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**Sector: The Pharmaceutical and Healthcare**

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**Abstract:**

Good experience, high quality production and attractive prices - these are the main competitive advantages that characterize the Bulgarian pharmaceutical industry as an attractive destination for investments.

The Bulgarian pharmaceutical industry has established itself as one of the fastest growing sectors of the Bulgarian economy in recent years. The traditions and the good experience in the production of high quality medicines on competitive prices are advantages that make the Bulgarian pharmaceutical market an attractive destination for the initiation of a successful business.

## Introduction

The pharmaceutical industry is one of the leading and fastest growing sectors of the Bulgarian economy. It is characterised by high quality production at competitive prices.

Since Bulgaria's EU accession in January 2007, the Bulgarian pharmaceutical legislation has been harmonized with the EU regulations in that field. Bulgarian manufacturers are continuously making significant investments in modernization of their production facilities. Moreover, some of the multinational players of the pharmaceutical industry have entered the Bulgarian market either through acquisition of Bulgarian pharmaceutical producers or via local distributing companies.

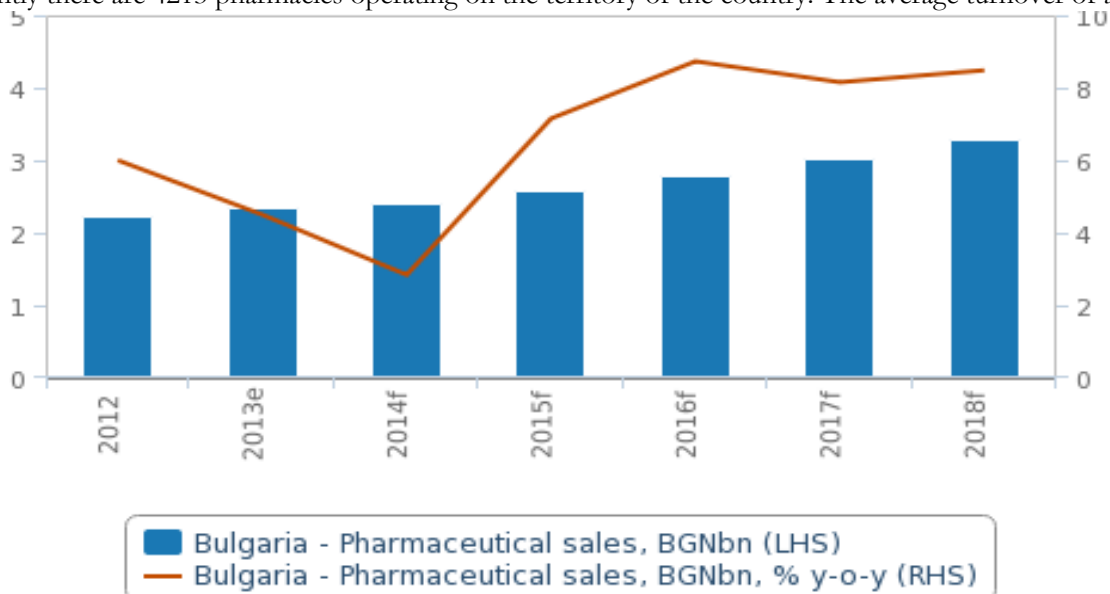
Despite historically strong growth, a prolonged recession, as well as cuts to reimbursement spending and anticipated negative exchange rate pressures means that the short-term outlook for Bulgaria is relatively unattractive. However, despite a poor macroeconomic performance in 2009 and throughout 2010, Bulgaria's pharmaceutical market continued to grow at rates higher than in more developed CEE markets, with this situation expected to remain in place over the coming years. Downward pressures are exerted by factors such as the relatively limited size of the market due to the population size, as well as limited potential for high value products due to low per-capita consumption and income in comparison to other markets in the region. The small market is susceptible to shocks caused by funding shortfalls and other one-off factors. Nevertheless, the country's drug sector is likely to be boosted by modernisation of production and foreign investment in the industry resulting from EU membership. Imports account for well over half of the total market, but exports have also grown rapidly as drug makers target high-growth CIS (Common Wealth of Independent States) markets.

## Market overview

Bulgaria's accession to the EU in 2007 and related improvements in the country's commercial ties with Europe – as well as in its regulatory environment – provided a solid base for market growth in the pharmaceutical and healthcare sectors.

The latest data on the Bulgarian pharmaceutical market confirms the historical forecast for 2013 pharmaceutical sales; the expectation of growth of 4.5% to a value of BGN2.32bn (US\$1.57bn) proved correct. Growth was attributed to two factors: an increase in spending by the National Health Insurance Fund (NHIF) on cancer drugs and expensive therapeutics and consumer spending on over-the-counter (OTC) medicines. Generic drug prices saw further cuts moderating their year over year growth, as a highly competitive market adjusted to the new pricing.

Currently there are 4213 pharmacies operating on the territory of the country. The average turnover of an



apothecary is around 500 thousand leva and the data shows that each month in Bulgaria 20 new apothecaries are

opened. In 2011 amendments to the Medical products in the humane medicine Act were introduced. The Parliament kept the current restriction over pharmacies according to which one juridical person could own only 4 pharmacies. This is an attempt to restrict the consolidation of the sector but it doesn't work in practice because one physical person could establish unrestricted number of companies and thus have more than 4 pharmacies.

For a developed European country the life expectancy for men is 71 years, and 77 for women in comparison the Life expectancy at birth for the total population is 73.84 years , while by official data from Eurostat the estimated rate for males is 70.24 years and for females is 77.65 years.

According to World Health Statistics 2013 made by WHO, data reveals that non-communicable diseases represents the leading cause of death in Bulgaria, about 88%, followed by 4.5% caused by communicable diseases. In the same report for Bulgaria, about 47% of all deaths are caused by cardiovascular diseases and diabetes and 29% caused by cancer. For the European Union the trend is that 26% die of cancer, 38% of cardiovascular disease and diabetes.

### ***General view of the market***

Bulgaria's market of pharmaceuticals has not declined in spite of the economic crisis.

The Bulgarian pharmaceutical market is one of the smallest in the EU, but it has grown substantially over the past few years. The market reached 2,098 m. BGN (around 1,400 m. USD) in 2011, a 12 percent increase compared to 2010, and an 18 percent increase compared to 2009 (2012 IMS Health). Drug expenditure accounts for 2.45 percent of GDP , and the sector is expected to grow. Generic drugs accounted for more than 50 percent of sales in volume terms and more than 80 percent in value terms in 2011. The most important market is the pharmacy segment, which accounts for about 90 percent of the total. About 30 percent of the over-the-counter (OTC) market is for flu and cough medicine. Pharma exports have increased sharply over the past five years, and now account for 3 percent of Bulgaria's overall exports.

The fast-growing pharmaceutical sector is characterized by relatively cost-efficient and high-quality production at a competitive price without a high level of R&D expenditures. The sector benefits from considerable investment by both Bulgarian and foreign producers, in boosting production capability and modernizing facilities to harness competitive advantage presented by strong traditions and geographic proximity to markets in the Middle East and the CIS. Actavis and Sopharma have developed substantial exports of generic drugs to Russia and CIS countries, which could signal a turning point for their regional competitiveness. The major importers of Bulgarian drugs are Russia (27 percent of total exports), Romania (11 percent), Croatia (8 percent), Ukraine (7 percent), Germany (6 percent) and Serbia (6 percent) as of 2011.

The pharmaceutical market in Bulgaria is 670 million euro and similarly to the other East European countries, Bulgaria has a high market share of generic medicines which is 39%, while the share of the original ones is 61%. As a value the market for original medicines is 400 million euro which puts Bulgaria on one of the last places in EU.

Further for the optimism of the companies ensures the fact that 58% of the organizations in the sector hired new personnel.

During the last year the households have covered their medical dues with around 44%, which is in contradiction with the fact that actually the Bulgarians pay additionally the biggest sum of all EU citizens for drugs of the Health funds which is 56%, while in countries such as France it is 1%, in the Netherlands 0.5% and in Italy - 3.2%. According to the National Statistics Institute, Bulgarians spent BGN 2.2 billion for medicine in 2013.

Against this background and demographic collapse of the National Health Strategy makes it clear that in 2020 the state will provide about 3.8% of GDP per year for health care while now the rate is 4%.

This trend indicates that the Bulgarian government will continue to reduce its spending for medications, and people will be relying mostly on their savings in order to purchase necessary medicines.

Medications for the treatment of high blood pressure, asthma, urological diseases, and cancer have seen the greatest sales increases. IMS Health experts are quoted as forecasting that over the next 5 years Bulgarians' spending on medications will grow further because of the unsatisfactory healthcare. Prescription drugs are said to be up for a sales boost as a result of the introduction of newer medications.

As a conclusion, the pharmaceutical market in Bulgaria is presently highly competitive, well-structured and fast growing.

### ***Foreign trade***

Bulgaria's pharmaceutical trade balance is largely in favour of imports, a situation that is reflective of the country's historically minimal manufacturing base and improving access to modern innovative pharmaceuticals. This dynamic has shifted somewhat over the last five years, however, as the country's pharmaceutical export profile improved dramatically, with EU accession playing a major factor. In 2004, export value was just 20.3% of import value, a situation which improved marginally to 23.8% in 2006. However, following EU accession, this figure rose to 41.3% in 2007 and increased further to 62.0% in 2010. The latest data shows that export of pharmaceuticals has increased with 22%.

Leading export destinations for Bulgarian pharmaceuticals are Russia (33% of total exports), Romania (14%), Croatia (10%), Ukraine (9%) and Serbia (7%). The six Bulgarian companies – Sopharma, Medica, Sevtopolis, Momina Krepost, Unifarm and Septona – attributed the strong performance to exports. Leading sources of imports are Germany (19%), France (17%), Switzerland (10%), Slovenia (5%) and Italy (5%).

As according to the law the Health Fund is obliged to buy at the lowest prices of producers in the EU, many wholesalers take advantage of the situation. Producers have no right to refuse sales of medicines (after they have agreed to sell to the Health Fund) at the same low price. Afterwards, the wholesalers repack them and sell them in countries where the prices are relatively higher. In 2012 the parallel export sales reaching a value of 300 million BGN which is 3 times more than the year before.

### **Manufacturers of drugs in Bulgaria**

For decades, Bulgaria has been proud to be among the largest producers of pharmaceuticals in Eastern Europe. The period after the privatization of the old factories have brought new Bulgarian and foreign investors who revived Bulgarian pharmaceutical production. The Bulgarian industry comprises around 30 domestic companies with a sizeable manufacturing base and substantial sales force. Leading domestic players include Medica (which deals both in pharmaceuticals and medical supplies), Biovet, and Sopharma (including Unifarm).

The largest local producer is "Actavis", which is an international company that is located in the top five global generic manufacturers. The most successful Bulgarian pharmaceutical company is "Sopharma" which possesses several factories and continues developing by building new and modern facilities. ☒ The company has realized a growth in pre-tax profit of nearly 100% realized "for April 2014 compared to the same period of 2013, growth in the financial result of the company is estimated to BGN 690 thousand in 2013 to BGN 1,364 thousand. for 2014..

Both companies develop serious business with production oriented for export to different countries and significant sales in the international market. The only state pharmaceutical manufacturer is "Bul Bio - National Inspectorate", which is specialized in products such as vaccines and immune stimulants. Among the new Bulgarian entrepreneurs in the sector stands is "Tchaikapharma" which won a strong position among the top 20 companies on the Bulgarian market.

"GE Pharmaceuticals" is a joint investment in BOTEVGRAD the Austrian company "Genericon Pharma" and Bulgarian business group "Ecopharm" that develops serious activity in the marketing of drugs and supplements in clinical trials and health information through its media company "Health"; "Adipharm" is a company that

manufactures a range of generic medicines and food supplements marketed its own team. "Boro" is one of the companies that offer comprehensive health services, but also have their own product range with a focus on natural products.

Pharmaceutical producers operating in Bulgaria for 2013 amounted for more than 100. The 10 main competitors are responsible for owning nearly 80% of the market. The rest of the companies in the sector are small and medium-sized pharmaceutical enterprises.

Domestic companies mainly manufacture generic drugs, which account for more than 50% of drug sales in volume terms. A substantial proportion is also exported to Russian, Polish, Ukrainian, Latin American and Asian markets. Domestic production accounts for around 30-40% in terms of value and up to 75% of volumes.

Local manufacturers have tried to balance performance between market strategy and the socio-political change. They have improved their operations management by building new production facilities, and maintaining GMP and other quality assurance standards. They have also cut costs by raising the standards of professional expertise and strengthening their financial management results. Every year local producers tend to register between 20 and 30 new generics on the market.

There is a strong presence of international producers in the Bulgarian pharmaceutical market. Bulgaria remains attractive to foreign companies who continue to benefit from their investments in the country in terms of sales, volumes and value. The direct presence of multinationals in the country's pharmaceuticals market is limited, although foreign ownership of local companies has increased significantly in recent years. However, more than 100 international pharmaceutical companies have representative offices in Bulgaria, with 23 of them being members of the Association of Research-Based Companies. Most of these are members of the Association of Foreign Pharmaceutical Manufacturers in Bulgaria. Many multinationals licence production to local companies or import products directly

### ***Advertising and Funding***

According to amendments to the Law on Medicinal Products in Human Use effective since August 5, 2011, Bulgarian drug manufacturers are not required to seek approval to advertise their products. However, permission will be needed in cases where it is addressed to medical professionals. The law stipulates that the contents of the advertisement must be registered with the Bulgarian Drug Agency (BDA).

Disagreements between hospitals and the national funding bodies are a key concern for the financial sustainability of the healthcare system and a hazard for drug companies operating in the country. This situation is further compounded by the large number of uninsured people in the country, as well as by high out-of-pocket payment levels. Underfunded healthcare and medical services are an on-going concern. However, to date, despite declines in hospital expenditure on pharmaceuticals, increased out-of-pocket spending has been a key driver of market growth, though this feature also makes the market highly vulnerable to the wider economic situation. In terms of absolute values, government funding for healthcare is expected to improve marginally, although its relative contribution to the overall healthcare spending in the country will continue to decline, partly due to the difficulties regarding the collection of insurance contributions.

## SWOT Analysis

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>- Strong traditions in pharmaceutical research and drug production, good medical research base, highly qualified researchers</li> <li>- Local pharmaceutical companies with modern and EU compliant manufacturing facilities that are successful in exporting generic drugs</li> <li>- Potential for innovation and R&amp;D collaboration with international partners in new drug and medicinal compound production and associated early stage clinical trials leveraging the presence of multinational pharmaceutical companies</li> <li>- High export volumes of generic drugs to markets in Western Europe, Russia and CIS and the Middle East</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>- Poor collaboration between pharmaceutical companies, medical research institutions and universities</li> <li>- National funding for research is limited and EU financial resources are not used effectively</li> <li>- Limited experience in R&amp;D associated with new drug development and early stage clinical trials activities</li> <li>- Limited connectivity of Bulgarian research networks with European Research Platforms and insufficient knowledge and information exchange</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>- Exploring established markets for generic drugs in Western Europe, Russia and CIS and the Middle East for exports in the higher value-added market segment: new drugs, medical compound, medicinal ingredients delivery systems to markets</li> <li>- Qualified researchers, well developed medical research base at hospitals is an opportunity to engage in all stages of clinical trials for developing new drugs, medicinal compounds and ingredients delivery systems</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>- Strong dependency on generic drugs - competition from Asian companies in the generics drugs segment could have negative impact on the sector</li> <li>- Onerous business regulation/high barriers to entry of new generic products on the market</li> <li>- Lack of transparent regulation and procedures for early stage clinical trials</li> <li>- Third countries' informal competition, parallel imports of generic drugs</li> <li>- Brain-drain of qualified researchers engaged in collaborative R&amp;D due to low salaries in Bulgaria</li> </ul>

## Conclusions and recommendations

Even though the fact that the market is saturated and mature, it is projected that there will be a positive trend in medicine supply so it is anticipated that the business will continue expanding its affairs and especially the ones orientated towards export. In the past years, Bulgaria managed to comply with all relevant EU pharmaceutical directives and regulations, most of them well ahead of other accession countries, without any transition periods for the local industry. Due to the EU requirements in this sector, local manufacturers have made significant investments for modernisation of their production facilities. Many of the country's leading manufacturers have been privatised and multinational activity has become increasingly significant for the development within the sector.

The Bulgarian pharmaceutical industry has established itself as one of the fastest growing sectors of the Bulgarian economy in recent years. The traditions and the good experience in the production of high quality medicines on competitive prices are advantages that make the Bulgarian pharmaceutical market an attractive destination for the initiation of a successful business.

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