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SEE PHARMACEUTICAL MARKET

AUGUST 2014

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OVERVIEW

The pharmaceutical market in Southeast Europe (SEE) continued to grow in most of the countries in the region in 2013. Pharmaceutical sales in SEE are still dominated by generic drugs, especially in terms of volume, due to low per capita income and underinvestment in research and development activities focused on new medicines.

The growth of the over-the-counter (OTC) pharmaceutical market in SEE in 2013 was driven by higher sales of analgesics, digestives, vitamins and minerals. Oncology drugs also recorded higher sales because of an increase in prices and in the number of cancer patients.

Pharmaceuticals producers in the region kept their focus on the manufacturing of low-cost generic drugs with the major companies generating the bulk of their sales revenue abroad. On the other hand, pharmaceutical demand in the SEE countries continued to be covered mainly by imports.

Table 1. Value of Pharmaceutical Market in Some SEE Countries (EUR bln)

| Value of Pharmaceutical Market in Some SEE Countries (EUR bln) | | | | | |
|----------------------------------------------------------------|---------|-------------|-------|-------|-------|
| Country | 2013 | Y/Y change* | 2012 | 2011 | 2010 |
| Bosnia and Herzegovina | 0.269 | -4.4% | 0.282 | 0.262 | 0.269 |
| Bulgaria | 0.971** | 49.5% | 0.649 | 0.955 | 0.854 |
| Croatia | 0.910 | -7.3% | 0.994 | 0.951 | 0.919 |
| Moldova | 0.152 | 5.4% | 0.162 | 0.164 | 0.141 |
| Romania | 2.620 | 0.3% | 2.645 | 2.500 | 2.208 |
| Serbia | 0.791 | 11.2% | 0.718 | 0.717 | 0.636 |
| Slovenia | 0.720 | -2.4% | 0.738 | 0.762 | 0.744 |

*in terms of local currency; **preliminary data

Sources: Bulgarian Drug Agency; Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina; Business Monitor International; IMS Health; Cegecim Romania

LATEST DEVELOPMENTS

Romania's pharmaceuticals market rose by 2.0% on the year to RON 6.02 bln (EUR 1.4 bln) in the first half of 2014, according to a survey by market research company Cegedim Romania.

In the second quarter alone, the market was up 5.7% on the year to RON 3.01 bln (EUR 0.677 bln).

The retail segment generated sales worth RON 5.2 bln (EUR 1.2 bln) in the first half of 2014, up by 2.1% year-on-year. The sales were up 5.8% on the year to RON 2.6 bln (EUR 0.585 bln) in the three months through June 2014.

In the 12 months through June 2014 the total market edged down 0.4% on the year to RON 11.9 bln (EUR 2.7 bln). Switzerland's Hoffmann La Roche and France's Sanofi, including Zentiva, led the Romanian market in terms of sales value in the 12 months through June 2014 with market shares of 6.9% each, followed by Novartis, including Sandoz, and Servier, including Egis, with 5.7% each.

Bulgaria's pharmaceutical market grew by 6.9% on the year BGN 619 mln (EUR 317 mln) in the first quarter of 2014, according to data of market research firm IMS Bulgaria. Oncology, diabetes, biologics, anti-infectives and anti-thrombotics were the key growing therapy areas in the period under review.

The over-the-counter (OTC) market rose by an annual 5.3% to BGN 153 mln (EUR 78.2 mln) in the three months through March 2014 as cold and respiratory remedies posted growth of nearly 11% to BGN 48 mln (EUR 24.5 mln), whereas nutritional supplements saw an increase by 9.0% to BGN 14 mln (EUR 7.2 mln). Pain relievers generated BGN 28 mln (EUR 14.3 mln) in sales in the first quarter of 2014, down by 3.3% from the same period in 2013.

MAJOR COMPANIES

Pharmaceutical manufacturers

In Bulgaria, the country's largest Bulgarian-owned generic drugs maker is Sopharma AD, which ended up in the fifth spot among the 20 biggest SEE pharmaceutical companies in terms of total revenue for 2013. Sopharma AD's exports increased by 1.4% and totaled BGN 78.3 mln or 70.8% of its net sales revenue in 2013.

Serbia's major pharmaceutical producers are state-owned Galenika AD and Hemofarm AD, controlled by German generic drug-maker Stada Arzneimittel. Hemofarm AD ranked fourth among the SEE pharmaceutical companies in 2013, while Galenika AD was 14th.

Four Romanian companies featured among the biggest pharmaceutical makers in the region in 2013. However, their combined total revenue accounted for only 5.9% of the total revenue of the top 20 drug makers in SEE.

Slovenia is home to two of the largest pharmaceutical companies in the region – Krka d.d. and Lek d.d. Krka d.d. was the region's top drug maker in 2013 in terms of total revenues with Lek d.d. as the runner-up. Their combined total revenue accounted for more than 50% of SEE's leading pharmaceutical producers' total revenue.

Only one Bosnian company featured among the biggest pharmaceutical makers in the region in 2013. Bosnalijek d.d. ranked 13th after posting a total revenue of EUR 51 mln, down from EUR 58 mln in 2012.

Slovenia's Krka d.d. was the leader on the Bosnian market with sales of EUR 22.9 mln. Among the other major foreign companies, which sell their products on the local market are Swiss Roche, Serbia's Hemofarm AD, Slovenia's Lek d.d., Croatian Pliva d.o.o., France-based Sanofi SA, Macedonia's Alkaloid AD, Danish Novo Nordisk A/S and German Bayer AG.

Croatia's largest pharmaceutical manufacturer Pliva Hrvatska d.o.o, part of Israeli-based Teva Group, took third place in the SEE ranking for 2013 despite a 6.7% drop in total revenue.

Annual Change in Total Revenue of Major SEE Pharmaceutical Companies - graph

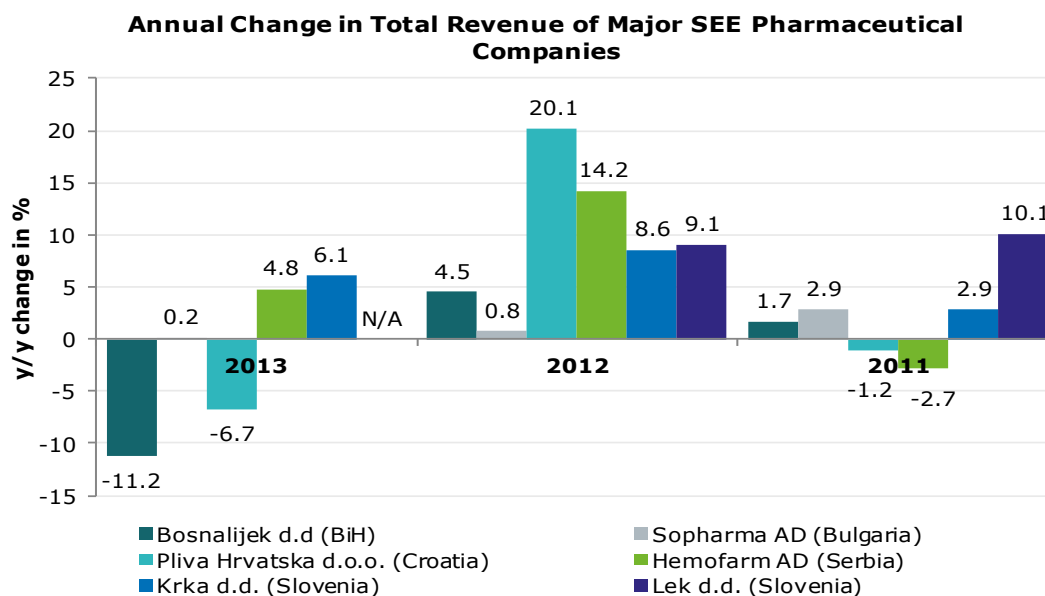


Table 2. Largest SEE Pharmaceutical Companies (EUR mln)

| Largest SEE Pharmaceutical Companies (EUR mln) | | | | | |
|------------------------------------------------|------------------------|--------------------|-----------------------|----------------------|----------------------|
| Company | Country | Total revenue 2013 | Y/Y change in revenue | Net profit/loss 2013 | Net profit/loss 2012 |
| Krka dd | Slovenia | 1,125 | 6.1% | 164.7 | 154.6 |
| Lek d.d. | Slovenia | 774.7 | 14.0% | 88.8 | 75.9 |
| Pliva Hrvatska d.o.o. | Croatia | 405.6 | -6.7% | 44.0 | 89.7 |
| Hemofarm AD | Serbia | 245.2 | 4.8% | 30.3 | 24.6 |
| Sopharma AD | Bulgaria | 126.6 | 0.2% | 17.2 | 20.9 |
| Balkanpharma Dupnitsa AD | Bulgaria | 124.5 | 14.9% | 12.5 | 12.7 |
| Bayer d.o.o. | Slovenia | 104.2 | 0.1% | 3.1 | 4.4 |
| Alkaloid AD | Macedonia | 94.7 | 0.7% | 10.1 | 9.9 |
| Biovet AD | Bulgaria | 93.7 | -1.6% | 5.0 | 4.2 |
| Belupo d.d. | Croatia | 85.3 | 2.3% | 12.2 | 18.3 |
| Antibiotice SA | Romania | 76.4 | 6.2% | 7.0 | 6.1 |
| Zentiva SA | Romania | 68.0 | 16.3% | 9.0 | 7.3 |
| Bosnalijek d.d. | Bosnia and Herzegovina | 51.0 | -11.3% | 0.1 | 3.3 |
| Galenika AD | Serbia | 48.0 | -21.8% | -42.9 | -45.7 |
| Zdravlje AD | Serbia | 38.5 | 20.8% | 1.3 | -0.9 |
| Gedeon Richter Romania SA | Romania | 33.5 | -8.2% | -9.9 | -6.6 |
| Biofarm SA | Romania | 27.8 | 12.0% | 5.7 | 4.7 |
| Balkanpharma Troyan AD | Bulgaria | 23.1 | 3.8% | 2.4 | 1.9 |
| Balkanpharma Razgrad AD | Bulgaria | 18.2 | 22.3% | 0.8 | 1.0 |
| Unipharm AD | Bulgaria | 17.3 | 2.3% | 0.4 | 0.2 |

Source: Companies' annual financial statements

Wholesalers

In 2013, most of the largest drug wholesalers in the SEE countries managed to increase their total revenue on an annual basis. The sharpest year-on-year growth in total revenue was reported by Bulgaria's Huvepharma AD, Serbian Farmalogist DOO and Romanian Sensiblu SRL. Almost all of the major companies reported net profits with Huvepharma AD topping the list with net earnings of EUR 33.4 mln.

Table 3. Largest Pharmaceutical Wholesalers in SEE

| Largest Pharmaceutical Wholesalers in SEE | | | | | | | | |
|-------------------------------------------|----------------------------------------------------|----------|-----------------------------|-----------------------|-------------------------------|-------------------------------|--------------------------|---------------------------------|
| Rank | Company | Country | Total revenue in 2013 (EUR) | Y/Y change in revenue | Net profit/loss in 2013 (EUR) | Net profit/loss in 2012 (EUR) | Per capita in 2013 (EUR) | Return on revenue in 2013 (EUR) |
| 1 | Mediplus Exim SRL | Romania | 741.0 | 2.7% | 3.6 | 14.2 | 34.0 | 0.5% |
| 2 | Farmexpert D.C.I. SRL | Romania | 507.6 | 9.6% | 20.6 | 19.5 | 23.3 | 4.1% |
| 3 | Polisano SRL | Romania | 329.9 | 11.4% | 2.0 | 6.4 | 15.1 | 0.6% |
| 4 | Sensiblu SRL | Romania | 292.2 | 16.5% | -8.7 | -14.3 | 13.4 | -3.0% |
| 5 | Medika d.d. | Croatia | 290.0 | 1.8% | 5.4 | 4.6 | 64.8 | 1.9% |
| 6 | Fildas Trading SRL | Romania | 289.5 | 14.6% | 7.8 | 5.7 | 13.3 | 2.7% |
| 7 | Farmexim SA | Romania | 287.8 | 14.6% | 4.3 | 2.8 | 13.2 | 1.5% |
| 8 | Sopharma Trading AD | Bulgaria | 262.2 | 9.6% | 4.9 | 3.8 | 37.6 | 1.9% |
| 9 | Kemofarmacija d.d. | Slovenia | 245.9 | -9.5% | N/A | N/A | 123.4 | N/A |
| 10 | Phoenix Farmacija d.d.* | Croatia | 241.4 | -4.3% | 3.8 | 2.0 | 53.9 | 1.6% |
| 11 | Sting AD | Bulgaria | 222.6 | 10.1% | 0.5 | 0.3 | 31.9 | 0.2% |
| 12 | Europarm Holding SA | Romania | 216.8 | 5.8% | -1.1 | 0.4 | 9.9 | -0.5% |
| 13 | Phoenix Pharma EAD (formerly known as Libra EAD) * | Bulgaria | 215.8 | 2.5% | 0.0 | 0.9 | 30.9 | 0.0% |
| 14 | Phoenix Pharma DOO | Croatia | 207.8 | 10.3% | 5.7 | 3.9 | 46.4 | 2.7% |
| 15 | Sanofi-Aventis Romania SRL | Romania | 187.4 | -12.0% | 2.6 | 9.5 | 8.6 | 1.4% |
| 16 | Farmalogist DOO | Serbia | 179.1 | 18.2% | 3.6 | 3.2 | 24.7 | 2.0% |
| 17 | Oktal Pharma d.o.o. | Croatia | 164.4 | -4.2% | 2.8 | 1.9 | 36.7 | 1.7% |
| 18 | Huvepharma AD | Bulgaria | 158.9 | 19.3% | 33.4 | 25.6 | 22.8 | 21.0% |
| 19 | Actavis EAD | Bulgaria | 94.4 | -6.7% | 5.9 | 5.5 | 13.5 | 6.2% |
| 20 | Pharmaswiss DOO | Serbia | 76.3 | -9.7% | 7.5 | 8.7 | 10.5 | 9.8% |

*denotes gross profit

Sources: Companies' annual financial statements

MERGERS AND ACQUISITIONS

Macedonian pharmaceutical company Alkaloid AD set up in August 2014 a subsidiary in Slovenia as part of plans for expansion on EU markets. The Ljubljana-based subsidiary, Alklab, will serve as a laboratory for testing new products aimed for the EU markets. Alkaloid AD's investment in the new company totalled EUR 600,000.

In August 2014 Serbia's Privatization Agency issued a public call for expressions of interest from potential investors for the privatization of drug maker Galenika AD after in June 2013 Valeant Pharmaceuticals North America, the only candidate to qualify to submit a letter of intent in a tender for Serbian drug maker Galenika AD, gave up on the acquisition due to other takeover plans and hostile attitude of Galenika's trade unions.

Also in August 2014 Serbia's Commission for Protection of Competition cleared local drug maker Hemofarm AD, a unit of Germany's Stada, to take over the production, marketing and sales operations of Belgrade-based peer Pharmanova DOO. The deal, notified to the anti-trust regulator on July 8, 2014 also covers relevant licences and trademarks.

Stada completed the acquisition of Hemofarm, located in Vrsac, northeast Serbia, in 2006.

Bulgarian drug producer Sopharma AD submitted for approval the merger between Balgarska Roza - Sevtopolis AD and Sopharma AD to Bulgaria's Financial Supervision Commission. The merger deal was signed on June 19, 2014. Sopharma AD held a 49.99% stake in Balgarska Roza - Sevtopolis AD as of end-June 2014.

In May 2014 Croatian generic drug maker PharmaS d.o.o. set up a production and marketing unit in Switzerland as part of plans to boost its market presence beyond the SEE region. In addition to Switzerland, the Croatian company also operates abroad in Serbia, Bosnia, Kosovo, Macedonia and Albania.

Also in May 2014 Croatia's Ministry of Economy issued a public call to find a buyer for the Zagreb-based Institute of Immunology d.d. (IMZ), a local state-run maker of immunobiological medicines. The future strategic partners would be required to maintain production as well as to ensure the return of IMZ's licenses, the long-term sustainability of the business and the jobs it provides. IMZ's product portfolio comprises viral and bacterial vaccines, human plasma preparations and antitoxins.

In April 2014 Romanian investment fund SIF Muntenia SA bought an 18.75% stake in drug maker Biofarm SA EUR 14.1 mln in a takeover bid. In March 2014,

the Romanian stock market regulator, ASF, ordered investment funds SIF Muntenia SA and SIF Banat Crisana SA, which act in concert, to launch a takeover bid for the shares they did not own in Biofarm SA. The two funds held a combined 54.28% stake in the drug manufacturer and according to Romanian legislation, a shareholder who acquires more than 33% of a listed company's shares is obliged to launch a mandatory takeover bid within two months after exceeding the threshold.

Moldova sold its 94.6% stake in pharmaceutical company Farmaco SA for EUR 2.8 mln in April 2014.

INVESTMENTS

Croatia's drug maker Belupo d.d. plans to invest EUR 51.1 mln in new production facilities by the first quarter of 2017. The company will invest the sum in the construction in plants for semi-solid and liquid, and for solid pharmaceutical forms.

Belupo d.d. also plans to build a new EUR 66 mln production facility in Koprivnica, northern Serbia, by 2016. The new plant should increase Belupo's overall capacity by one third.

Antibiotice SA plans to invest EUR 10 mln by the end of 2016 in a new production line for salves and suppositories. The new products will be sold both on the local and foreign market.

Biovet AD plans to invest EUR 2.0 mln in the expansion of its granulated veterinary production facility in Peshtera, southern Bulgaria, by mid-2015. The project, which involves the construction of a new building and the purchase of equipment, is expected to result in a 20% increase of Biovet AD's capacity for production of granulated veterinary products, which account for 30% of the company's output.

Zentiva SA, the Romanian arm of France-based generic drug maker Sanofi SA, plans to invest EUR 1.6 mln in new facilities and equipment in 2014.

In July 2014 Lek d.d. announced it plans to invest EUR 23.5 mln in the expansion of its packaging centre in Lendava, eastern Slovenia. Ljubljana-based Lek d.d. is a part of the Swiss-owned Sandoz group. It has also production facilities in Slovenian towns of Prevalje and Menges.

In June 2014 UK's GlaxoSmithKline PLC (GSK) announced it will gradually close down its drug production unit in Brasov, central Romania, by the end of 2015 after failing to have found a buyer for the plant. GSK announced in June 2013 it planned shut down the unit unless it found a buyer in the following six months. The decision was triggered by a decrease in output at the facility, which is operating below capacity after many patents expired, with no improvement in sight. Production at the Brasov plant will continue until all products will be transferred to GSK's sites located in Poland and Spain.

GSK will continue its pharma, consumer healthcare and distribution operations in Romania. The company plans to invest between EUR 8.0 mln and EUR 10 mln in research and development by 2018.

In December 2013 Alkaloid AD opened a new EUR 1.2 mln warehouse for finished goods in Macedonia's capital Skopje. The warehouse has a total built-up area of 1,600 sq m.

In October 2013 Pliva Hrvatska d.o.o. opened in Croatia's capital Zagreb a solid oral drug forms plant worth EUR 73 mln. The new plant will improve the company's capacity for production of tablets and capsules and will boost its exports, since most of these products are intended for international markets. Pliva Hrvatska d.o.o. is part of Israeli-based Teva Group.

Zdravje AD, the Serbian unit of generic drug maker Actavis PLC, completed the project for a new EUR 3.7 mln plant in Leskovac, southern Serbia in August 2013.

The new 1,000 sq m unit will produce a Parkinson's disease treatment drug and has an annual capacity of 50 million pills. Actavis PLC bought a majority stake in Zdravlje AD in 2003.

In June 2013 Sopharma AD launched a EUR 38.3 mln plant for solid drug forms in Bulgaria's capital Sofia. The new plant has an annual capacity of 4.0 billion tablets. Its output will be sold both on the domestic market and abroad.

FORECAST

According to market experts, the SEE pharmaceutical sector will slow down its growth throughout 2014 as well as over the next few years. The market's development will be supported by the ageing population and the improving health consciousness among the middle class. As the pharmaceutical market will continue to rely on imports, currency exchange fluctuations could impact its growth in value terms in countries like Romania, Croatia and Serbia. The major pharmaceutical producers in the SEE region will keep their focus on manufacturing of generic drugs for export markets to achieve better sales revenues. The industry's development, however, could be impeded by factors such as slow economic growth, rising unemployment, a weak healthcare system, especially funding difficulties experienced by the government hospitals, low per capita income, a lack of clear government policy for promotion of investments in the sector and the latter's strong focus on generic drugs.

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SeeNews 2014