

Pharmaceutical and Biotechnological Sector in Poland

**Economic Information Department
Polish Information and Foreign Investment Agency**

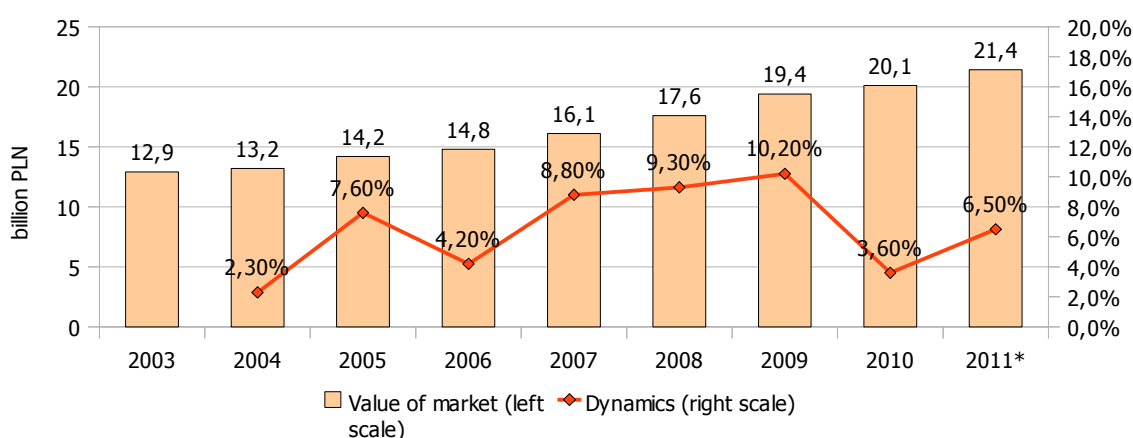
Introduction

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



* estimated values

Source: *Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011* [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

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)¹. 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%)².

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)³.

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 future⁴.

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 branches⁵.

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 billion⁶.

¹ Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011 [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

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

³ Poland – World Pharmaceutical Market Q2 2011, Raport, Espicom 2011.

⁴ Polish Pharmaceutical Distribution, Raport, Erste Group 2011.

⁵ The 2010 EU Industrial R&D Investment Scoreboard, Report, European Commission 2010.

⁶ Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011. [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

Legal regulations

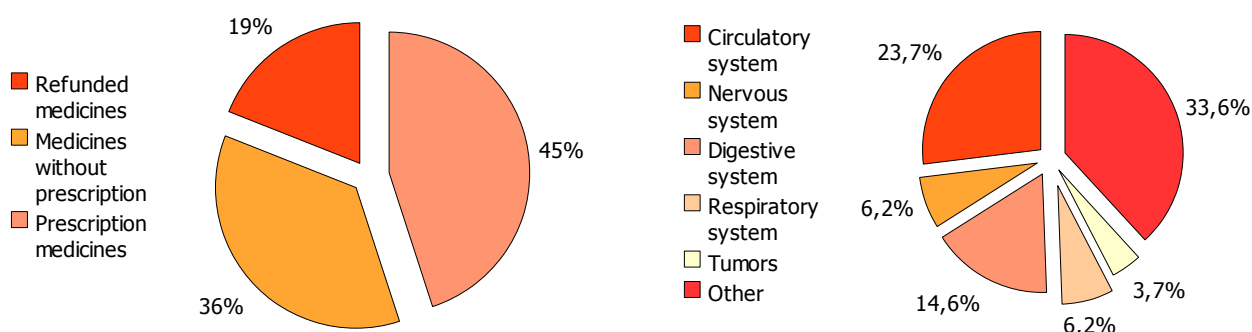
In Poland the rules of admitted to marketing and performing research on new medicines are laid down by the Act on Pharmaceutical Law⁷. In order for a pharmaceutical product⁸ to be admitted to marketing, it has to receive a "permit of admission to marketing" issued by the Office for Registration of Medicinal 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 days⁹.

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.



Source: *Polish Pharmaceutical Distribution, Report, Erste Group 2011. Pharmaceuticals in Poland, Report, Datamonitor 2010.*

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 market¹⁰, in Poland 50% of market is represented by biotechnology applied in medicine, 30% in industry, 15% in agriculture and activity related to the environment¹¹.

⁷. Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne (Dz.U. 2001 nr 126 poz. 1381). [Act of September 6, 2011 on Pharmaceutical Law (Official Journal 2001 no. 126 item 1381)]

⁸. The law contains a notion of "medicinal product" which refers to what is generally defined as "medicine".

⁹. Ministry of Health 2011.

¹⁰. 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.

¹¹. 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 biotechnology¹². 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 Studies¹³. The number of graduates amounted to 4100 in the 2009/2010 academic year.

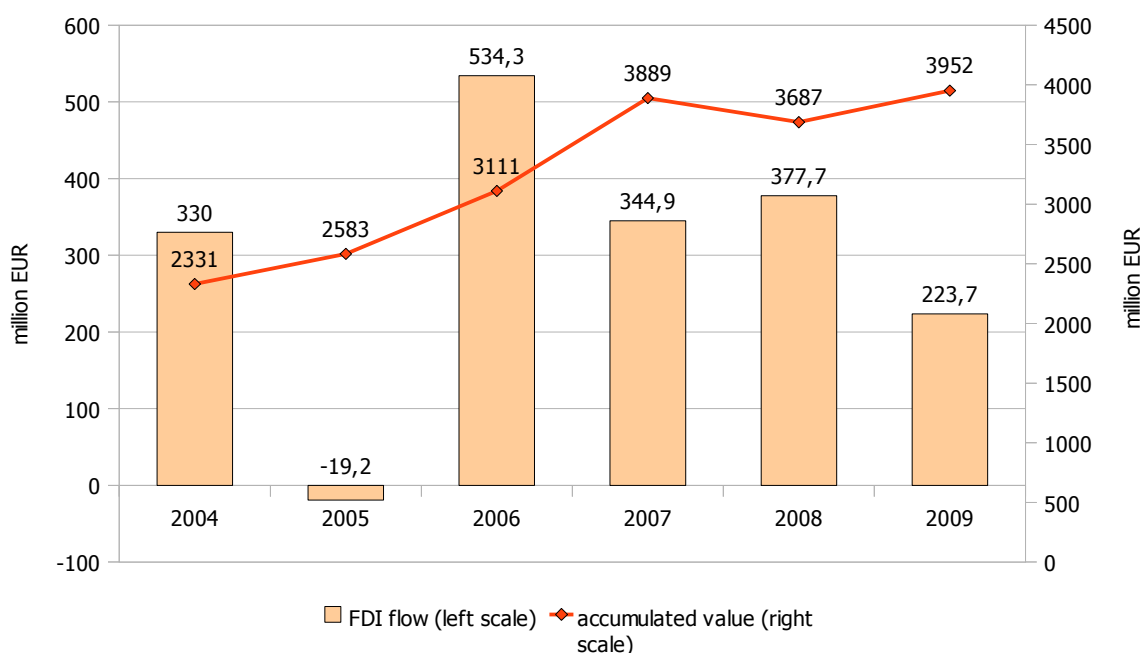
The highest number of persons studying on this faculty was in Śląskie Province (12.3% of the total number of students of pharmacy), in Lubelskie

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%)¹⁴.

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



Source: *Zagraniczne inwestycje bezpośrednie w Polsce*, NBP 2008, 2009, 2010. [Foreign Direct Investments in Poland, National Bank of Poland 2008, 2009, 2010.]

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 2004-2009¹⁵.

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.

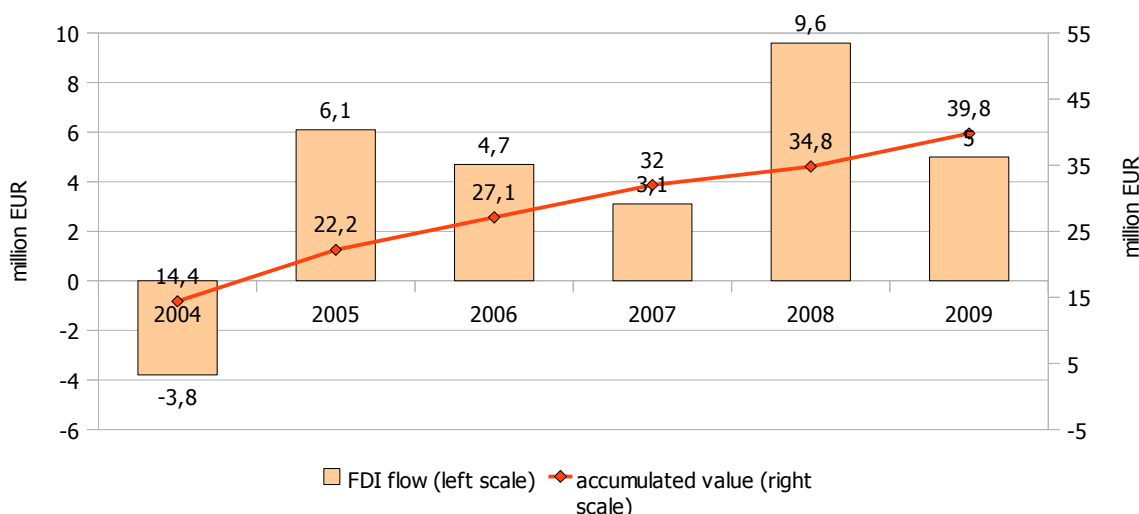
¹². Biotechnology is included in one of the four chemical, biological, technical and agricultural disciplines.

¹³. Pharmaceutical biotechnology in Poland: current conditions and forecasts, PMR 2011.

¹⁴. GUS [Central Statistical Office], 2011.

¹⁵. Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011 [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

:: Graph 4 Foreign direct investments in science



Source: *Zagraniczne inwestycje bezpośrednie w Polsce, NBP 2008, 2009, 2010* [Foreign Direct Investments in Poland, National Bank of Poland 2008, 2009, 2010.]

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%.

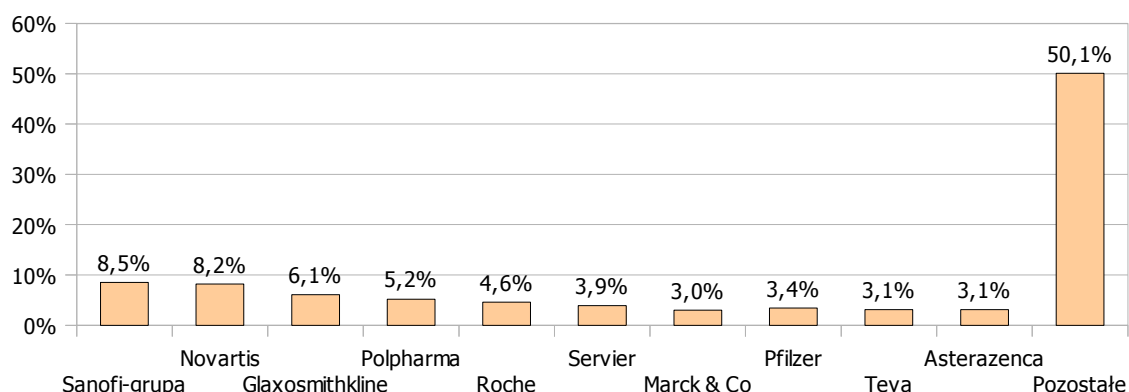
The share of sales by national producers (in terms of value) in the Polish market amounted to about 25% in 2010, and in the recent years it was relatively stable (about 28% in 2003). However, they lost from the quantitative point of view where their share decreased from 61% to 47% in years 2003-2010¹⁶.

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

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

Source: *Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011* [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

¹⁶. Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011 [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

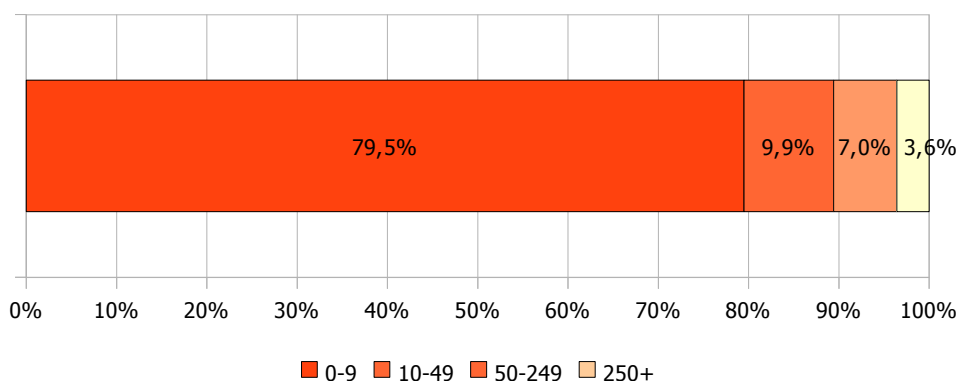
:: Graph 5 The largest pharmaceutical enterprises present in Poland (market share by value)

Source: *Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC, wrzesień 2011* [Contribution of the Innovative Pharmaceutical Industry to the Development of Polish Economy, Report PwC, September 2011].

In accordance with the data of GUS [Central Statistical Office] by the end of quarter 3 of 2011, in Poland there were 687 of 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.

:: Graph 6 Companies operating in the pharmaceutical and biotechnological sector in Poland by employment size

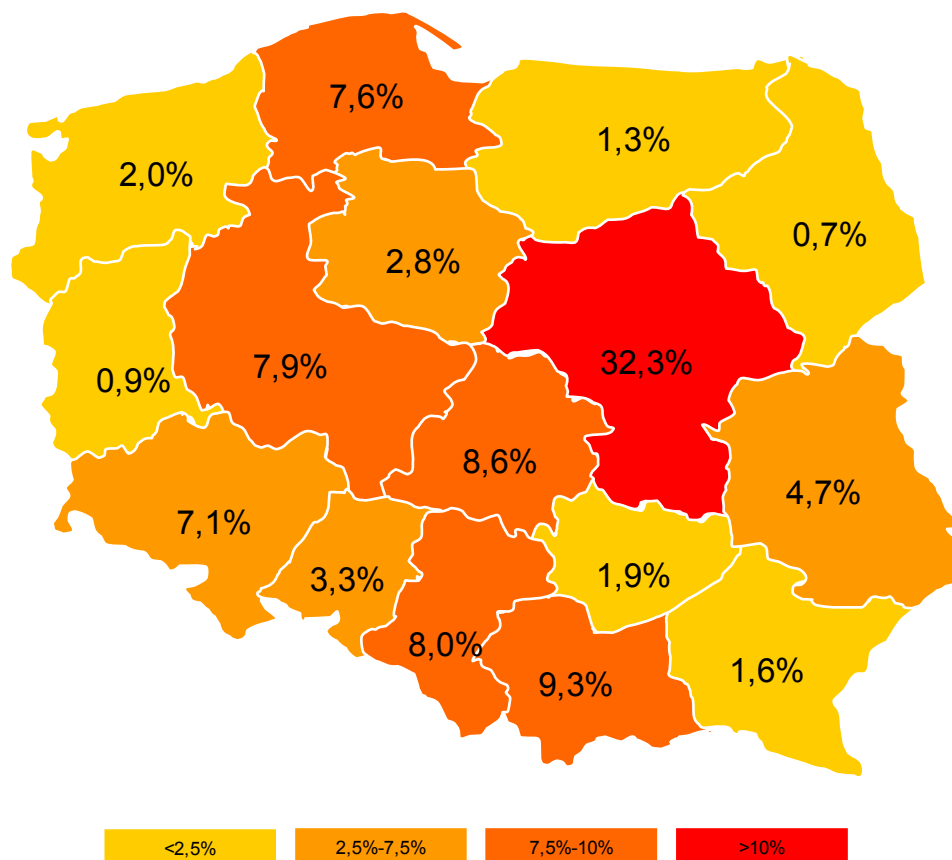
Source: *Own work on the basis of the data of GUS [Central Statistical Office] (as for the end of quarter 3 of 2011).*

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 million¹⁷.

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

Name	Capitaliztion (PLN million)
Bioton	459,27
Cormay	457,46
Euroimplant	36,82

Source: *Warsaw Stock Exchange as for November 2, 2011*

Support

Government Assistance

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

automotive, electronic, aviation, biotechnological, modern services and research and development sectors. The assistance is granted on the basis of a minimum number of the workplaces created or the amount of investment expenses incurred.

Supported sector	Minimum workplace number	and	Minimum investment value	Maximum amount of assistance
Support for the creation of new workplaces				
automotive, aviation, biotechnology, IT and electronic	250		40 million PLN	from PLN 3 200 to 15 600 PLN per one workplace
BPO	250		2 million PLN	
R&D	35		3 million PLN	
Other	500		1 billion PLN	

Supported sector	Minimum workplace number	and	Minimum investment value	Maximum amount of assistance
Support for the creation of new workplaces				
automotive, aviation, biotechnology, IT and electronic	50		160 million PLN	2-10,5% of the investment value
Other	500		1 billion PLN	

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 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.

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.