CBI MARKET SURVEY

THE PHARMACEUTICAL PRODUCTS MARKET IN BULGARIA

Publication date: February, 2010

Introduction
This CBI market survey gives exporters in developing countries information on some main developments in the pharmaceutical products market in Bulgaria. The information is complementary to the information provided in the CBI market survey 'The pharmaceutical products market in the EU', which covers the EU in general. That survey also contains an overview and explanation of the selected products dealt with, some general remarks on the statistics used, as well as information on other available documents for this sector. It can be downloaded from http://www.cbi.eu/marketinfo.

1 Market description: consumption and production

Data concerning consumption of pharmaceutical products in Bulgaria are derived from the European Federation of Pharmaceutical Industries and Associations (EFPIA). The latest report from this organisation (The Pharmaceutical Industry in Figures, 2009 Edition) provides data as of 2007. Data for previous years are derived from previous editions of this report. Please note that data are given at ex-factory prices.

Consumption
Bulgaria was the twentieth largest pharmaceutical market in the EU in 2007, accounting for 0.4% of the EU pharmaceutical market (slightly larger than the Slovenian market). Funding for healthcare in Bulgaria is provided by compulsory health insurance, administered by the National Health Insurance Fund (NHIF). NHIF's role is to provide a basic package of health services for the entire population. Germany and France, the largest pharmaceutical markets in the EU, individually accounted for 18% of the EU market. Between 2005 and 2007, Bulgaria's consumption of pharmaceutical products increased at an annual average rate of 5.3%, amounting to € 542 million in 2007. Bulgaria's pharmaceutical consumption increased at a lower rate than the average EU pharmaceutical consumption, which grew by 6.1% between 2005 and 2007.

Please, note that data on consumption of specific pharmaceutical products is fragmented and cannot be presented in a structured manner. Additional information can be found under the section 'Trends in consumption'.

Generic medicines
Generic medicines have a sizeable market presence in Bulgaria, due to their low cost. They represent around 80% of the market by volume and 50% by value. Domestic producers play an important role in this market (Pharmaceutical Pricing and Reimbursement Information - PPRI, 2007).

Generics are so far not mentioned in Bulgarian legislation. However, the introduction of generic substitution, prescription and promotion is regularly discussed in the professional societies and the Association of Bulgarian Pharmaceutical Manufacturers (ABPM) is actively participating; however, no practical legislative steps have been taken. Nonetheless, there is some government pressure towards price containment, which is contributing to the expansion of the generics market (PPRI, 2007).

Trends in consumption
- **Generic medicines:** Generic products are likely to gain ever larger market share as it is likely that the Bulgarian government will increasingly focus on cost-containment measures and the strong local manufacture of generics. Product quality has been significantly

improved as a result of compliance with EU production requirements (Research and Markets, 2008).

- **Non-prescription products:** The non-prescription pharmaceutical market, which is currently of a very limited size in Bulgaria, will increase strongly due to an increasing health awareness among consumers, strong advertising support for such products and the focus on cost containment in healthcare (Research and Markets, 2008).

For more information on trends in pharmaceutical products, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Production
EFPIA does not provide data on Bulgaria's production of pharmaceutical products.

An estimated 78% of the pharmaceutical market is supplied by imports (Espicom, 2009). In 2007 the share of generic medicines in the total pharmaceutical market of Bulgaria was 40 percent (CEE Pharma, 2009).

Local producers mostly produce generic products. In recent years, many mergers and acquisitions by foreign investors have taken place. Still, the number of domestic players has been increasing. However, their role in total pharmaceutical sales has been decreasing, dropping from 36% in 2000 to 13% in 2005 also because they focus mostly on cheaper generic products. However they still supply almost 60% of pharmaceuticals in volume. Between 2000 and 2005, consumption of locally produced pharmaceuticals increased by 80% in value, but decreased by 30% in number of packs (PPRI, 2007). 14 major producers are organised in The Association of Bulgarian Pharmaceutical Manufacturers. Since applying GMP standards, Bulgarian producers are also entering export markets (Reuters, 2008).

Leading pharmaceutical companies in Bulgaria:
- Sopharma - http://www.sopharma.bg
- Unipharm - http://www.unipharm.bg
- Actavis - http://www.actavis.bg
- Zentiva - http://www.zentiva.bg
- Adipharm - http://adipharm.com

Most of the major producers are also involved on the retail level. However, they are only allowed to sell their own pharmaceutical products through this channel.

Sopharma, the biggest pharmaceutical manufacturer in Bulgaria, produces both original and generic medicines. The company was state-owned until the year 2000. Between 2000 and 2002, Sopharma united six enterprises in a corporate structure: Sopharma AD, Unipharm ASD, Vramed AD, Pharmachim Holding AD, NIFHI AD and Rostbalkanpharm. The company has four production plants and is the only producer of ampoules in Bulgaria. 2007. In 2007 Sopharma added another member to its group of companies - Bulgarian Rose - Sevtopolis AD. The latter has a pharmaceutical substances plant for production of phyto substances. The plant is a module for extracting active ingredients from herbs (Sopharma, 2009).

Sopharma trades with companies in Europe, Asia, Africa and North America. Its major export markets are Russia, Ukraine and Poland. The company exports mainly its original drugs to these markets.

The turnover of the Sopharma group members shows varying results. Bulgarian Rose - Sevtopolis AD almost doubled its net profit to €160,500 in Q1 2009 as compared to €83,400 in Q1 of the previous year. On the other hand, Medica registered a sharp decrease of net profit in Q2 2009, which amounted to €197,000. The net profit of the company during the same period in 2008 was €600,000

No information is available on R&D in pharmaceutical products in Bulgaria. Please also note that data concerning the production of specific product groups in Bulgaria are not available.

Trends in production

- **Compliance with EU standards and industry developments:** Due to Bulgaria's entry into the EU, pharmaceutical manufacturers are now required to comply with EU GMP standards, and many of them have invested heavily to modernise production facilities. Furthermore, several domestic companies have been privatised in recent years, and large multinationals increasingly acquire local companies (Business Monitor, 2008).
- **Consolidation of the pharmaceutical industry:** During the last few years, there has been a number of mergers and acquisitions in the Bulgarian pharmaceutical market. The German manufacturer Merk will shortly acquire Aquachim, a pharmaceutical wholesaler. Sopharma, the leading Bulgarian pharmaceutical company has been uniting a number of smaller companies in its corporate structure and is planning to acquire Briz of Latvia (PMR, 2009).
- **Positive Drug List:** As of 2007, the Bulgarian government announced a new committee to manage price settings for all publicly funded medicines. The new *Positive Drug List* was presented in March, 2009. However, it has caused considerable concern among pharmaceutical manufacturers, as the new pricing requirements seem unacceptable to some manufacturers, as they are afraid that they will have to lower their current prices of specific medicines (Association of European Self-Medication Industry - AESGP, 2009).

For more information on trends in pharmaceutical products, please refer to the CBI survey 'The pharmaceutical products market in the EU'.

Opportunities and threats

+ The Bulgarian government is expected to increase its focus on health care cost-containment, which would lead to more sales of generic medicines.
+/- Bulgarian companies play an important role on the market of generics, especially lower-priced products.
+/- Pharmaceutical legislation has been harmonised with that of the EU. However, problems still exist concerning the duration of authorisation procedures and the lack of clarity regarding the criteria used to determine which pharmaceuticals make it onto the reimbursement list. Without this, the demand for a pharmaceutical product is very limited.
+ Market prospects further improved as membership of the European Union (EU) was gained at the start of 2007. This has vastly improved the country's intellectual property (IP) regime, facilitating access for foreign products.
- The Bulgarian market for pharmaceuticals is still very limited in size. Moreover, the market is increasing at a slower rate than the EU market. Funding shortages could hamper growth.
- The strict regulations and requirements for the entry of pharmaceutical products into the EU might represent one of the greatest threats to the access of exporters in developing countries, specifically to the Bulgarian market in specific.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

2 Trade channels for market entry

National policies and regulations impact the distribution trends in the different EU countries. The trade structures of these markets are mostly similar, but also deviate according to the different pharmaceutical and healthcare systems. Nonetheless, the major variations lie at the end of the distribution chain – in the manner how the product is dispensed to the end-consumer - which does not affect a supplier's market approach.

Wider variations amongst different EU countries are found in the distribution trends and channels for non-prescription products in the different markets, since weaker regulations apply to these products, and major drugstore chains and retailers often play a large role. In this manner, the trading structure for pharmaceutical products in Bulgaria does not differ significantly from the structure at the EU level. However, some of the specific characteristics of the Bulgarian pharmaceutical trade channels and trends therein are outlined below:

- Until recently, the Bulgarian producers and foreign manufacturers were selling their products through different wholesalers. Now, **some leading wholesalers** are owned by local producers, either set up or purchased by these companies in the last couple of years. Others were bought by foreign investors. As such, the trade channels are becoming more mixed. There are two registered wholesale associations. One is called the Association of the Wholesalers of Medicines (AWM) and the other is called the Professional Chamber of Wholesalers (PCW).
- According to Art. 54 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, **only licensed wholesalers** may perform wholesale activities in Bulgaria. In 2008, there were 138 wholesalers registered in Bulgaria. In 2009, there were **4,282 pharmacies** in the country, of which 3,977 were private.

Major wholesalers in Bulgaria include:

- Pharmachim - http://clients.ttm.bg/pharm/index.htm
- Aquachim - http://www.merck-aquachim.bg
- Libra AG - http://www.libra-ag.com
- Commercial League - http://www.comleague.com
- Sting LTD - http://www.stingpharma.com

Please, refer to the CBI survey 'The pharmaceutical products market in the EU' for further information on EU pharmaceutical trade channels.

Price structure

In Bulgaria, price control is applied to pharmaceutical products which are subject to full or partial public funding. Prices of these products are negotiated between government and the manufacturer, and fixed by a maximum price proposed by the manufacturer. Publicly funded pharmaceuticals must have the lowest price from among eight reference countries. Prices of non-prescription pharmaceuticals are no longer controlled as from January 2003.

A new drug act in 2007 stipulated a new committee to manage price setting for all pharmaceuticals where some form of public funding can be provided. The specific requirements for price setting of prescription pharmaceutical products are managed in special regulation. However, the price setting mechanisms of the Bulgarian government seem unacceptable to some pharmaceutical manufacturers, who have withdrawn products from the markets (AESGP, 2009).

Generic medicines

Different prices apply throughout the various trade channels. No information on specific margins for manufacturers and wholesalers is available. The standard Value Added Tax (VAT) rate is 20%. There is no discounted VAT applicable to pharmaceutical products (AESGP, 2009).

For further information on price structure of pharmaceutical products in Bulgaria, please refer to: http://ppri.oebig.at/Downloads/Results/Bulgaria_PPRI_2007.pdf

3 Trade: imports and exports

Imports

In 2008, Bulgaria was only the 21st largest importer of pharmaceutical products in the EU, accounting for 0.4% of total EU imports (about the same size of Slovenian pharmaceutical imports). Between 2004 and 2008, Bulgaria's imports increased by an annual average rate of 12% in value and 0.8% in volume, amounting to € 425 million or 5.9 thousand tonnes in 2008. The majority of Bulgaria's imports (87%, in terms of value) is sourced in EU countries. Imports from EU countries increased by an annual average rate of 15% in terms of value between 2004 and 2008. Germany, which accounted for 21% of imports in 2008, was the leading supplier of pharmaceutical products to Bulgaria. Other important EU suppliers of pharmaceutical products to Bulgaria in 2008 were France (11%) and Hungary (10%). Extra-EU countries (excluding DCs) accounted for a share an 11% share of Bulgarian imports, of which Switzerland (with a market share of 10%) was the leading supplier.

The role of developing countries in supplying pharmaceutical products to Bulgaria is small, but it is significant when compared to other EU countries. In 2008, imports sourced in DCs accounted for 2.3% of Bulgaria's total imports. Moreover, imports from developing countries increased by an annual average rate of 34% between 2004 and 2008. Turkey and India were the main DC suppliers, accounting for 0.6% and 0.5% of total imports, respectively. Whereas imports from Turkey increased at an annual average rate of 18%, imports from India increased by an even stronger annual rate of 74% in the review period.

In 2008, Bulgaria's imports of pharmaceutical products consisted of packed pharmaceutical products (99%) and non-packed pharmaceutical products (1%).

Exports

Bulgaria is one of the smallest exporters of pharmaceutical products in the EU. In 2008, the country was only the twentieth largest EU exporter, accounting for only 0.1% of total EU exports. Nonetheless, Bulgaria's exports increased by a significant annual average rate of 31% in value and 2.5% in volume between 2004 and 2008, amounting to € 187 million or 11 thousand tonnes in 2008. Approximately 25% of Bulgaria's exports was destined for EU countries, and another 30% to countries outside the EU, excluding DCs. Developing countries accounted for the remaining 45% of total Bulgarian exports. Russia, the leading destination, accounted for 29% of Bulgarian exports, followed by Romania (20%) and Ukraine (11%).

In 2008, Bulgaria's exports of pharmaceutical products consisted of packed pharmaceutical products (99%) and non-packed pharmaceutical products (1%).

Opportunities and threats

- Bulgaria is one of the smallest importers of pharmaceutical products in the EU. Although imports in terms of value increased considerably during the review period, they were stable in terms of volume.

+/-Imports from developing countries are relatively more important and are increasing strongly. However, imports are dominated by Turkey and India. New entrants to the market will face tough competition from these countries.

Exporters should take into account that the same trend can be an opportunity for one exporter and a threat to another. Please, review these opportunities and threats according to your own situation. Chapter 7 of the CBI market survey 'The pharmaceutical products market in the EU' presents an example of an analysis of whether a trend/development is an opportunity or a threat.

Useful sources

- EU Expanding Exports Helpdesk - http://exporthelp.europa.eu
- Eurostat – official statistical office of the EU - http://epp.eurostat.ec.europa.eu
- Understanding eurostat: Quick guide to easy comext

http://epp.eurostat.ec.europa.eu/newxtweb/assets/User_guide_Easy_Comext_20090513.pdf

4 Price developments

Pricing systems vary in the individual EU countries, thus this is also the case for price developments. The main price developments observed in Bulgaria in recent years are the following:

- After receiving market authorisation, a maximum price for a pharmaceutical product is registered by the Bulgarian Pricing Committee. The State regulates prices of prescription-only pharmaceuticals and registers the prices of non-prescription pharmaceutical products. At the manufacturer level, the maximum price is determined based on external price referencing (price control at the manufacture level) and, at wholesale and pharmacy levels, maximum margins are applied to prescription-only pharmaceuticals (price control at the distribution level).

Useful sources

- ITC market news service (MNS) - http://www.intracen.org
- PPRI – Pharmaceutical Pricing and reimbursement Information - http://ppri.oebig.at

5 Market access requirements

As a manufacturer in a developing country preparing to access Bulgaria, you should be aware of the market access requirements of your trading partners and the Bulgarian government. For information on legislative and non-legislative requirements, go to 'Search CBI database' at http://www.cbi.eu/marketinfo, select 'Pharmaceutical products' and 'Bulgaria' in the category search, click on the search button and click on market access requirements.

Detailed information on packaging can be found at the website of ITC on export packaging: http://www.intracen.org/ep/packit.htm

Information on tariffs and quota can be found at http://exporthelp.europa.eu

6 Doing business

Information on doing business like approaching potential business partners, building up a relationship, drawing up an offer, handling the contract (methods of payment, and terms of delivery) and cultural differences can be found in CBI's export manuals 'Export Planner', 'Your image builder' and 'Exporting to the EU'. These can be downloaded from http://www.cbi.eu/marketinfo - go to search publications. For more information on doing business in Bulgaria, visit the following websites:

Trade associations

- The Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM) - http://www.arpharm.org
- The Association of Bulgarian Pharmaceutical Manufacturers (ABPHM) - http://www.abphm.bg
- Bulgarian Generic Pharmaceutical Association – http://bgpharma.bg
- The Bulgarian Pharmaceutical Group - http://www.bulgarianpharmaceuticalgroup.com - represents Bulgarian distributors of pharmaceutical products and leading Bulgarian manufacturers.

Trade press

- Online Bulgaria is a comprehensive source of information about the Bulgarian pharmaceutical sector - http://www.online.bg/BOL_ENG.asp

Trade fairs

- Medicus Dento Galenia - http://www.fair.bg/en - the international exhibition of medicine, dentistry and pharmaceutics. This fair takes place once a year in Plovdiv. The next event will be held 20-23 October, 2010.
- For more information on trade fairs related to pharmaceuticals in Bulgaria, please check the website of BulgarReklama - http://www.bulgarreklama.com

This survey was compiled for CBI by ProFound – Advisers In Development
in collaboration with Jan Ramakers Fine Chemical Consulting Group