



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. Despite the economic decline in 2009 and negligible real growth in 2010, the drug market returned strong growth of 8.1% and 9.2%, respectively.

Despite its composite score being 1% lower on a quarter-on-quarter (qo-q) basis, Bulgaria remains 13th in the latest Pharmaceutical and Healthcare Business Environment Ratings (BERs) for emerging Europe.

The health status of the Bulgarian population worsened notably with the deteriorating state of the economy during the 1990s and early 2000s. From the middle of the decade, however, the country has witnessed improvements in this area, with life expectancy rising to 70 for men and 77 for women, according to official 2010 estimates. For The European country the life expectancy for men is 71 years, and 77 for women.

According to World Health Statistics 2012 made by WHO, data from 2008 reveals that non-communicable diseases represents the leading cause of death in Bulgaria, about 90%, followed by 4% caused by communicable diseases. Figures for the European Union show that 82% dies of communicable diseases and 7% of communicable diseases.¹ In the same report for Bulgaria, about 49% of all deaths are caused by cardiovascular diseases and diabetes, and 29% caused by cancer. For the European Union 26% dies of cancer and 38% of cardiovascular disease and diabetes.²

The pharmaceutical market in Bulgaria is presently highly competitive, well-structured and fast growing.

¹ WHO categorize the mortality rate in three groups: Communicable, non-communicable and injuries.

² The data is taking from the age of 30-70 among the population.

General view of the market

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

The growth of the whole sector is 9% in 2010, of pharmacies it is 12%. There are three factors for the double-digit growth. One of them is the two influenza epidemics at the end of 2010 and the beginning of 2011. At least 50% of the market growth is due to increased consumption of drugs for the respiratory system, antibiotics and immune stimulants. The second reason for the increase in sales is the transfer of payment of part of the expensive cancer and rare diseases treatment from the Ministry of Healthcare to the Health Fund (40 million BGN for 2010). The third factor is long-term and is due to the Bulgarian membership in the EU, namely the parallel export.



In 2010 the patients paid 66% of the money for medicines while the state paid only 34% which is a 1% decrease in comparison to 2009. On more special medicines, e.g. for cancer diseases, the citizens spent 66 million BGN additionally to their therapy while the State paid 87 million BGN. The Bulgarians pay additionally the biggest sum of all EU citizens for drugs of the Health funds- 66%.

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.

There was a tendency for a deficit of particular medicines because of the requirement for producers that they sell in Bulgaria at the lowest price in the EU. That's why more and more companies refuse to register drugs and sell them in Bulgaria. The reason is the common European reference system. The Health Funds in the EU compare the prices between themselves at which they pay for medicines and if they discover a lower price, they automatically lower it in their list.

Demand in internal markets

Although the domestic consumption per capita of pharmaceutical products sustains relatively low levels compared to other EU member-states, there is a clear tendency of growth in domestic demand, including demand for food supplements. Since 2000, the overall consumption of pharmaceutical products in Bulgaria has grown more than threefold.

Foreign drugs for the treatment of chronic diseases such as hypertension and diabetes characterise the list of bestselling medicines in Bulgaria, indicating that the prescription market is approaching Western European standards. However, local players dominate the table of leading pharmaceuticals by number of packs sold.

The volume of the pharmaceutical market reached almost 2 billion BGN in 2010. The purchases from the pharmacies were worth over 1.6 billion BGN while the treatment of patients that hospitals financed was worth about 280 million BGN.

Pharmacies make the biggest turnover in the sector. Their sales grew by 10%. In 2010 4300 pharmacies were licensed, 3900 of them had commercial activities. The number of sold packages of drugs is 2% less but this decrease doesn't mean that the Bulgarians used less medicaments. It is due to the fact that producers started putting more pills in one package and producing more combined products, which requires the intake of fewer pills.

The medicines with prescription mark a 10% growth in comparison to 2009. This is owed to the easier access to drugs in the positive list and the increase of the rights of the GPs to prescribe drugs. The revenues from medicines without prescription increased by 4% in 2010. The sales of the so called original products grew by 7.8% (as packages) and by 15% (as revenues). The generic products marked a decrease of 4.5% in packages and an increase of 3.5% in revenues.

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.

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 2010 the parallel export represents 4% of the sales reaching a value of 60 million BGN. It is expected that that kind of export will be 5% in 2011 reaching a value of 90-100 million BGN.

Companies

Pharmaceutical producers operating in Bulgaria for 2010 amounted for more than 100. The 10 main competitors are holding a share of nearly 80% of the market. The rest of the companies in the sector are small and medium-sized pharmaceutical enterprises.

Ahead of EU accession, Bulgaria's pharmaceutical market experienced consolidation around a small number of large players, including Sopharma, which merged with Unipharm in 2000. Additionally, a number of the country's leading manufacturers have been privatised in recent years, and multinational activity has become increasingly significant, illustrated by the joint development of drugs by GlaxoSmithKline (GSK) and Sopharma and other similar partnerships.



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). 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.

In 2010 again the biggest pharmaceutical company in Bulgaria is Sopharma whose annual income from sales of medicines is 238 million BGN. The company produces over 150 medicines in 13 factories in Bulgaria and abroad and it sells them in 32 countries. In 2010 Sopharma marked a growth of 12% in sales and of 21% in profit. Its export was worth 146 million BGN and marked a double-digit growth of 41% in 2010. The second company in the ranking according to turnover is the producer Biovet which marked an increase of 10.37% in comparison to 2009.

With three manufacturing sites in the towns of Dupnitsa, Razgrad and Troyan, the company Actavis has the biggest product portfolio which consists of 320 medicaments (it introduced 19 new products in 2010). Formerly known as Balkanpharma, the company has more than 50 years of production experience. The other two big companies are Rosh Bulgaria and Sanofi-Aventis Bulgaria. The fastest growing company in recent years is the logistic centre of Glaxo Smith Kline, the company itself has been operating at the Bulgarian pharmaceutical sector for 15 years.

Sopharma and eight other companies (active in both manufacturing and distribution) in early 2010 were under investigation by Bulgaria's anti-trust watchdog (CPC), over allegations of formation of a cartel. The cartel had reportedly manipulated processes to win tenders for the supply of expensive medicines, thus breaching rules on the market. In addition to Sopharma, Hygia, Targovska liga, AltaPharmaceuticalsRoche Bulgaria, Johnson & Johnson (J&J), and Alkaloid were also among the companies involved in the investigation, with no details available regarding the outcome.

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

Distributors

Companies with the highest turnovers are wholesale traders that distribute medicines of all producers as well as food additives, sanitary materials, cosmetics. Unlike pharmaceutical producers distributors operate with quite low profit margin – under 1%.

Bulgaria has around 157 distributors of medicines, although most of those are small and medium-sized, with consolidation ongoing. In fact, in 2010, one of the leading wholesalers, Hygia, was purchased by the country's largest pharmacy chain Mareshki Pharmacies, changing the name into Pharmnet. Nevertheless, the number is still substantial, given that some pharmaceutical producers (such as Sopharma) also register as wholesalers, in order to keep track of distribution of their products as well as to participate in tender procedures for certain products under the central funding programme.

The leader in the supply of medicines, medical equipment and additional services like clinical trials is Sopharma Trading whose turnover was over 400 million BGN in 2010. In the first quarter of 2011 the company reaches a share of over 25% for the first time on that market. In regard to the incomes from sales the second in the ranking is Libra followed by Sting. The company Commercial League marks a drop in sales and it orients itself to development of private cardiologic hospitals which receive the highest payment from the Health Fund.

New legislation limiting the ownership of pharmacies to four per person or company was adopted in Bulgaria on July 31 2008, after its second reading in parliament. The rules eliminated a previous

requirement that meant only people with a Master's degree in pharmacy could open a drug store. However, the proprietor does need to contract a licensed pharmacist in order to sell medicines.

Pharmacies

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.



The number of pharmacies continues decreasing and now it is below 4000. According to data of IMS Health in the first half of 2011 3956 pharmacies have had a license out of which 3700 have been operating. It was expected that the annual turnover of each pharmacy would reach 457 000 BGN in 2011 which means that part of the small pharmacies will drop off the market.

The average price for a medicine without a prescription is 4.23 BGN, for food supplements- 5.77 BGN. It was expected that the market for medicines without prescription will grow and reach 495 million BGN at the end of 2011 which is an increase of 25%. The biggest share of sales of the medicines without prescription belongs to the pain killers while among the food supplements the leaders are the multivitamins.

Advertising

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).

Pricing system

Despite the changes made by the positive list in 2009, the pricing system in Bulgaria remains opaque and lacking in transparency, for which it continues to receive strong criticism from both domestic and foreign companies. The government controls both reimbursed and non-reimbursed drug prices through the Ministry of Health's Drug Pricing Committee, which is to be merged with the Commission on the Positive Drug List into a single Reimbursement Commission, although newer drugs are often arbitrarily classified with their older and generic versions for pricing purpose. The government also uses the price approval mechanism to regulate the market for newer products, with bureaucratic barriers often limiting patient access to novel drugs.

Prices of reimbursed medicines (whether fully or partially subsidised) must be set at the lowest level of the eight reference countries, namely Slovenia, Greece, Czech Republic, Poland, Slovakia, Romania, Hungary, and Latvia. Value-added tax (VAT) on medicines and medical equipment is charged at a standard rate of 20% (despite proposals to reduce it). OTC drugs have been priced freely since 2003.

Funding

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 ongoing 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.

Brief SWOT-Analysis

Status of the Bulgarian Pharmaceutical Industry

<p><i>STRENGTHS</i></p> <ul style="list-style-type: none">-Experience in the production of generic pharmaceutical products-Low manufacturing costs-Compliance with the EU regulations in the field-Greater transparency in the market as well as opportunities for more foreign firms to enter the market through acquisitions.-Significant investments in modernization of local production facilities-Large number of pharmacies-New positive list should help patented drugs sector to develop.	<p><i>WEAKNESSES</i></p> <ul style="list-style-type: none">-Relatively small domestic market-Comparatively low levels of reimbursement, provided by the state-Ineffective management and debts accumulated by local hospitals-The government aiming to restrain price growth in order to decrease public sector expenditure.-High levels of out-of-pocket payments limiting the take-up of more costly, innovative medicines.-Wholesalers dominating dealings with hospitals and private retail channels.
<p><i>OPPORTUNITIES</i></p> <ul style="list-style-type: none">-Rapidly growing domestic demand-Increase in export to EU markets-Increase of funds for healthcare, provided by the state-Extension of GPs rights to prescribe medicines without an additional specialist consultation will benefit innovative drug sales in the short term.-An ageing population, in addition to more prevalent chronic and long-term diseases, providing opportunities for growth.-Privatisation of health insurance funds should increase treatment options.	<p><i>THREATS</i></p> <ul style="list-style-type: none">-Lack of sufficient control over the chain: producer-distributor-pharmacy- Fake pharmaceutical products-Payment delays deterring investment in the sector-The government's programme to shift costs to the private sector to potentially result in a decline in pharmaceutical consumption, as the financial burden on the public increases-High level of corruption to continue deterring some foreign investors

Conclusions and recommendations

The Bulgarian pharmaceutical market is expected to experience a significant development in the coming years, reaching a valuation of approximately EUR 1.3 billion in 2011. The market prospects have been improved by the recent alignment of the local legislation with the EU requirements, as well as by the country's removal from the 'Special 301' Watch List of countries with questionable intellectual property (IP) regimes. 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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