy in Slovenia is a member of the Slovene Chamber of Pharmacies which was established in 1992.

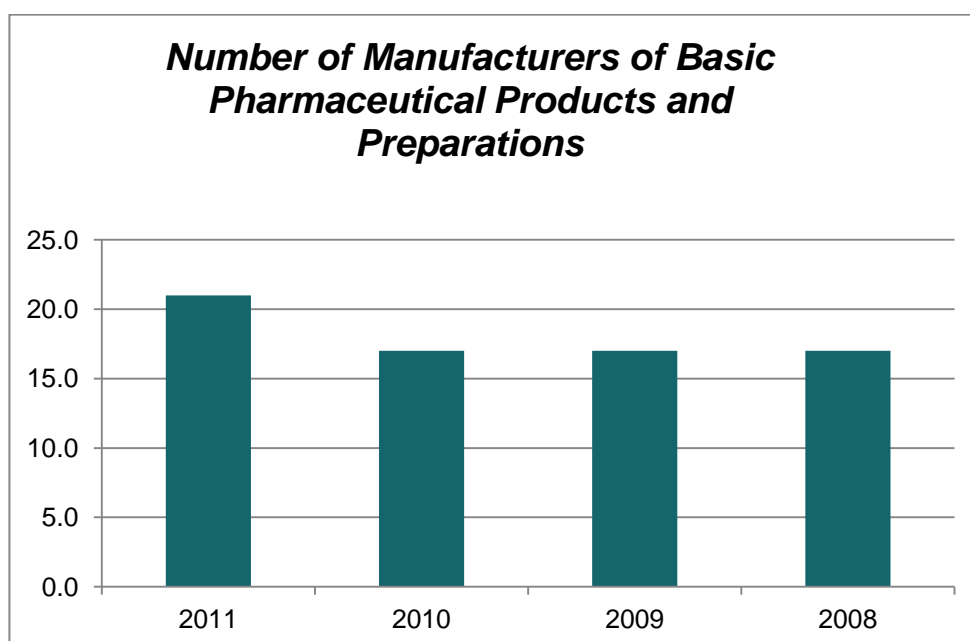
Slovenian Pharmaceutical Society is a voluntary association of employees in the pharmaceutical sector whose works include publishing the Pharmaceutical Journal of Slovenia and national bulletin of medicinal products Farmakon.

5. Manufacturing of pharmaceuticals in Slovenia

5.1 Market size

The number of enterprises working as manufacturers of basic pharmaceutical products and preparations increased to 21 in 2011 from 17 in the period between 2008 and 2010 according to the Statistical Office of the Republic of Slovenia.

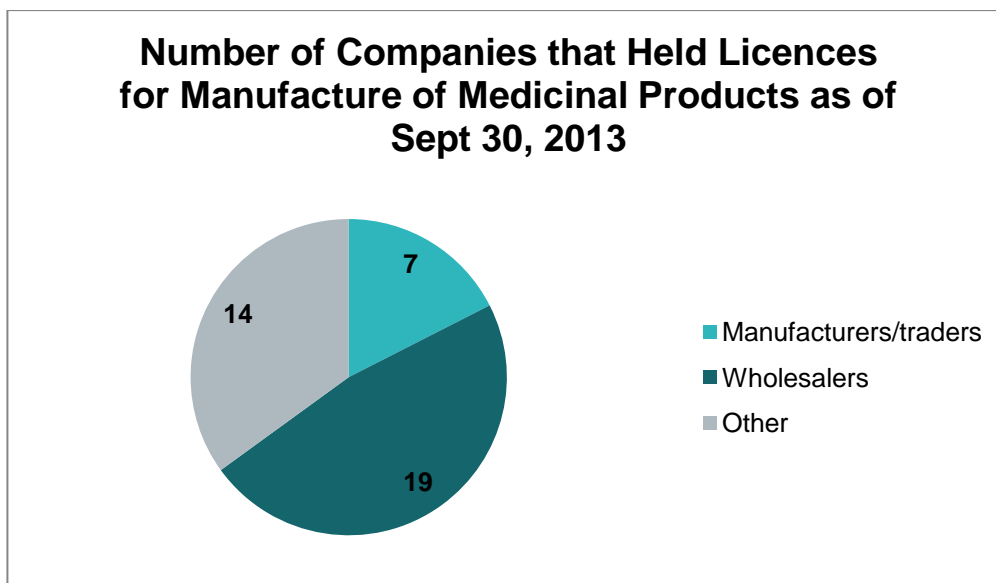
Chart 5 - Number of Manufacturers of Basic Pharmaceutical Products and Preparations



Source: Statistical Office of the Republic of Slovenia

The number of companies that held licences for medical products manufacturing issued by JAZMP as of end-Sept, 2013 was 40. Seven of them were operating on the Slovenian market as pharmaceuticals manufacturers and traders, and 19 companies' main activity is wholesale of pharmaceuticals. The majority of them are representative companies of foreign pharmaceutical companies.

Chart 6 - Number of Companies that Held Licences for Manufacture of Medicinal Products as of Sept 30, 2013



Source: SeeNews

The net sales revenue of the seven pharmaceutical manufacturers totalled EUR 1.71 bln in 2012, with a compound annual growth rate (CAGR) of 4.56%.

Table 3 - Slovenian Pharmaceuticals Manufacture Market

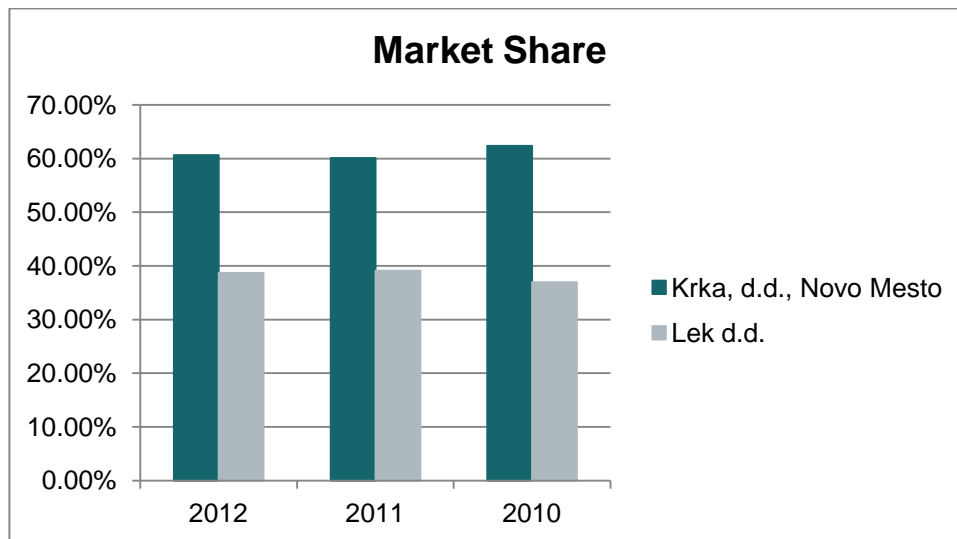
Slovenian Pharmaceuticals Manufacture Market							
Name	Net sales revenue 20 12 (mln EUR)	Market share 20 12	Market penetration 20 12	Net sales revenue 20 11 (mln EUR)	Market share 20 11	Net sales revenue 20 10 (mln EUR)	Market share 20 10
Krka, d.d., Novo Mesto	1,035	60.6%	60.6%	957.65	60.1%	932.37	62.4%
Lek d.d.	660.43	38.7%	99.3%	623.08	39.1%	552.52	37.0%
Marifarm d.o.o.	4.38	0.3%	99.5%	3.45	0.2%	1.74	0.1%
Farmicom d.o.o.	3.56	0.2%	99.7%	3.05	0.2%	2.58	0.2%
Galex d.d.	2.45	0.1%	99.9%	4.44	0.3%	5.34	0.4%
Lekarna Ljubljana	2.15	0.1%	100.0%	1.82	0.1%	N/A	N/A
Gorenjske Lekarne	0.09	0.0%	100.0%	0.10	0.0%	0.07	0.0%
Total	1,708	100%		1,594		1,495	

Source: Slovenian Trade register, Companies' non-consolidated annual reports

5.2 Main players

The pharmaceuticals manufacturing market in Slovenia is small and highly concentrated by the two big players, Krka d.d. and Lek d.d.

Chart 7 – Market Share of Krka d.d. and Lek d.d.

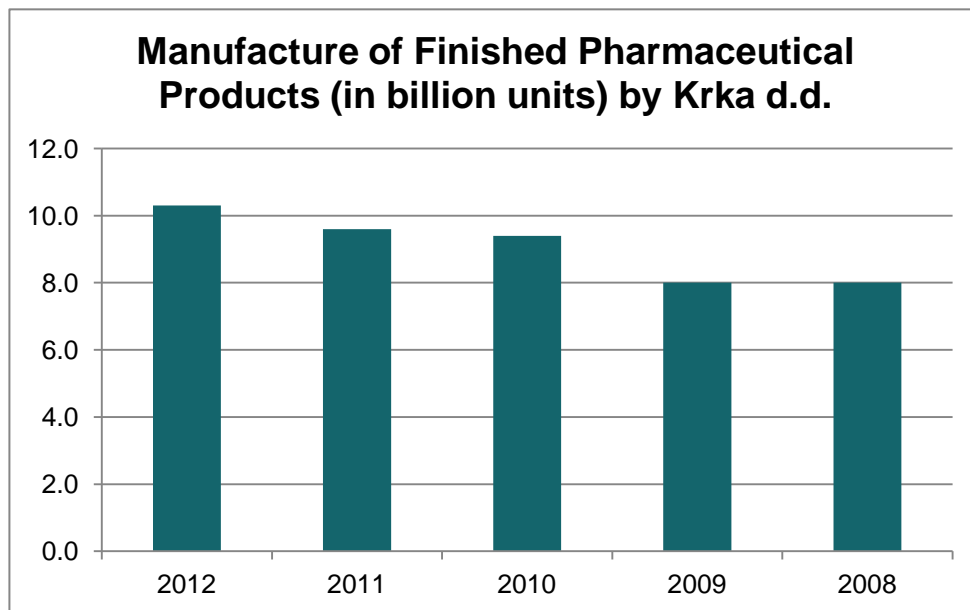


Source: SeeNews

The market share of Krka d.d. in terms of net sales revenue was 61.0% in 2012, up by 1.0% year-on-year and down by 1.0% compared to 2010. In 2012 Lek d.d. kept its position with 39.0% market share in terms of net sales revenue as in 2011, up by 2.0% compared to 2010.

Krka manufactures generic medicines, its main business is manufacturing and sale of prescription pharmaceuticals. Krka is one of Slovenia's top exporting companies. It sells its products to more than 70 countries worldwide. In 2012 the exports value of Krka accounted for 92% of the company's net sales revenue. The company is listed on Ljubljana Stock Exchange and Warsaw Stock Exchange. Krka owns and manages plants in Slovenia, Croatia, Germany, Poland and Russia.

Chart 8 - Manufacture of Finished Pharmaceutical Products (in billion units) by Krka d.d.



Source: Krka d.d. annual report 2012

Table 4 – KRKA d.d. Profile

Name	Krka d.d.
Date of establishment	July 13, 1989
Headquarters	8000 Novo mesto, 6 Smarjeska cesta Str.
Website	www.krka.biz
E-mail	info@krka.biz
Phones	+386 7 331 21 11
Fax	+386 7 332 15 37
Owners	<ul style="list-style-type: none"> • Slovenska Odskodninska Druzba d. d. - 14.99% • Kapitalska Druzba d. d. - 9.86% • Societe Generale-Splitska Banka d. d. - 3.40% • Hypo Alpe-Adria-Bank d. d. - 2.38% • New World Fund Inc. - 2.13% • Luka Koper d. d. - 1.23% • Zavarovalnica Triglav d. d. - 1.10% • American Funds Insurance Series – New World - 1.00% • Unicredit Bank Hungary Zrt - 0.98% • Unicredit Bank Austria AG - 0.97%
Top management	<ul style="list-style-type: none"> • Joze Colaric - CEO • Ales Rotar - R&D Director • Danica Novak Malnar - Worker Director • Vinko Zupancic - Director of Product Supply • Zvezdana Bajc - Director of Accounting and Controlling • Marko Lampret - Technical Director • Zdravko Cuk - Director for Southeastern Europe

Products and Services	<p>Products:</p> <ul style="list-style-type: none"> • prescription drugs • non-prescription products • veterinary products <p>Services:</p> <ul style="list-style-type: none"> • health resort and tourist services
Exports to:	<p>Europe</p> <p>Africa (Southern Africa, Northern Africa, Western Africa)</p> <p>Australia and New Zealand</p> <p>America (Caribbean, Central America, Northern America, South America)</p> <p>CIS countries</p> <p>Asia (Eastern Asia, South-central Asia, South-eastern Asia, Western Asia)</p> <p>Middle East: Israel, Lebanon, Saudi Arabia, United Arab Emirates, Yemen</p>
ISO certification	<p>BS OHSAS 18001:2007 Safety and health management certificate, valid until November 30, 2014</p> <p>ISO 9001:2008 Quality management systems certificate, valid until November 30, 2015</p> <p>ISO 14001:2004 Environmental management systems certificate, valid until November 30, 2014</p> <p>ISO/IEC 27001:2005 Information security management systems, valid until November 06, 2013</p>

Table 5 – Lek d.d. Profile

Name	Lek d.d.
Date of establishment	Aug 23, 2002

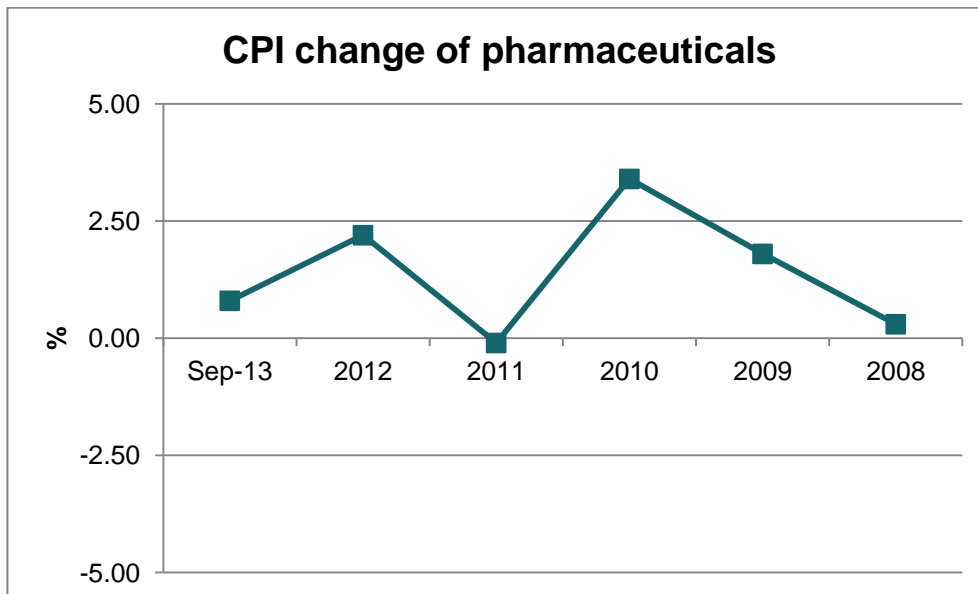
Headquarters	1000 Ljubljana, 57 Verovskova Str.
Website	www.lek.si
E-mail	info.lek@sandoz.com
Phones	+386 1 580 21 11
Fax	+386 1 580 24 32
Owners	Novartis AG
Top management	Patrick Donnelly - CFO Barbara Kozina - IT manager Samo Ros - HR manager
Products and Services	<ul style="list-style-type: none"> • prescription medicines • over-the-counter medicines • active pharmaceutical ingredients • veterinary products • cosmetics
Exports to:	<p>Europe</p> <p>Africa (Southern Africa, Northern Africa, Western Africa)</p> <p>Australia and New Zealand</p> <p>America (Central America, Northern America, South America)</p> <p>CIS countries</p> <p>Asia (Eastern Asia, South-central Asia, South-eastern Asia, Western Asia)</p> <p>Middle East</p>
ISO certification	ISO 14001 Environmental management systems certificate OHSAS 18001 Safety and health management certificate

Lek is owned by Novartis AG. It has representative offices in more than 20 countries around the world and has pharmaceutical plants in Slovenia, Romania and Poland. In 2012 the exports value of Lek accounted for 90% of the company's net sales revenue.

6. Prices

Consumer prices of pharmaceuticals in 2013 went up by an average of 0.8% year-on-year as of September 2013. They increased with an average of 1.8% in the period between 2009 and 2012. Rise was registered each year, except for 2011 when the prices slightly fell. The consumer prices in 2008, before the crisis in Eurozone, increased by 0.3% year-on-year.

Chart 9 – CPI change of pharmaceuticals



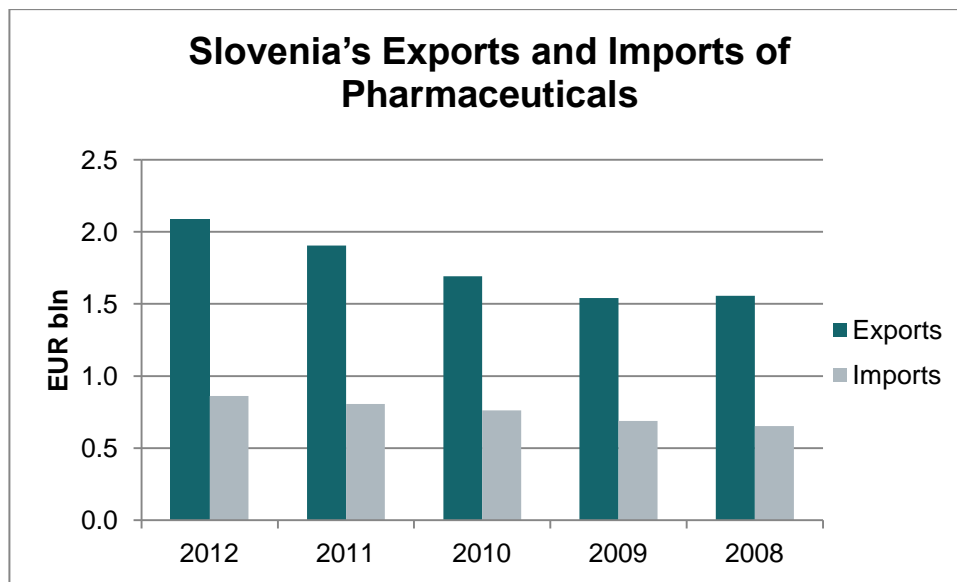
Source: Statistical Office of the Republic of Slovenia

The market value of prescription medicines in Slovenia in 2012 amounted to EUR 529 mln, down by 3.8% on the year, according to the annual report of Slovenian pharmaceutical company Sanofi-Aventis d.o.o. The main reasons for the decrease were the measures taken by the Health Insurance Institute of Slovenia (HIIS) which resulted in decreased medicines prices. The prices of reference medicines also dropped due to decreased prices in the reference countries such as Germany, France and Austria and due to great market penetration of generic pharmaceutical companies. The prescription medicines' share of the total pharmaceutical market in 2012 accounted for 16%.

7. Exports and imports

The value of pharmaceuticals import to Slovenia did not undergo major changes in the period between 2008 and 2012 and an average of EUR 0.8 bln was registered. However the value of pharmaceuticals exports from Slovenia increased in 2012 by 10% year-on-year and stood at EUR 2.1 bln compared to EUR 1.6 bln in 2008.

Chart 10 – Slovenia's Exports and Imports of Pharmaceuticals



Source: Statistical Office of the Republic of Slovenia

8. Number of employees

The total number of employees in the pharmaceutical industry in EU in 2012 was 700,000 according to the European Federation of Pharmaceutical Industries and Associations (EFPIA). In Slovenia the number of employees working in the seven pharmaceuticals manufacturing companies in 2012 totalled 7,885. Out of all employees, 57% worked in KRKA d.d. and 22% in Lek d.d.

Table 6 - Number of Employees in Slovenian Pharmaceuticals Manufacturing Companies in 2012

Company	Number of employees
Krka, d.d.	4,495
Lek d.d.	2,779
Marifarm d.o.o.	105
Farmicom d.o.o.	16
Galex d.d.	36
Lekarna Ljubljana	301
Gorenske Lekarne	153
Total	7,885

Source: Slovenian Trade Register, Companies' annual reports

9. Investments

Krka Group invested more than EUR 153 mln in 2012 in more than 20 projects. The most considerable investment in the company's history was allocated for the solid dosage forms production plant, Notol 2. The projects are expected to expand Krka's production capacity by 40% which conforms to Krka's plans to manufacture and sell a lot more than the current 10 billion tablets, capsules and other products per year. The construction works for Notol 2 began in June 2012 in Novo Mesto, Southeastern Slovenia. Its area is projected to be 55,000 sq m and its value - EUR 200 mln. The planned capacity of Notol 2 is 4.5 billion finished pharmaceutical products annually.

In 2012 Lek invested in new equipment, in a molecular laboratory in its Biopharmacy unit and started building of Control centre in Ljubljana. The company invested some EUR 18 mln in increasing the production capacity of the Viale 2 project.

10. Future trends

According to IMS Health, the world pharmaceutical market is expected to amount between USD 1,175 bln and USD 1,205 bln by 2016, an increase by more than USD 219 bln compared to 2011. Increased sales in emerging markets and revenue growth of generic medicines worldwide will be the main drivers for the projected increase of the global pharmaceutical market. World reference medicinal products' spending is expected to rise to USD 645 bln in 2016 from USD 596 bln in 2011. Significant rise is anticipated for world generic spending - to USD 430 bln by 2016 from USD 242 bln in 2011. More than USD 224 bln of the growth is projected to be generated from low-cost generic medicines in emerging markets. The European share of global pharmaceuticals spending is expected to decrease to 19% in 2015 from 27% in 2005.

Chart 11 – Total World Pharmaceutical Market



**Actual quarterly exchange rates are used*

Source: IMS Health

The percentage share of reference medicines in Slovenia is expected to slightly decline according to BMI. The main reason will be the regulations issues related to the patents of reference medicines and the expiry of many patents. On the other hand, the share of generic medicines is projected to grow and their prices to fall due to the need for cost-containment in the public health field.

Our estimations on the Slovenian pharmaceuticals manufacturing market growth is to be EUR 1.8 bln in 2013, a 6.0% increase year-on-year and EUR 1.9 bln in 2014, again up by 6.0% year-on-year.

Slovenia is a small country but it has big pharmaceuticals manufacturers and its power is concentrated in the exports to other countries. Exports are projected to expand further in 2013 and 2014.

Krka is expected to keep its bigger market share in terms of net sales revenue compared to Lek. However Lek, as a part of Sandoz, the generic drugs arm of Swiss Novartis, is anticipated to increase its market share.

11. References and information sources

International:

World Health Organization (WHO) - <http://www.who.int>

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) - www.ifpma.org

Forum of International Research & Development Pharmaceutical Companies, EIG - <http://www.firdpc.com>

PHIS – Pharmaceutical Health Information System - <https://phis.goeg.at/>

Market intelligence company Business Monitor International (BMI) - <http://www.businessmonitor.com/>

Market research and consulting company IMS Institute for Healthcare Informatics (IMS Health) - <http://www.imshealth.com>

European:

European Federation of Pharmaceutical Industries and Associations (EFPIA) - <http://www.efpia.eu/>

European Generic Medicines Association (EGA) - <http://www.egagenerics.com/>

Slovenia:

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) - www.jazmp.si

Ministry of Health of Republic of Slovenia - <http://www.mz.gov.si>

Slovenian Pharmaceutical Society - <http://www.sfd.si/>

Slovene Chamber of Pharmacy - <http://www.lzs.si/>

Statistical Office of the Republic of Slovenia - <http://www.stat.si/>

Database of Slovenian Exporters Sloexport - <http://www.sloexport.si/>

Official Gazette of the Republic of Slovenia - www.uradni-list.si

InvestSlovenia website - operating within SPIRIT Slovenija (Slovenian Public Agency for Entrepreneurship, Innovation, Development, Investment and Tourism) - www.investslovenia.org

Leading companies' official websites:

www.lek.si

www.krka.biz

Official media publications:

www.reuters.com

www.dnevnik.si

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