

White Paper

THE BIOTECHNOLOGY SECTOR IN POLAND

F R O S T & S U L L I V A N

In Cooperation With



POLISH INFORMATION AND
FOREIGN INVESTMENT AGENCY

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About This Document

The following whitepaper outlines the findings of a study conducted by Frost & Sullivan for The Polish Information and Foreign Investment Agency (PAIiIZ) on the biotechnology sector in Poland. This paper focuses on the recent trends and developments in this sector, and on the key challenges, drivers and restraints impacting it. It also discusses prospects for the sector's further development.

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Executive Summary

Modern biotechnology, one of the important enabling technologies of the 21st century, is proving its potential in sectors such as health, agriculture and industrial processes. The potential of life sciences and biotechnology is being increasingly leveraged, and is poised to create a new economy with a wealth of information for a number of diverse application areas.

On a global level, biotechnology has exhibited significant progress with a growth rate of 8 per cent in 2007. With the emergence of different ‘-omics’ technologies, the sector has demonstrated new focus and strength. Companies have reinvented themselves with novel strategies to speed up the product development process. Europe, in its own way, has made efforts to keep pace with its global counterparts, and demonstrated a revenue growth rate of 13 per cent in 2007. The European biotechnology market depicted consistent progress with technology transfer initiatives, corporate alliances, financial considerations and novel products.

The biotechnology sector in Poland, though in a nascent phase, is experiencing numerous changes in terms of funding and research initiatives, new laws in favour of the wider acceptance of the technology and novel applications. Being a member country of Europe’s Framework Programme 7 (FP7), Poland can leverage funding opportunities across the four components of cooperation, ideas, people and capacities, to better the knowledge economy and society in the country. Interestingly, backed by financial support and government encouragement, several research projects from ‘bench top’ or laboratory stage, are moving to different stages of development, allowing Poland to be a part of the emerging biotechnology countries.

Agriculture, an integral part of Poland, is looking at biotechnology to increase crop yield and to develop crops with desired traits. Consultations have begun in the country to relax the GMO ban. Nutritional sciences have drawn attention in Poland, owing to new foods with desired constituents and health benefits, and are gradually being introduced by several food industry giants. Biotechnology has had a significant impact on industrial applications such as sewage and water treatment, the bioremediation of oil-contaminated soil as well as generation of biofuels. Biotechnology in healthcare has a relatively novel approach with regard to the legislations that govern the acceptance of the products derived from this technology. Poland has been holding a key position with regard to clinical trials. Over the last five years, CROs (Contract Research Organization) have grown in number in Poland; at present, there are more than 60 active CROs in the Polish market, carrying out preclinical and clinical development work.

The proponents of the technology claim that much of the slow progress regarding the adoption of biotechnology is attributable to the lack of social awareness and the legal issues imposed by the EU. With better awareness of the labelling and coexistence strategy, which elaborates on providing nutritional information developed by biotechnology and growing genetically modified crops with conventional crops respectively, there will be a wider acceptance of this versatile technology. Most of the further deployment of biotechnology depends on legal developments, including intellectual property rights and social aspects, including public perception. Considering the immense potential agrobiotechnology, industrial biotechnology and

biotechnology in healthcare hold in Poland, venture capitalists are competing to establish their footprint in this eastern European country.

In terms of converting the current weaknesses of Poland into opportunities, the country can adopt two approaches. Firstly, it can co-ordinate research at a national level and carry out innovation and clinical research in a strategic manner. Secondly, by increasing investment in this area, Poland can facilitate the entry of researchers from abroad, forming an attractive biotechnology research base

Given the existing potential of biotechnology to satisfy many requirements related to healthcare, industrial applications and food requirements, Poland holds prime importance in terms of public investments and private funding for the wider implementation of biotechnology-based applications. There has been growing research interest in the country, due to the high-level project initiatives undertaken by universities and centres of excellence.

1. An Overview of the Biotechnology Industry

1.1. The Global Perspective

Table 1: Growth in Biotechnology Market – Global Scenario

Year	Revenues (\$ Million)	R&D Expense (\$ Million)
2004	54,367	19,542
2005	64,213	20,934
2006	76,432	27,782
2007	82,634	31,806

Source: Data from IMS Health Inc and Ernst & Young

The revenue growth for the global biotechnology industry continued to be robust in 2007, developing on the strong gains of 2006. Global trends indicate that despite the profitability and revenue gain observed in recent years, major biotechnology companies continue to depend on a single or a few products to stimulate their growth. Some of the top public drug-based biotech companies like Amgen, Genentech, Genzyme, Gilead Sciences and Biogen Idec continue to generate strong revenues and remain as the industry's key growth drivers. Though a volatile field for investors, the Biotech industry is now putting in significant R&D in 2 areas – biomarkers and personalized medicine in the medical biotechnology segment and biofuels within the environmental biotech segment. Taking into account examples of targeted therapies with Herceptin, Gleevec, Erbitux and others only demonstrate initial steps of how personalized medicine can bring about a transformation from efficacy to efficiency. Similarly, the nascent biofuels industry (first generation biofuels from food crops) has become more active over the last few years with second generation biofuels from non-food feedstocks. 'Innovation' is the key solution for companies to keep pace with the transformation occurring in this sector.

1.2. The European Perspective

Table 2: Growth in Biotechnology Market – European Scenario

Year	Revenues (\$ Million)	R&D Expense (\$ Million)
2004	7,729	4,151
2005	9,781	3,272
2006	11,489	3,631
2007	12,945	4,567

Source: Data from IMS Health Inc and Ernst & Young

Although Europe experienced the biotechnology revolution much later than the United States, several European initiatives have shown interest in the recent past. 2007 saw considerable changes in the European biotechnology industry, with steady progress in revenue growth, of around 13 per cent when compared to 2006, the year Europe recovered after years of downturn. There is immense government support for biotechnology, apparent in a myriad of technology transfer initiatives, driving bioscience research and development. The growing number of biotechnology firms and the raft of research in life sciences is testimony to the fact that Europe's science base is inventive and that the inventors are entrepreneurial.

The basic ingredients for the success of biotechnology – commercializable ideas from academic research laboratories, an entrepreneurial spirit among researchers and access to venture capital, have fuelled the growth of the European biotechnology industry. Further below are highlighted a few signs of maturity of the European biotechnology sector:

The FP is the EU's prime financial tool to aid research and development activities in several scientific areas. The FP7 has been operational since January 2007, and will end in 2013.

In 2007, the European biotechnology industry experienced strong public financing with more initial public offerings (IPOs) than 2006, in addition to strong post-IPO performance. Public investors with a focus on other sectors have diverted their funds to biotechnology, and have also supported the public offerings of relatively new companies. The three major elements of financing - IPOs, venture capital and secondary offerings - played a major role in the 45 per cent increase in the total equity infusion and a grand total of 4.7 billion euros (\$5.9 billion) for the industry.¹ In addition, there was increasing attention from institutional investors in the European and international stock markets, as indicated by the proceeds of around €2 billion from private investments in public equity and other public financing instruments. Venture financing, amounting to an all-time high of €1 billion, helped the growth of the public markets.²

¹ Ernst & Young: Beyond Borders 2007, Global Biotechnology Report

² Ernst & Young: Beyond Borders 2007, Global Biotechnology Report

By the look of the research in biotechnology, it is obvious that the embedded techniques in biotechnology are likely to take several years to produce results in the form of products, services and revenues. With contributions or funds from both the government as well as corporations, Europe's commercial biotechnology sector is witnessing significant growth. The 28 per cent increase in the number of products developed signifies the existing pipeline of around 600 compounds in development by public European biotechnology companies. This is further validated by the presence of a few of the medical products of European biotechnology into the approval process of European and American regulatory bodies. Despite the transfer of some of the pipeline products from the private sector to the public company domain, private firms still have a strong hold. This could pave the way for more successful IPOs or attractive transactions going in the future

In Europe, the medical biotechnology sector has demonstrated significant success with companies successfully phasing out drugs from their development pipeline into the market. The nature of the compounds being researched upon, primarily cover three main therapeutic areas of - oncology, neurodegenerative diseases and infectious diseases. One of the key products to gain approval in 2007 was a small pox vaccine ACAM 2000 by UK-based Acambis.

January 2008, saw Speedel and its partner Novartis obtaining FDA approval for Tekturna HCT, a single-tablet combination of Tekturna and a diuretic hydrochlorothiazide (HCTZ). Tekturna inhibits the enzyme renin, a key regulator of blood pressure.

UK based Prostrakan, received US approval for in September 2008 for its transdermal 5HT3 antagonist. With the trade name of Sancuso, this transdermal patch of granisetron can be used for the prevention of chemotherapy-induced nausea and vomiting in patients receiving moderately/highly emetogenic chemotherapy for up to 5 consecutive days

Belgium drug maker UCB has received approval in Europe for lacosamide, trade name Vimpat, for the adjunctive treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy. UCB hopes to launch lacosamide in Germany and the UK shortly and the FDA has also accepted their filing for a new drug application (NDA).

Swiss speciality pharmaceutical company, Santhera Pharmaceuticals has received the first marketing authorisation for Freidreich's Ataxia therapy, following a conditional approval by Health Canada for Catena (ibedenone). Launch is expected in at the end of October. The product is also under review by health authorities in the EU and Switzerland.

In the cardiovascular category, Germany's Jerini received the European Commission Approval of marketing authorization in July for Firazyr (Icatibant) in the treatment of acute attacks of hereditary angioedema (HAE).

Counting another product in registration, Merck Serono has filed a marketing approval application with the EMEA for its hyperphenylalaninaemia (HPA) drug

sapropterin. As there are currently no approved products for the treatment of HPA, sapropterin could be of potential benefit to tens of thousands of HPA patients.

Industrial Biotechnology is also very promising in Europe with companies like Novozymes and Danisco-Genencor having a strong foothold in the metabolic engineering segment of enzyme development.

With biotechnology gaining momentum as one of the most promising frontier technologies, Europe is making progress in keeping pace with the United States in terms of innovation and investment. The strong science base with centres of excellence in specific technologies is poised to offer new opportunities and sustained growth to this evolving industry in Europe.

2. The Biotechnology Scenario in Poland

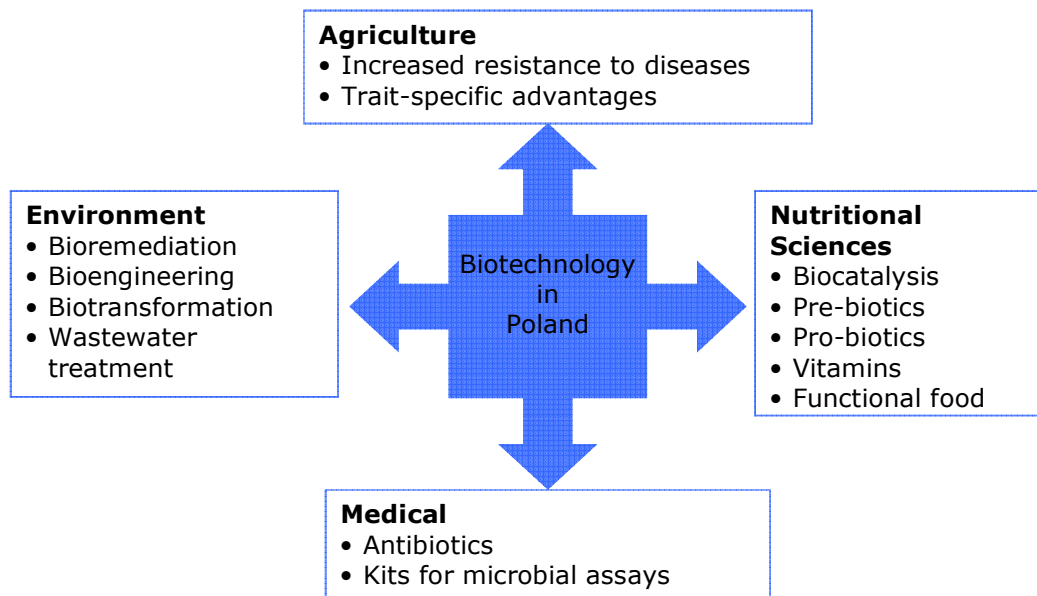


Figure 1: Polish Biotech Segmentation

Source: Frost & Sullivan

Biotechnology in Poland is still in its early stages. Much of the research in the country has been focused on molecular biology and classical biotechnology. The latter centres on the use of microbes in the fermentation industry, industrial applications such as sewage treatment and the production of vaccines and other tools for medical applications. In recent years, biotechnology has been concerned with health, the food industry, agriculture and environmental protection. Most of Poland's biotechnology efforts have been confined to the laboratory. With more than 40 laboratories across the country, the extension of efforts largely depends on regulatory bodies.

Proponents of biotechnology are a part of the Polish Biotechnology Committee, which falls under the European Federation of Biotechnology. The Polish Academy of

Science is also involved in monitoring biotechnology research in the country. Being in the development stage, biotechnology in Poland is characterised by the institutionalisation of research, field trials and legal acts regulating its practical applications. There are also numerous initiatives that foster the dynamic development and integration of academia and industry. The development of biotechnology in Poland is highly diversified, depending on its area of application. As innovation gathers momentum, technology or knowledge cannot remain as a part of a single company. Corporates are stimulated to make complementary products or offer complementary services; therefore, innovation encourages companies to cooperate with each other or with research and development entities. These efforts are taking Polish biotechnology to greater heights.

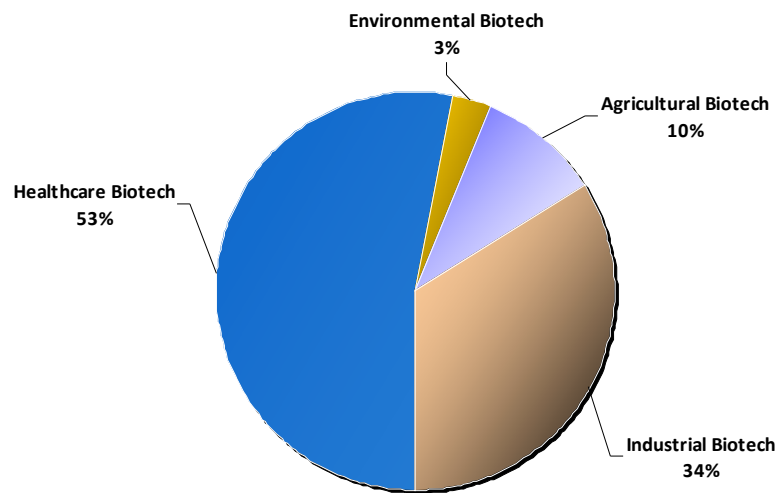


Figure 2: Revenue by Market Segments of Biotechnology in Poland

Source: Frost & Sullivan Analysis, 2008

The most significant source of funding in the biotechnology segment is the biotechnology section of the State Committee for Scientific Research, which provides grants for conducting R&D activities. On average, the grant varies from \$50,000 to \$100,000. For receiving a grant, the research work has to be published. There is tough competition among the grant seekers with only 35 per cent of those that apply being successful. However, government funding for biotechnology has been increasing at an annual rate of 20 per cent and the availability of private funds is expected to give a boost to this segment during the period 2008-2010.

Imports constitute a significant portion of biotech products in Poland. The largest importers are pharmaceutical companies such as Novartis, Bayer, or Monsanto and other medical or scientific diagnostic laboratories that do not have production facilities in Poland.

2.1. Biotechnology in Polish Agriculture

The food industry is one of the key sectors of the Polish economy. Its share in the GDP was around 6 per cent (2007), and the gross added value it generated was around €6 billion.³ Agrobiotechnology, constituting the strengths of modern biotechnology, is becoming competitive or even alternative to the existing contemporary forms of agriculture. Experts opine that biotechnology is the solution to the challenge concerning the need for increased food productivity. Growing concerns regarding alleviating hunger, in addition to producing crops with better resistance and increased yield, disease resistant animals and trait-specific varieties is further enabling the incorporation of biotechnology into common agricultural practices. Areas of interest in developing transgenic animals include better and higher milk production, better growth rate, increased meat production and improved resistance.

A sizeable part of the global agro-biotechnological industrial sector is thriving on the production of genetically modified organisms (GMOs). The genetic engineering of crops contributes to more profitable farming by extracting genes bearing a specific, hereditary trait from one organism and artificially inserting them into another organism. The aim of genetic modification is to make crops resistant to insects, herbicides, drought and so on. In food, GMOs can make products more nutritious, improve their taste and increase their shelf life.

In May 2006, Poland signed a ban on the sale and registration of genetically modified seeds and joined Greece and Austria as the third country with a complete GMO-free status. Currently, more than 300 farms in different areas of Poland have been stated as GMO free-zones.

Reports from Polish media in 2008 suggest that the Polish government may ease its stance over GMO production in the country. They intend to launch public consultations on the draft of new legislation prepared by the Ministry of Environment that would take account of the European Union's (EU) regulations obliging member countries to introduce GMO and yet at the same time respect the anxieties of those very many Poles who argue that genetically modified food is dangerous.

On the research front in Poland, there have been some interesting findings with respect to increasing the efficiency of cereals post-harvesting.

- Molecular studies at the Warsaw University have highlighted the relationship between moisture content and the increase in harvesting efficiency.
- In another study at the Maria Curie-Skłodowska University (UMCS), Lublin, researchers have examined the possibility of genetically modifying plants to allow nitrogen absorption from the atmosphere, so as to reduce the usage of nitrogen fertilisers.
- Transgenic cucumber has been the area of focus for researchers at the Warsaw Agricultural University. The team developed sweet cucumber and cucumber with the feature of parthenocarpy – the ability to produce fruits without pollination.

³ The European Commission

- The growing of transgenic crops in Poland in 2007 marked a new beginning in the country's agriculture. GMO field trials in Poland have looked at insect resistance, herbicide tolerance and modified composition.
- The Institute of Soil Science and Plant Cultivation (IUNG), Pulawy, contributes to increasing farm productivity and efficiency as well as to improving quality of agricultural products by providing farmers with agrotechnical recommendations and crop management technologies for cereals, legumes, tobacco and hops.

On a global scale, Poland holds a key position in terms of the production of several crops such as potatoes, rye, apples, strawberries and carrots, and is one of the leading producers of meat, milk and eggs. Biotechnology can be used to improve the performance of animals through better nutrition, enhanced production potential and improved health status. Researchers and corporate experts claim that with the wider adoption of the technology, aspects in addition to the designing of regulatory systems that are rigorous will significantly increase productivity, reduce the environmental footprint of agriculture and create more sustainable agriculture in the future.

To implement biotechnology as a routine tool for agricultural practices, Poland could leverage the existing resource potential in genetic mutation, molecular analysis and genotyping. The main role of biotech in creating transgenic animals and breeding them would be primarily related to obtaining human recombinant proteins for therapeutic purposes. Moreover, in continuum with the existing research, organs from genetically-engineered animals (such as pigs) could be used for transplantation.

2.2. Nutritional Sciences Biotechnology

Food science and biotechnology have led to substantial innovation in the production of healthier food, in addition to increasing profits for the manufacturers. Nutritional scientists and biologists are focused on understanding the effects of the gene expression of compounds in food, so as to study the ensuing metabolic pathways. There has been much interest in studying the relationship between genes and several constituents of food, namely, carbohydrates and fats, to study the regulation of enzymes in disease onset and progression. There is a significant initiative to establish industry-wide standards for the implementation of biotechnology for the benefits of the food industry.

In recent years, there has been a linkage of nutritional sciences to biotechnology in Poland. Research initiatives have been centred on determining the profiles of the potential biological activity of food proteins and the subsequent classification of these into groups or families. Functional food or food and food components that provide a health benefit beyond basic nutrition have been an area of interest for Polish consumers. These foods are becoming increasingly popular with the mineral fortification of foods and beverages.

- Probiotics is drawing public attention with the advertising campaigns staged by companies like Danone, for products such as Activia.

- Nutraceuticals sales in Poland reached \$200 million, positioning it in second place within Eastern Europe. Most of its revenues were due to the prominent trends in supplements and other across the globe.
- Nutrigenomics to understand the complexity between diet and genetic make-up has exploded since 2000. Researchers at the Jagiellonian University Medical College, Cracow, are working extensively to establish the relationship between nutrition-genes, gene-disease prevention, nutrition-stress.
- ZPOW Pektowin, Jaslo, is engaged in the production of enzyme preparations for food industry. At present, the company produces on a large scale 3 groups of enzymes - amylases (starch hydrolysis), pectinases (hydrolysing pectin substances) and proteases (protein hydrolysis).
- PURAC creates a variety of possibilities in mineral fortification of food for successful product innovations in a broad range of food applications.
- According to Professor Krzysztof Kyrgier from the Food Technology Department of Warsaw Agricultural University, "On Polish market more than 300 functional - or rather "functional-like" products are available. Among them there are about 40 dairy products, 70 juices and beverages, 60 confectionary, 60 cereals and 70 soybean products. The most widely used healthy ingredients are: vitamin C (123 products), soybean protein (77 products), fiber (59), vitamin A (54), vitamin E (50), folic acid (45), calcium (43) and beta-glucan (34)."
- Extensive research is also occurring in the probiotic arena. To cite some examples - role of *Lactobacillus rhamnosus* strains in treatment of acute infectious diarrhea in infants and children (Department of Pediatrics, St. Hedwig of Silesia Hospital, Trzebnica); influence of probiotics on the pouch mucosa inflammation in patients with ulcerative colitis (Poznan University of Medical Sciences); effect of *Lactobacillus casei* and *casei/paracasei* strains on atopic dermatitis (The Children's Memorial Health Institute, Warsaw).

Driven by the need to keep pace with other countries, Poland has established a government-backed group that will develop criteria relating to the classification of a range of nutrients under either food or medicine law. This is expected to improve consumer safety and facilitate market entry and functioning for manufacturers and distributors. With the increasing awareness and the insights gained from genetic research, current innovations in functional foods provide opportunities to prevent disease and improve quality of life. Research organisations in Poland are looking into fields such as nutrigenomics, proteomics, bioinformatics and metabolomics to allow the rapid development of functional foods.

2.3. Environmental Biotechnology

As many first-wave biotechnological products have become commodities, some of the promising applications are still shaping up. Environmental biotechnology is not a new field; composting, sewage treatment and wastewater treatment have been familiar approaches even before the term biotechnology came into being. However, the recent success of molecular biology, ecology and environmental engineering has opened up new avenues to modify the existing biological make up of organisms to efficiently degrade high volumes of waste products. Although the concept of environmental biotechnology has been extrapolated, its potential benefits are far from fully realised. Bioremediation has been one of the most exploited approaches within the broad spectrum of environmental biotechnology.

Poland has been instrumental in attempting to allow the wider adoption of environmental engineering for commercial applications such as sewage and water treatment and the bioremediation of oil-contaminated soil.

- The interest in environmental biotechnology in the country is clearly indicated by the efforts of the Environmental Biotechnology Department (EBD), a leading research centre in Poland, with research centred on environmental engineering and biotechnological remediation.
- The Institute for Ecology of Industrial Areas (IETU), Katowice, is a research and development unit acting under the Polish Ministry of Environment. Building on their knowledge and expertise, the institute has got wide experience in international co-operation due to its participation in projects realised for many foreign organisations like World Health Organisation, U.S. Environmental Protection Agency, U.S. Department of Energy, Economic Commission for Europe and the European Union.
- On the corporate side, Hantpol, Warsaw, has developed a wide range of products and services - from environmental monitoring equipment to introducing bugs and biotechnology to wastewater systems in industrial practice, including sewage with high petrochemical product concentration. The company's strong technical expertise is positively impacting this growing market.
- With dwindling non-renewable sources of fuel, biofuels extracted from crops such as rapeseed, sugar and maize have been used to power vehicles. In 2006, Poland produced close to 75,000 tonnes of biodiesel. Many farms in the country have shown an optimism towards culturing crops like rapeseed for biodiesel.
- bioArcus Ltd., Warsaw, is a pioneer in application of microorganism cultures, enzymes, as well as implementation of anti-odor techniques and products. The company renders service in the field of environmental protection conducting the following activities: anti-odor installations including indoor and outdoor industrial and municipal osmogenic barriers. Applications of biofilters and chemical filters for malodor inactivation.

- Based on biotechnology, Bio-Ecology Services, Warsaw, was formed in 1992 and has successfully implemented waste-water treatment, modernized sewage treatment plants, rehabilitation of contaminated sites and several other environmental projects.

Wastewater treatment in Poland, driven by the expanding industrial and manufacturing sector, along with EU directives that regulate this market, is estimated to reach \$639 million in 2013, considering that the market earned revenues of \$344 million in 2006. Keeping abreast with global developments, Poland also has new biodiesel plants under construction, with plans for building ethanol plants, and ideas of cereals and sugar beet as main raw materials. The country is also conducting studies on increasing biogas utilisation in transport.

With the underlying ecological advantages of this technology, and economic issues in addition to unmet environmental needs, there are numerous opportunities for companies that can offer the required technologies at competitive prices.

2.4. Biotechnology in the Field of Pharmaceuticals and Medicine

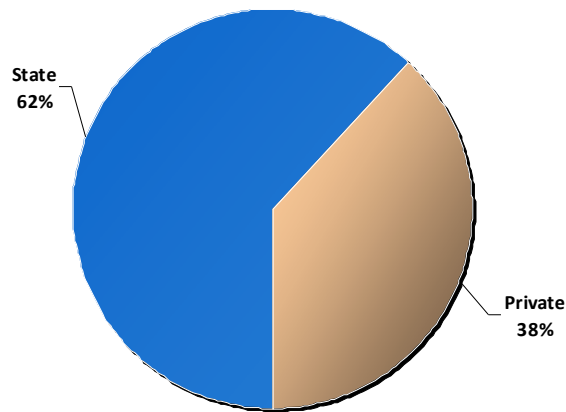


Figure 3: Contributions of State and Private in Total Healthcare Funding in Poland

Source: Frost & Sullivan Analysis, 2008

The accession of Poland to the EU led to the growth of the Polish healthcare industry, with the country gaining access to the European market. Additionally, Poland's standardisation of regulations with the EU has enabled free trade with other member nations, increasing the exchange of pharmaceutical products. Much of the increase in the investment for the healthcare industry has been due to the government's support

through tax deductions and favourable policies for foreign investors. In the recent past, a large number of prescribed drugs have been converted to over-the-counter (OTC) drugs, pushing the OTC drugs to greater heights. In addition to benefiting consumers in terms of accessibility, the rise in revenues and the competition in the market are driving manufacturers to develop innovative drugs. This is encouraging foreign investment in Poland.

Incidentally, being a part of the 'new' EU countries, the pharmaceutical and biotechnology markets are expanding in Poland, though they are in the nascent stage at present. The pharmaceutical market in the 'new' EU countries, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia, represents around 8 per cent of the EU 15 market,⁴ Poland has been a major contributor with more than 45 per cent of the accession countries' total pharmaceutical market share. Market trends indicate that the pharmaceutical market has been growing fast and the best numbers were observed for the period 1998-2001 with an average rate of 10 per cent per annum. Poland has been primarily involved in the production of generic drugs owing to insufficient funds, low purchasing power and lengthy patent policies. The generic drug market was greatly encouraged by the limited availability of originator medicines and the three-year exclusivity period. With domestically produced drugs being cheaper than imported drugs, there was an increase in revenues in addition to the increase in export.

The biotechnology segment (pertaining to healthcare) has been experiencing several changes with regard to the legislations that govern the acceptance of products derived from this technology. The Industry Property Law clearly defines the rules of accepting biotechnology products. In an attempt to emphasise the significance of healthcare biotechnology, a major government initiative was made - the Warsaw Scientific Consortium agreement, according to which a technology park in Warsaw will be set up to conduct research in medicine and biotechnology. The Park is expected to be realized in the years 2007-2015. Phase I of the Project will be completed by the year 2010. It consists of creating a Technology Incubator and a Research Centre financed by public funds.

On the clinical trials front, there have been some recent developments in Poland. Over the last five years, CROs (Contract Research Organization) have grown in number in Poland; at present, there are more than 60 active CROs in the Polish market, carrying out preclinical and clinical development work. With the Central Register of Clinical Trials taking steps to streamline and simplify the registration process, Poland's clinical trial market is expected to grow at 10 to 12 per cent in 2008.

Drug manufacturers are looking at centralised data and information management to prevent errors and to comply with the large number of strict regulatory requirements.

- Polish pharmaceutical manufacturer, Polpharma SA, Starogard Gdanski, has adopted a technology platform to improve quality processes, which should speed up decision-making, make trend analysis easier and prove to be cost-effective

⁴ European Federation of Biotechnology

- The new Web-based tracking software, TrackWise, from Sparta Systems, demonstrates the company's dedication towards the continuous improvement in terms of quality and effectiveness. This initiative by one of the leading Polish drug manufacturers highlights the significant efforts of the market participants to keep pace with the other EU markets
- Some enterprises operate the entire production cycle from development to production to sale and the largest enterprises in Poland include Polfa Tarchomin, Polpharma and Jelfa.
- The 4 companies in Poland that together hold 22.6% of the total Polish pharmacy market share include Glaxo Smith Kline, Novartis, Servier and Polpharma.
- Herbapol Inc. specialises in the manufacture of pharmaceutical products from herbal raw materials. For over 50 years the company has been a large manufacturer of herbal preparations in Poland.
- In pace with global developments, Medical University, Institute of Cardiology, and Maria Skłodowska-Curie Memorial Institute at Warsaw are conducting research on angiogenic and antiangiogenic gene therapy, a new therapeutic approach to the treatment of cardiovascular and cancer patients.
- Currently, the Jagiellonian University Medical College, Cracow is actively pursuing research in the emerging therapeutic area of stem cells. Though Poland has a restrictive policy on embryonic stem cell research, stem cell research is permitted on a defined number of previously established embryonic stem cell lines. The Polish Stem Cell Bank is an independent umbilical cord blood bank in Poland for the supply of cord blood. Moreover, the Stem Cell Excellence Centre was established to integrate the Polish clinical centres working in the field of stem cell progenitors with the European research area through networking, exchange and twinning.

In Poland, therapeutic biotechnological products have a significant share and can be broadly classified into two basic groups. The first generation drugs include hormones and enzymes (like recombinant insulin), erythropoietin, cytokines and vaccines. However, the market for the first generation biotechnological drugs is becoming more competitive with a risk of appearance of alternatives. The second generation biotechnological drugs could include monoclonal antibodies and therapies based on genes, proteins and metabolites that have the biggest market capability. Technology progress in these areas could offer best benefits.

Trends in the country indicate an expansion of the private healthcare sector and an increase in investments by healthcare organizations. There appears to be emphasis and bigger investments on major health initiatives and programs in the areas of oncology and cardiology.

3. Technology Adoption Factors for Polish Biotechnology

By nature biotechnology takes several years to produce tangible results from its R&D, in the form of products, services and revenues. In Poland, biotechnology is backed by several factors that drive its implementation. The following segment outlines some of the major drivers, restraints and challenges that have a direct effect on the Polish biotechnology sector.

3.1. Drivers and Restraints

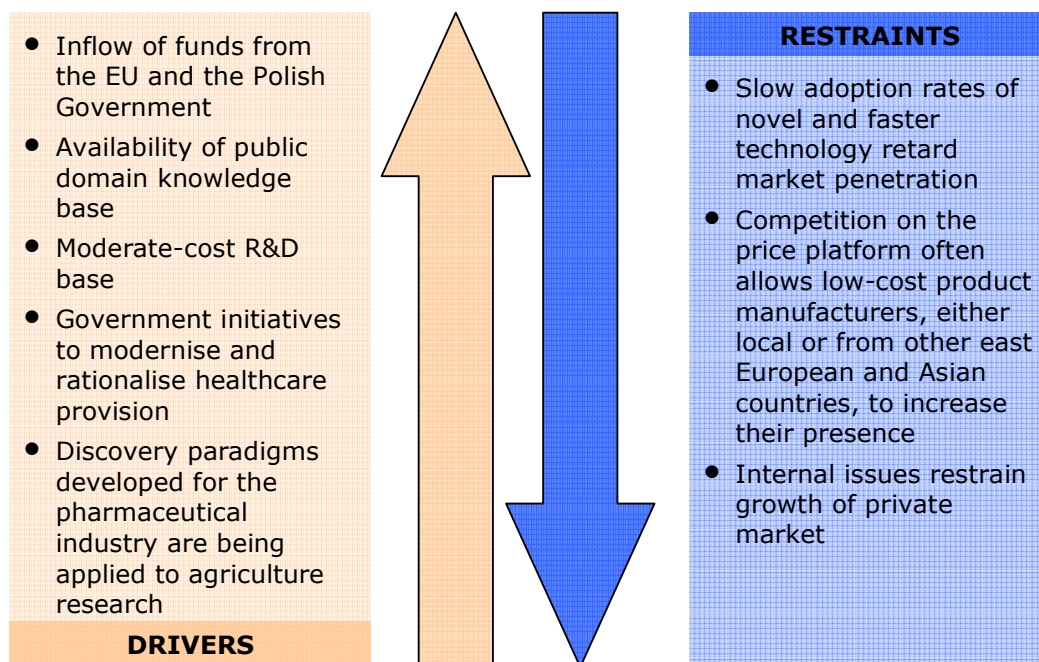


Figure 4: Drivers and Restraints for Biotechnology in Poland

Source: Frost & Sullivan Analysis

3.2. Industry Challenges

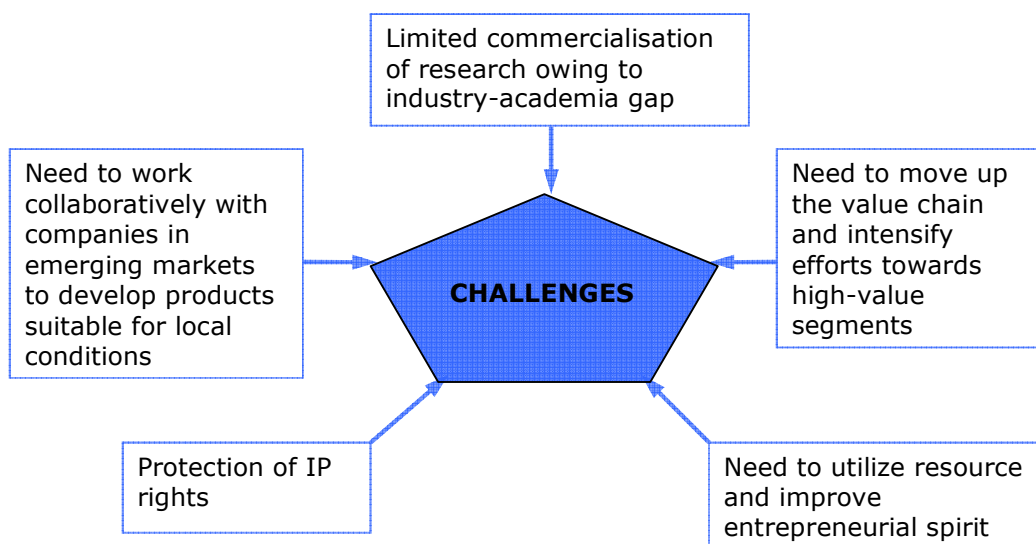


Figure 5: Challenges Surrounding Biotechnology in Poland

Source: Frost & Sullivan Analysis

3.3. Education and Resources in Poland

Young educated people are the powerhouse of the country. Poland exhibits a high level of education in lifesciences and particularly in the biotechnology sector. About 30 universities and institutes across the country offer education in biotechnology with about 8000 students passing out annually. Further, the quality of education is controlled by two institutions: The State Accreditation Board and The University Accreditation Board on the basis of standards introduced for this field of study.

Table 3: List of academies and organizational units with a biotechnology facility

Name of university	Students
Warsaw University Faculty of Biology	363
Copernicus University, Torun Faculty of Biology and Sciences about the Earth	179
Collegium Medicum, Bydgoszcz Medical Department	176
Wroclaw University Faculty of Biotechnology	282

<i>Maria Curie-Skłodowska University, Lublin</i> Faculty of Biology and Sciences about the Earth	183
<i>Jagiellonian University, Cracow</i> Faculty of Biochemistry, Biophysics and Biotechnology	295
<i>Gdansk University</i> Intercollegiate Faculty of Biotechnology in Gdansk University and Medical Academy in Gdansk	182
<i>The University of Silesia, Katowice</i> Faculty of Biology and Environmental Protection	298
<i>University of Warmia and Mazury, Olsztyn</i> Faculty of Biology	316
<i>Rzeszow University</i> Faculty of Biotechnology	-
<i>Adam Mickiewicz University, Poznan</i> Faculty of Biology	213
<i>Szczecin University</i> Faculty of Natural Sciences	256
<i>Wroclaw Technical University</i> Faculty of Chemistry	933
<i>Lodz Technical University</i> Faculty of Biotechnology and Food	791
<i>Warsaw Technical University</i> Biotechnology Centre	472
<i>Gdansk Technical University</i> Faculty of Chemistry	566
<i>Agricultural Academy, Lublin</i> Faculty of Food and Biotechnology	227
<i>University of Natural Sciences, Wroclaw</i> Faculty of Food	296
<i>J.J. Sniadeckich University of Technology and Natural Sciences, Bydgoszcz</i> Faculty of Agriculture	167
<i>August Cieszkowski Agricultural Academy, Poznan</i> Faculty of Agriculture	404
<i>Hugo Kollataj Agriculture Academy, Cracow</i> Biotechnology Study	273
<i>Agriculture Academy in Szczecin</i> Faculty of Biotechnology and Animal Breeding	300
<i>Warsaw University of Life Sciences</i> Biotechnology Study	187

<i>Jan Dlugosz Educational Academy in Czestochowa</i> Faculty of Mathematics and Natural Sciences	187
<i>Silesian Medical Academy, Katowice</i>	111
<i>Karol Marcinkowski Medical University, Poznan</i>	30

Source: Polish Ministry of Science and Education

3.4. Trends In The Polish Biotechnology Sector

With biotechnology gaining priority in recent years, Poland has looked at several opportunities to widen its outlook towards this emerging application-oriented field. Considering the immense potential of the country in agrobiotechnology, industrial biotechnology and biotechnology in healthcare, venture capitalists are competing to establish their footprint in Poland. The research and scientific expertise of scientists at the country's leading universities is one of the reasons behind the growth of the biotechnology sector in Poland.

Table 4: Large Foreign Investors in the Polish Biotechnology Sector

Name of Institution	Country of Origin	Role
Baxter Healthcare Corporation	The Netherlands	
Biofarma	France	
Egis Pharmaceuticals Ltd	Hungary	
Glaxo SmithKline	The United Kingdom	Manufacture of pharmaceuticals, and medicinal chemicals
Hexal AG	Germany	
ICN Switzerland AG	Switzerland	
Fatro SpA	Italy	
IVAX Corporation	The United States	
Eli Lilly Nederland	The Netherlands	
East Springs International NV	France	Human health activities; manufacture of beverages
Bayer AG	Germany	Manufacture of chemicals and chemical products

Source: PALiZ

Table 5: Biotechnology Research Projects Currently Being Conducted

Project Type	Institution	Planned End Date
Ageing research for cancer prevention and therapy	Nencki Institute of Experimental Biology - Polish Academy of Sciences	30 Sep 2008
Preparation and identification of new HIV reverse transcriptase inhibitors targeted against HIV strains resistant to anti-HIV/AIDS drugs	Institute of Biochemistry and Biophysics – Polish Academy of Sciences	31 Dec 2009
Development of novel multitarget compounds and approaches to interact with specific receptors and treat pain in patients with advanced stages of cancer	Medical Research Centre - Polish Academy of Sciences Neuropeptide Laboratory of Medical Research	30 Nov 2009
Potential of diagnostic markers as well as biomarkers of exposure to study how diet and hereditary factors can influence environmental cancer risk, with the ultimate goal of reducing the cancer burden in Europe	Nofer Institute of Occupational Medicine	30 Apr 2010
Combined study of nanostructured magnetic materials	Bialystok University	28 Feb 2009
Create a system of stable thermo-responsive capsules for the controlled release of chemicals	Institute of Catalysis and Surface Chemistry - Polish Academy of Sciences	30 Apr 2009
Analysis of DNA repair mechanisms leading to etoposide-induced MLL rearrangements and therapy-related leukaemia	Medical University of Warsaw	13 Aug 2009
Research on the structural studies of membrane proteases	International Institute of Molecular and Cell Biology Laboratory of Structural Biology MPG/PAN	31 Oct 2010
Research on new chemical and biochemical sensors for the analysis of food, environmental and medical samples	Institute of Animal Reproduction and Food Research - Polish Academy of Sciences	30 Sep 2009
Research on the functional analysis of new acute-phase proteins	Jagiellonian University	31 Oct 2010
Research on the mechanisms of the rh BMP-2 mediated osteogenesis of human bone marrow stromal cells.	Jagiellonian University	31 Jan 2009

Source: Cordis Europa and Frost & Sullivan Analysis

3.5. Standards and Regulations in Polish Biotechnology

Biotechnology in Poland has been segmented into four broad heads each represented by specific colours.

Agrobiotechnology, represented by green, signifies agriculture and other constituents of the food industry. Red represents medicine, pharmacy and the diagnostics derived from biotechnology. Industrial biotechnology, one of the widely exploited applications of biotechnology, is indicated by white. With legislation and socio-economic effects being an integral part of how biotechnology is used for various applications, violet has been adopted to represent this important aspect. Proponents of the technology claim that much of the slow progress regarding the adoption of biotechnology is attributable to the legal and social aspects imposed by the EU and further embraced by the Polish Government.

Poland's accession to the EU has necessitated several changes in the regulatory framework pertaining to biotechnology. One of the areas where there have been changes is agriculture. The food industry, one of the key sectors of the country's economy, has gained access to a market of around 400 million consumers as a result of joining the EU. At present, Poland follows most of the EU regulations with respect to GM products. Regarding biodiversity and biosafety, the country follows the Cartagena Protocol. Being a signatory of this protocol, there are basics for the import, export and handling of GMOs which may have adverse effects on the conservation and sustainable use of biological diversity and human, animal and environmental health.

The application of biotechnology greatly depends on intellectual property rights, legal norms that include both domestic and international regulations and the consumers. At present, the negativity centered on biotechnology is impeding the introduction of biotech products into the Polish market. In 2006, 300 farms in Poland were declared GMO-free. Recently, the Ministry for the Environment prepared a draft bill on GMOs, allowing the creation of GMO-free zones and the introduction of the close monitoring of GM plantations. Amid these stringent rules, there is some hope for biotechnology in Poland, as indicated by the country's farmers and feed companies requesting a law that delays the introduction of rules banning the use of GM animal feed. Further, in June 2008, the Environment Ministry introduced a new bill on GMO, which does not include a formal ban on the cultivation of transgenic plants, but provides tools that allow the practical exclusion of GMOs.

There has been much hostility from the public concerning the adoption of biotechnology. However, EU law forbids member states to overtly ban the cultivation of transgenic food. Existing Polish regulations protect agriculture from GMOs, and are in conflict with the European Commission. With better awareness of the labelling and coexistence strategy, there will be wider acceptance of this versatile technology in Poland. Most of the further deployment of biotechnology greatly relies on legal developments, including intellectual property rights and the social aspects of biotechnology, including public perception.

On the healthcare front, biotechnology is taking its place with new laws ushering in sunny prospects for foreign investors. With the idea of modernising and rationalising

healthcare provisions, the Polish Government has implemented several programmes for providing health education and disease prevention. More autonomy to healthcare institutions for standardisation and supervision is allowing the further incorporation of several biotechnology techniques for healthcare applications. Clinical trials are one area where Poland holds potential in attracting foreign companies. However, the cumbersome process of registering for a trial with the Central Register of Clinical Trials - primarily the long time frame for the process - is one of greatest deterrents to running clinical trials in Poland. The recent initiatives on the part of CEBK, waiving the previous requirement for the notarial authentication of documents such as GMP certificates, each time a firm applied for permission to conduct a trial, will place Poland in a prime position to capture new business. It is encouraging to see that the country's Health Ministry is working on a new legislative framework for clinical trials, under the auspices of its Clinical Trials Act and the Ordinance on the Template of Application to Commence a Clinical Trial on a Medicinal Product and the Application for the Opinion of the Bioethics Committee on a Clinical Trial of a Medicinal Product. This would further ensure the continuing development of the market and enable an increasing number of trials in Poland.

4. Prospects for Biotechnology in Poland

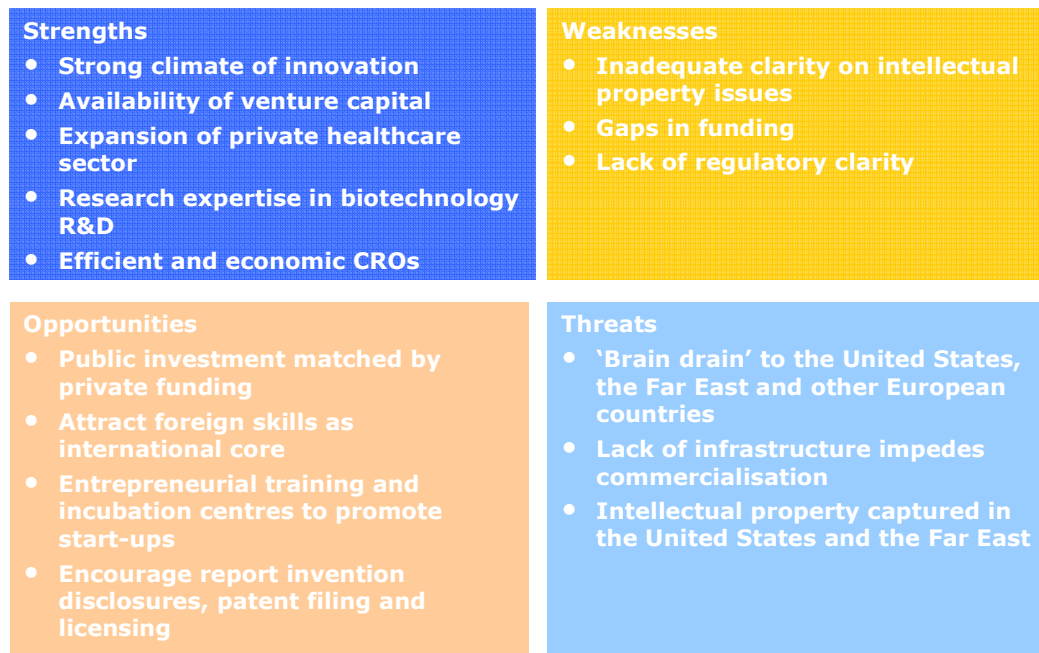


Figure 6: SWOT Matrix for Poland Biotechnology

Source: Frost & Sullivan Analysis

The biotechnology sector in Poland is still in the early stages of development. However, the recent efforts towards the wider adoption of the technology are poised to change the present landscape of biotechnology in Poland.

Poland has a strong science base in lifesciences. It would be ideal to facilitate the entry of more researchers from lifesciences into biotechnology research. This could be possible by increasing investment in this area and developing centres of excellence

With a strong climate of innovation and support from the Polish government towards different kinds of biotechnology research, there is more chance for a cross-match between the sub disciplines of biotechnology research. In effect, researchers within agricultural biotechnology space can work on pathway and metabolic engineering to make plant 'biofactories' which can serve as the source for biofuels or green plastics.

US and Europe have a strong presence in the field of biotechnology and it would be beneficial for Poland to have an international agenda to bridge the gap and gain visibility in this arena. This can be made possible by increasing the international inward investment by building relationship with foreign governments and urging them to initiate competitive grants and establish companies in Poland in the form of technology development centres.

In order to make significant contribution to development in medical biotechnology, Poland must also focus on the applied aspects of research. This would in turn attract investment from venture capitalist community and major pharmaceutical and healthcare companies. The current challenge is that biotechnology is an unknown business model and return on investment. Being a multi-disciplinary field, promoting high degree of collaboration between the researchers could help translate medical biotechnology research into clinical interventions.

Given the strong research background among Polish biotechnology researchers, a certain amount of exposure to the international business environments could accelerate the progress and open up doors for the long desired industry collaboration and foreign investment.

Poland should encourage the research community to file their inventions and open up to the idea of technology transfer. Legislative changes encouraging patent filing and licensing will protect biotechnology inventions and thereby initiate technological expansion.

About Frost & Sullivan

Frost & Sullivan, a global growth consulting company, has been partnering with clients to support the development of innovative strategies for more than 40 years. The company's industry expertise integrates growth consulting, growth partnership services and corporate management training to identify and develop opportunities. Frost & Sullivan serves an extensive clientele that includes Global 1000 companies, emerging companies and the investment community by providing comprehensive industry coverage that reflects a unique global perspective and combines ongoing analysis of markets, technologies, econometrics and demographics. For more information, visit <http://www.frost.com>.

About PAIIZ

The Polish information and Foreign Investment Agency (PAIIZ) has been serving investors for 15 years. Its mission is to increase Foreign Direct Investment (FDI) by encouraging international companies to invest in Poland. It guides investors through all the necessary administrative and legal procedures along the way to setting up their business in Poland.

PAIIZ offers investors: quick access to comprehensive information about the economic and legal environment, assistance in finding appropriate partners and investment locations and support at every phase of the investment process.

Another one of PAIIZ's roles is the creation of positive image of Poland and the promotion of Polish products and services abroad by organizing conferences, visits for foreign journalists and trade missions. PAIIZ also promotes Poland's regions. It has established a network of Regional Investor Assistance Centres throughout Poland. Their goal is to improve the quality of regional services for investors and to provide access to the most up-to-date information, such as the latest investment offers and regional microeconomic data. These specialized offices are staffed by PAIIZ trained employees and financed from local funds.

In order to help support and encourage FDI, the Polish government has passed many new resolutions this year. 90 billion Euro of EU funds has been allocated to Poland for the years 2007-2013. There has never been a better time to invest in Poland.

Come and see for yourselves. We are here to help you!

Contact us to learn more about how your company can profit from the unique business potential of Poland.

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