Pharmaceutical and Biotechnological Sector in Poland
The pharmaceutical and biotechnological sector is considered one of the most innovative branches of economy. The value of the pharmaceutical market in 2011 will reach about PLN 21.4 billion (EUR 5.0 billion). The average yearly pace of growth of its value in years 2003-2010 amounted to 6.5%. The estimated value will reach PLN 60 billion until 2016.

Nearly 33% of pharmaceutical and biotechnological enterprises have their registered office in the area of Mazowieckie Province. In turn almost 80% of all the companies may be classified as micro-enterprises. Poland’s asset in the scope of biotechnology and pharmacy is represented by almost 20,000 students and over 3000 graduates in these faculties at universities and medical universities. In addition, biotechnology is one of priority sectors supported by the government.

**Description of the Pharmaceutical Market in Poland**

:: Graph 1 Value and dynamics of the pharmaceutical market in Poland

![Graph](image)

* estimated values


The value of the pharmaceutical market in Poland in the first decat of 21 century was growing systematically. Since 2003 the dynamics counted in PLN has been always positive and the average pace of growth of the market value equaled 6.5%. By the end of 2010 its value was estimated as PLN 20.1 billion (EUR 5.0 billion). An estimated share of Poland in the European market (in terms of value) amounted to 4.0% which was the second position in the region of Central and Eastern Europe with Russia ranked first (4.4%).

It is estimated that the pace of growth in years 2011-2016 will reach even 10.2% a year and its value - even PLN 62 billion (about EUR 15.5 billion).

In the recent years the main factor contributing to the sector development have been pharmaceuticals sold without prescription. As in the countries of Central Europe, the share of this segment is higher than in developed countries, it is considered that specialized and expensive refunded medicines will be a growth factor in the nearest future.

The biotechnological sector is frequently considered related to the pharmaceutical one. They are considered the most innovative branch of economy in Europe. In 2009 the share of expenses for B+R in respect of the sales of value amounted to 15.4% and 21.2%, respectively. Over EUR 20.5 billion were spent for research and development in both branches.

Innovative companies operating in the sector also create proceeds to the national budget. It is estimated that in the recent years they have generated direct proceeds amounting to PLN 600 million, whereas the proceeds of the entire sector equaled about PLN 1 billion.

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2. *Industry Profile: Pharmaceuticals in Poland, Raport, Datamonitor 2010*.
Legal regulations

In Poland the rules of admitted to marketing and performing research on new medicines are laid down by the Act on Pharmaceutical Law. In order for a pharmaceutical product to be admitted to marketing, it has to receive a "permit of admission to marketing" issued by the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products which is then accepted by the Minister of Health. In this respect the Act provides for certain exceptions which include compounded medicines or medicinal products used for scientific purposes. The entire proceeding, from submitting the application to issuing the decision, should not exceed 210 days.

As a result of the entire process a medicine is listed in the Register of Medicinal Products Marketed in the Territory of Republic of Poland.

The Structure of Pharmaceutical Market

Products distributed in the pharmaceutical market may be divided in three main segments: They include refunded medicines, prescription non-refunded medicines, and medicines sold without prescription. Their value shares in the sales in 2010 were estimated as 45%, 19% and 36%. In the last years these shares did not change significantly.

:: Graph 2 The structure of pharmaceutical market including the type and purpose of medicine.


The largest market share was represented by medicines having effect on the circulatory system. Their share along with the medicines having effect on nervous and digestive systems amounted to over 55% of the market in terms of value.

Out of four generally defined segments of the biotechnological market, in Poland 50% of market is represented by biotechnology applied in medicine, 30% in industry, 15% in agriculture and activity related to the environment.


The law contains a notion of "medicinal product" which refers to what is generally defined as "medicine".

Ministry of Health 2011.

According to a division applied in literature, biotechnology may be classified as red – medicine, white (gray) – industry, green – agriculture and natural environment, blue – related to water.

Pharmaceutical biotechnology in Poland: current conditions and forecasts, PMR 2011.
Labor Market Potential - Students and Graduates

In the 2009/2010 academic year over 8000 persons studied on the faculty of pharmacy. In turn almost 13000 persons studied on the faculty of biotechnology. Several Medical Universities in Poland offer a possibility of studying pharmacy. Biotechnology was available, among others at the universities (also agricultural ones), and universities of technology. Generally, 30 colleges out of 36 providing these studies offered also Doctor Studies. The number of graduates amounted to 4100 in the 2009/2010 academic year.

The highest number of persons studying on this faculty was in Śląskie Province (12.3% of the total number of students of pharmacy), in Lubelskie Province and Małopolskie Province (11.3% in both of the cases). The lowest number of persons studying on this faculty was in Podlaskie Province (6.9%). In the case of biotechnology which was available in 15 provinces the highest number of students on this faculty was observed in Śląskie Province, Dolnośląskie Province and Łódzkie Province (14.3%, 14.0% and 11.9%, respectively). The lowest number of students was observed in Lubuskie Province (0.6%) and in Świętokrzyskie Province (0.4%).

Biotechnology was included on a list of ordered study disciplines established by the Ministry of Science and Higher Education.

Foreign Direct Investments in the Sector

:: Graph 3 Foreign direct investments in the chemical sector

![Graph 3 Foreign direct investments in the chemical sector](image)


In the statistics concerning foreign direct investments (FDI) the activity of pharmaceutical and biotechnological enterprises is included in the categories of: manufacturing of chemical products, and science. Since the accession of Poland to the European Union, that is since 2004, the accumulated BIZ value in the chemical industry has increased by almost 70% and in the case of research activity - by over 175%. The estimated value of investments in the pharmaceutical industry in Poland amounted to about PLN 6.7 billion in years 2004-2009. The average BIZ flow to the chemical sector amounted to EUR 300 million in years 2004-2009. For the research activity flew on average EUR 4.1 million.

12 Biotechnology is included in one of the four chemical, biological, technical and agricultural disciplines.
13 Pharmaceutical biotechnology in Poland: current conditions and forecasts, PMR 2011.
14 GUS [Central Statistical Office], 2011.
Enterprises operating in the pharmaceutical and biotechnological sector

In the Polish market out of 30 largest pharmaceutical companies 16 have their production plants located in Poland. From the value point of view 10 largest companies controls over 50% of the market, and 30 highest-ranked ones - over 80%.

The share of sales by national producers (in terms of value) in the Polish market amounted to about 25% in 2010, and in the recent years it was relatively stable (about 28% in 2003). However, they lost from the quantitative point of view where their share decreased from 61% to 47% in years 2003-2010.16

:: Table 1 Pharmaceutical enterprises from the list of the largest ones in Poland (by value) having production plants located in Poland in 2010

<table>
<thead>
<tr>
<th>Name</th>
<th>Location of production plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adamed</td>
<td>Pieńków, Pabianice</td>
</tr>
<tr>
<td>Biofarm</td>
<td>Poznań</td>
</tr>
<tr>
<td>Gedeon Richter</td>
<td>Grodzisk Mazowiecki</td>
</tr>
<tr>
<td>KRKA</td>
<td>Warszawa</td>
</tr>
<tr>
<td>LEK-AM</td>
<td>Zakroczym</td>
</tr>
<tr>
<td>Novartis</td>
<td>Stryków</td>
</tr>
<tr>
<td>Nycomed</td>
<td>Łyszkowice</td>
</tr>
<tr>
<td>Polfa Tarchomin</td>
<td>Warszawa (Tarchomin)</td>
</tr>
<tr>
<td>Polfa Warszawa</td>
<td>Warszawa</td>
</tr>
<tr>
<td>Polpharma</td>
<td>Starogard Gdański, Duchnice, Sieradz</td>
</tr>
<tr>
<td>Sanofi-Grupa</td>
<td>Rzeszów, Chociw</td>
</tr>
<tr>
<td>Servier</td>
<td>Warszawa</td>
</tr>
<tr>
<td>Teva Group</td>
<td>Kraków, Kutno</td>
</tr>
<tr>
<td>USP</td>
<td>Wrocław</td>
</tr>
<tr>
<td>Valeant Pharma</td>
<td>Rzeszów, Chociw</td>
</tr>
<tr>
<td>Adamed</td>
<td>Pieńków, Pabianice</td>
</tr>
</tbody>
</table>

In accordance with the data of GUS [Central Statistical Office] by the end of quarter 3 of 2011, in Poland there were 687 entities operating in the field of pharmaceutical products (including medicines), and dealing with biotechnological research. In the first group there were 532 enterprises (representing 77% of the specified group) of which 182 dealt with manufacturing of basic pharmaceutical substances, and 350 - with manufacturing of medicines and other pharmaceutical products. The activity related to biotechnological research was performed by 155 entities (23% of the specified entities). This segment constituted 6% of entities running an activity related to the research.

As regards the size, micro-enterprises which employed not less than 9 persons prevailed in the pharmaceutical and biotechnological sector. This group constituted as much as 80% of all the enterprises. There were 10% of small-sized enterprises employing from 10 to 49 persons, middle-, and large-sized enterprises, employing over 250 persons, represented 7% and 3.6%, respectively.

As regards geographical distribution, Mazowieckie Province prevails over other regions. 33% of all the enterprises under analysis have their registered offices there. In total, 74% of entities operating in the sector have their registered offices in six provinces.

In November 2011 four companies that operated in the pharmaceutical and biotechnological sector were listed on the Warsaw Stock Exchange. Their total capitalization amounted to PLN 955 million.\textsuperscript{17}

\textsuperscript{17} As for November 2, 2011.
Graph 7 Entities running an activity related to manufacturing of medicine and pharmaceutical products and research in the field of biotechnology

Source: Own work on the basis of the data of GUS [Central Statistical Office] (as for the end of quarter 3 of 2011).

Nepentes S.A. manufacturing pharmaceuticals sold without prescriptions in pharmacies was listed until 2010. The Board decided that the enterprise would not be listed on the stock exchange any more.

Table 2 Capitalization of enterprises operating in the pharmaceutical and biotechnological sector listed on the Warsaw Stock Exchange

<table>
<thead>
<tr>
<th>Name</th>
<th>Capitalization (PLN million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioton</td>
<td>459.27</td>
</tr>
<tr>
<td>Cormay</td>
<td>457.46</td>
</tr>
<tr>
<td>Euroimplant</td>
<td>36.82</td>
</tr>
</tbody>
</table>

Source: Warsaw Stock Exchange as for November 2, 2011
Government Assistance

Investments from priority sectors may apply for support in a form of government subsidy. They include:

<table>
<thead>
<tr>
<th>Supported sector</th>
<th>Minimum workplace number</th>
<th>Minimum investment value</th>
<th>Maximum amount of assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>automotive, aviation, biotechnology, IT and electronic</td>
<td>250</td>
<td>40 million PLN</td>
<td>from PLN 3 200 to 15 600 PLN per one workplace</td>
</tr>
<tr>
<td>BPO</td>
<td>250</td>
<td>2 million PLN</td>
<td></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>35</td>
<td>3 million PLN</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>500</td>
<td>1 billion PLN</td>
<td></td>
</tr>
</tbody>
</table>

Support for the creation of new workplaces

Supported sector | Minimum workplace number | Minimum investment value | Maximum amount of assistance |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>automotive, aviation, biotechnology, IT and electronic</td>
<td>50</td>
<td>160 million PLN</td>
<td>2-10,5% of the investment value</td>
</tr>
<tr>
<td>Other</td>
<td>500</td>
<td>1 billion PLN</td>
<td></td>
</tr>
</tbody>
</table>

Note: average exchange rate EUR 1 = PLN 4.00 (August 2010)

Funds of the European Union

In years 2007-2013 Poland is granted a significant flow of the EU funds which amount to over EUR 67 billion. Entrepreneurs may apply for the funds from the following Operative Programs (OP):

- 5 national Operative Programs:
  - Infrastructure and Environment,
  - Innovative Economy,
  - Human Capital,
  - Development of Eastern Poland,
  - Technical Assistance,
- 16 Regional Operative Programs,
- Programs of European Regional Cooperation.

Exemptions from the Tax on Real Estate

The exemption depends upon the number of new workplaces created and if the local self-government has a policy of tax exemptions. The rates of the tax on real estate are established locally in the framework of maximum rates in a defined year. In 2011 the maximum rates applied amount to PLN 21.05/ m² for buildings PLN 0.80/ m² for the land and 2% for the construction.

Exemptions from tax on legal persons CIT (rate: 19%)

They are available in Special Economic Zones that is in selected regions of Poland where economic activity is run on special terms. Exemptions from income tax amount to 30%-50% of investment expenses or costs of personnel employment in the period of 2 years, whichever are higher.