

Pharmaceutical sector in Poland



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Pharmaceutical industry

Sector profile 2014

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1. INTRODUCTION

The objective of this report is to analyze the latest trends occurring in the pharmaceutical industry and to present the attractiveness of the industry to potential investors. This report might be used as a study guide on pharmaceutical sector in Poland covering the topics of the structure of production, labour market analysis and indicates legal regulations and a macroeconomic environment of the sector. The report underlines, that Poland possesses both the scientific and technical facilities as well as the personnel required for the development of the sector's potential.

1.1. Global perspective

Pharmaceutical industry has shown a particular resistance to recent economic turmoil, compared to traditional manufacturing industries. Expenditure on pharmaceuticals, as a means of life-saving are not subject to clear limits, even in the event of an economic downturn.

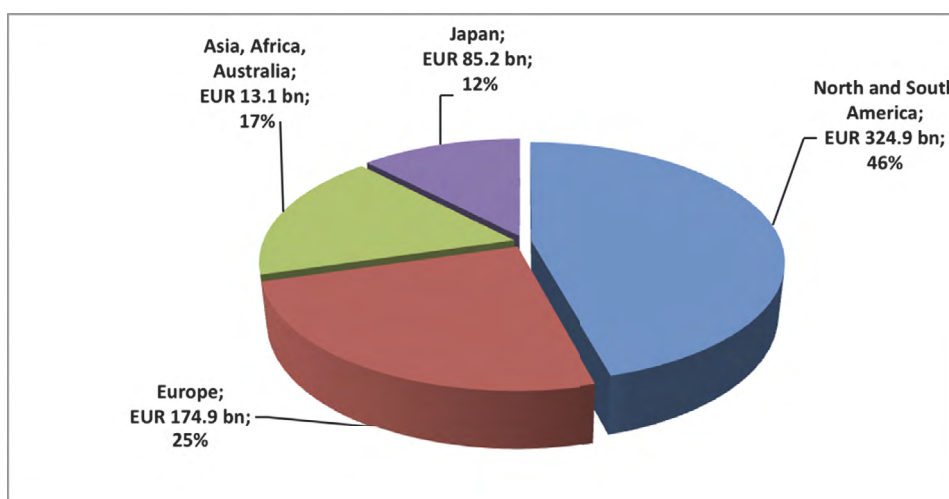
The total value of pharmaceutical industry reaches EUR 780 billion (PLN 3.3 trillion) in 2013. Through 2018 the total value of the sector might increase by 30% and reach the level of EUR 1 trillion (PLN 4.19 trillion)¹. Projected increase of the sector is to result mainly from the following factors:

- increasing life expectancy, population growth and development of new, more innovative kinds of medicines².
- It is predicted that during the following 5 years about 200 new medicines are to be introduced into the market³.
- Nowadays, the vast majority of pharmaceutical manufacturers is based in the Americas, Europe and Japan – **85% of the world pharmaceutical production** comes from those regions⁴.

The geographic structure of sales on the global pharmaceutical market is as follows⁵:

- North and South America EUR 324.9 billion (PLN 1.4 trillion),
- **Europe EUR 174.9 billion (PLN 732.3 billion),**
- Asia, Africa, Australia EUR 131.1 billion (PLN 549.3 billion),
- Japan – EUR 85.2 billion (PLN 357 billion).

Figure 1. The value of the pharmaceutical sector production in global terms in 2012 (in EUR bn).



Source: *EMIS Intelligence*

¹ Global Outlook for Medicines Through 2018, IMS Institute, 2014.

² Ibidem.

³ Ibidem.

⁴ According to the WHO

⁵ EMIS Intelligence, 2014.

- In addition, a growth of expenditures on research and development activity on the part of the pharmaceutical companies is forecast.

The highest revenues were obtained in the segment of oncological drugs, analgesic drugs, antihypertensive drugs, drugs used in diabetes, respiratory drugs and drugs used in psychiatry⁶.

- Sales growth is expected both in highly developed countries such as the United States and the UK, but also in the emerging markets – Brazil, Russia, India and China⁷.
- Among the developing countries, the largest increases are expected in China and India where the sale of drugs is expected to double by 2018⁸.

1.2. European Union

The pharmaceutical industry in the EU is one of its priorities. This sector is one of the best developed high-tech industries and is seen as one of the factors in boosting the EU economy and reconstruction of its global competitiveness.

- In 2013 the value of the sector's production (together with biotechnology and life science) amounted to EUR, 217.5 billion (PLN 911.3 billion) and increased by 2.1% (EUR 4.5 billion, PLN 18.8 billion) as compared to 2012⁹.
- The yearly average growth of the sold production of pharmaceuticals in the EU amounted to 2.5% in the years 2006-2013, but yearly increase in labour productivity was 3.6% in the years 2006-2011.
- Pharmaceutical industry in the EU is strongly consolidated. It is dominated particularly by capital-intensive corporations which has consolidated the industry.
- The EU is also one of the most important net exporters of pharmaceutical products in the world. In 2013, the value of exports amounted to EUR 107.4 billion (PLN 450 billion)¹⁰.
- In 2013, 690 thousand people were employed in the pharmaceutical sector in the EU, including 115 thousand in the research and development activities(R&D).
- Importantly, from the point of view of the sector development, it is important to note that in 2013 the value of research and development (R&D) expenditures in the pharmaceutical sector amounted to EUR 30.6 billion (PLN 128.2 billion), which accounted for 13.8% of the production value of the entire sector.

Pharmaceutical corporations in the EU will soon have to face the markets of emerging countries like China, India and Brazil which are recording the most dynamic growth in the sector. Therefore, according to the program *Horizon 2020* and EU funding 2014-2020, numerous initiatives are proposed in order to increase the competitiveness of the sector in the EU¹¹.

⁶ Ibidem.

⁷ Global Outlook for Medicines Through 2018, IMS Institute, 2014 r.

⁸ Ibidem

⁹ The Pharmaceutical Industry in Figures 2014, EFPIA, 2014.

¹⁰ Ibidem.

¹¹ Ibidem.

2. PHARMACEUTICAL SECTOR IN POLAND

Poland is a great place for production of medicines. We have got a strong starting point, because Poland is already a superpower in this regard. We have got well-trained employees, which we take advantage of and communicate the others¹².

Alan Knox, the President of Sandoz Polska

Pharmaceutical sector in Poland as one of with the longest tradition has been through radical changes throughout the last 25 years. There has been a transition from state-owned companies into private ones and new regulations have been introduced. The administrative system of public health care management has changed and the market shares have been consolidated. Moreover, the importance of foreign pharmaceutical companies as investors on the Polish market has increased.

A summary of the Polish pharmaceutical market:

- **The value of the Polish market is estimated at EUR 6 billion (PLN 25.1 billion)**
- In the years 2006-2013 the value of the Polish pharmaceutical market increased by nearly 40% and it is projected to grow to EUR 7 billion (PLN 29.2 billion) by 2018¹³.
- In 2013 the **value of the Polish pharmaceutical sector production** amounted to EUR 2.72 billion (PLN 11.4 billion), which puts the Polish pharmaceutical and biotechnological industry at the **9th place in the European Union**.
- The pharmaceutical sector makes up approximately **1% of the Polish GDP**.
- The majority of drugs used in Poland are generic drugs – substitutions of the original medicinal products. In 2012, the share of generic drug sales in Poland amounted to 84.5% in terms of volume and 63.5% in terms of value¹⁴.
- In 2012, approximately 55% of the drugs sold (in terms of quantity) came from domestic production¹⁵. In terms of value, it was 30%.
- The pharmaceutical sector is characterized by high efficiency – **in 2013 the ratio of gross profits to revenues reached 12.7%**.
- At the end of 2013 in the pharmaceutical industry in Poland there were cca. 100 enterprises, including 65 with foreign capital.
- At the end of 2013, there were 20.4 thousand persons employed in the Polish pharmaceutical industry (1% of the total number of people employed in manufacturing).
- In 2013, the exports of the Polish pharmaceutical sector amounted to EUR 2.4 billion (PLN 10 billion), which means an increase of 15.7% as compared to 2012, and the imports amounted to 4.3 billion EUR (PLN 18 billion), which means an increase of 16.2% as compared to 2012.
- At the end of 2013, **the value of the accumulated foreign direct investment** in the pharmaceutical industry in Poland amounted **EUR 2.21 billion** (PLN 9.25 billion). This stood for 4.6% of the cumulative value of FDI in the industrial manufacturing.

2.1. Production structure

The sold production of the sector in 2013 totaled to PLN 11.4 billion (EUR 2.72 billion) and increased by 3.2% comparing to 2012.

- **The value of sold production** of the pharmaceutical sector has increased by 14% in the years 2008-2013, which **related to EUR 380 million** (PLN 1.6 billion). It is mentioning that the value of sold production during this period has been significantly fluctuating. For instance, the value of sold production of the sector in 2011 had picked up to EUR 2.82 billion (PLN 11.6 billion) and afterwards decreased by about EUR 238 million (PLN 1 billion) in 2012. It was the result of the introduction by the Ministry of Health of the Bill from 12 May 2011 on the refund of medicines, foodstuffs for particular nutritional uses and for medical devices” [Dz. U. 2011 No 122 position

¹² Raport Go Global! Polish Pharma, 2012 (<http://headmaster.pl/wp-content/uploads/polpharma-1.pdf>).

¹³ Pharmaceuticals in Poland: Market Outlook, MarketLine Industry Profiles, May 2014.

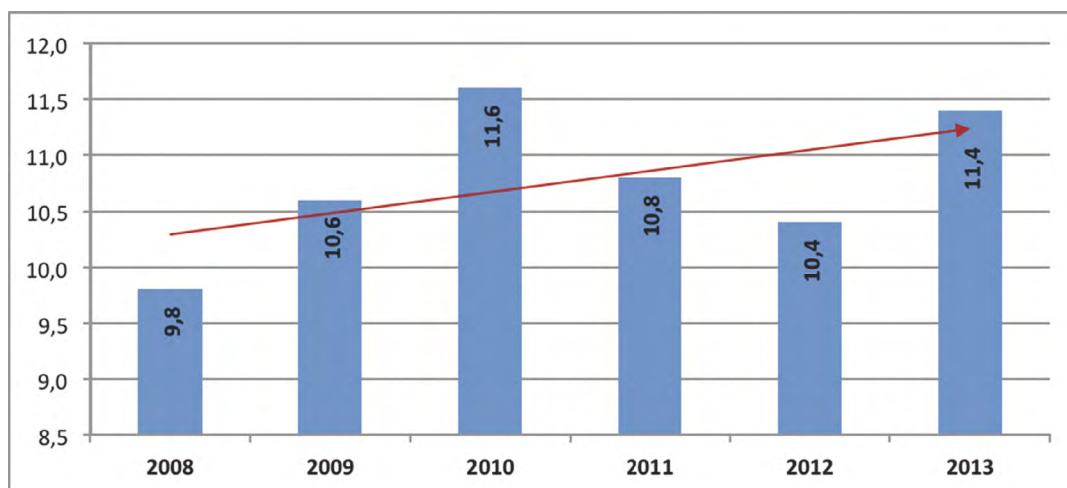
¹⁴ These figures also include innovative drugs for which patent protection has expired (so-called off-patent drugs), Institute for Market Economics (Instytut Badań nad Gospodarką Rynkową), 2014.

¹⁵ The development strategy of the domestic pharmaceutical industry until 2030, Institute for Market Economics, 2014.

696.], which led to a temporary market regression. This was due to the chaos associated with the new reimbursement lists and constantly changing positions of medical preparation available in this list.

- According to the Ministry of Health the National Health Fund (NFZ) expenses on refund of medicines in 2012, ie. the first year of application of the amended Bill of Reimbursement decreased from PLN 8.8 billion and PLN 6.8 billion. On the other hand, since the entry into force of the new legislation in January of 2012, more than 900 drugs have been covered by the system of refunds, including 39 of them for the first time¹⁶.

Figure 2. The sold production of pharmaceutical industry in Poland in the years 2008-2013 (PLN billion)



Source: GUS, 2014.

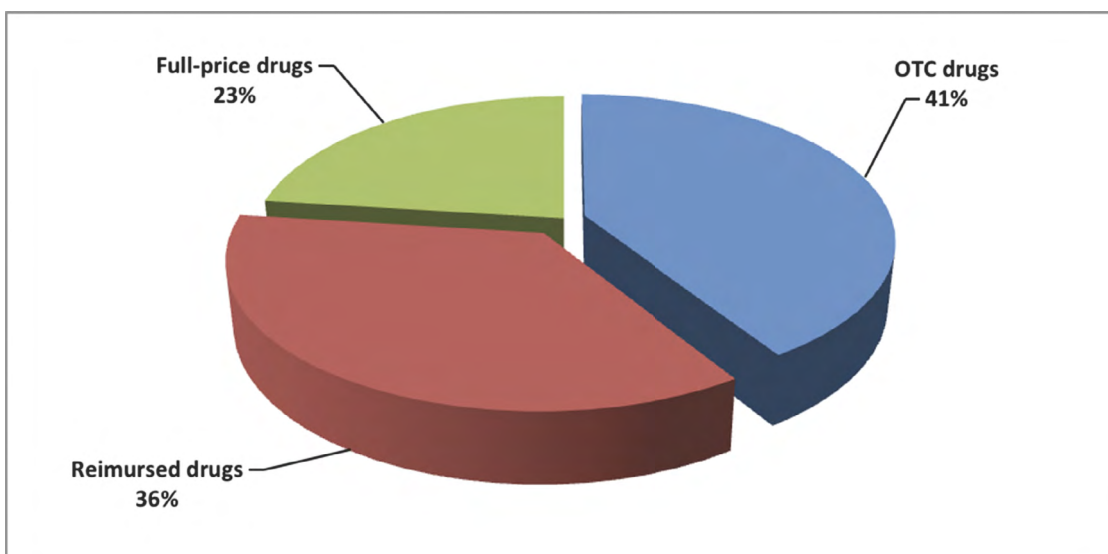
Structure of drugs sold over the counter (OTC) is the following:

- In 2013, the retail sales of OTC drugs amounted to EUR 2.67 billion (PLN 11.2 billion), which accounted for 41% of the entire market.
- The sales of reimbursed drugs amounted to EUR 2.38 billion (PLN 10 billion) – 36% of the entire market.
- The sales of fully-paid drugs amounted to EUR 1.47 billion (PLN 6.2 billion), accounting for 23% of the market¹⁷.

¹⁶ www.rynekzdrowia.pl, 2014

¹⁷ Ibidem.

Figure 3. Structure of sales of the pharmaceutical sector products on the Polish market in 2013



Source: *EMIS Intelligence, 2014.*

- The value of pharmacies market in a period of January-June 2014 has totaled up to EUR 3.4 billion (PLN 14 billion) and was higher by 1.9% comparing to the same period in 2013.
- According to the latest projections in 2014, the pharmaceutical market in Poland would reach the value of EUR 5 billion (PLN 21.2 billion) in net producer prices, what means a growth of 2.5%¹⁸.

The further development of the sector is possible, among others, through reinvestments done by already existing drug companies in Poland. Thanks to the production base and research facilities there is a large potential for the development of highly innovative products. In addition, Poland, as a key producer of generics in the region, has the chance to furtherly develop the sector through new investments due to the following factors:

1. Patents' expiration of more than 100 medicines in the years of 2012-2014, which stipulates new opportunities for development of the companies in the sector.
2. Austerity measures in developed countries will negatively affect the propensity of public authorities to reimburse innovative medicines in order to support generic drugs from the public resources.
3. Development of relatively low income per capita markets, where the demand for generic drugs could generate export opportunities for the Polish producers of pharmaceutical industry.

2.2. Enterprises and the labor market

The pharmaceutical sector in Poland has been under gradual consolidation in recent years. 14 of 18 state-owned corporates from the pharmaceutical sector have been privatised in the years 2007-2011. Tremendous transaction was the acquisition of Polfa Warszawa by Polpharma in 2012.

At the end of 2013, there were 100 companies active in the Polish pharmaceutical industry¹⁹.

- In 2013 the revenues from the sales of products, materials and services of the pharmaceutical sector amounted to EUR 3.48 billion (PLN 14.6 billion). Nearly 35%, i.e. EUR 1.22 billion (5.1 billion PLN) of these revenues came from export sales.
- Most of the revenues of the pharmaceutical sector EUR 2.93 billion (PLN 12.3 billion) were generated by 25 large enterprises (employing over 250 people)²⁰.

¹⁸ <http://biotechnologia.pl/farmacja/aktualnosci/dynamika-rynku-farmaceutycznego-w-polsce-w-2014r,14472>

¹⁹ Expenditures and financial results of industry in 2013, CSO, 2014 (companies employing over 9 persons)

²⁰ Financial results of economic entities in 2013, CSO, 2014.

- Profitability indicators for pharmaceutical industry in 2013 were significantly positive. Return on sales in pharmaceutical sector amounted to 11.9% in 2013. In comparison, return on sales in the whole industrial production totaled to 4.9%.

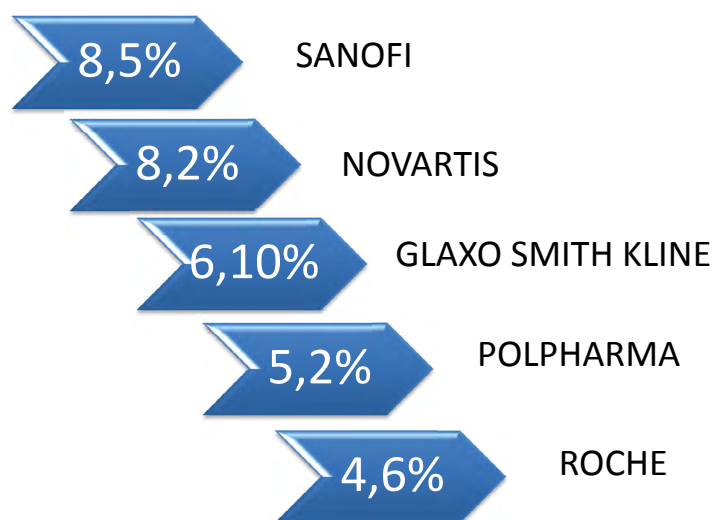
The Polish pharmaceutical industry, due to favorable business conditions, has attracted over the last 20 years a number of investors, who either took part in the privatization in the industry, or pursued a greenfield investments. **The main countries-of-origin of investors in the industry in Poland include Germany, France and the United Kingdom.**

The pharmaceutical industry in Poland consists of two main groups of companies.

- The first groups consists of companies controlled by domestic capital, including both private enterprises and non-privatized SOEs. **The biggest domestic companies include Polpharma, USP Zdrowie, Adamed, Bioton, Biofarm, Hasco Lek and LEK-AM.**
- The second group of pharmaceutical companies operating on the Polish market consists of companies with foreign capital. **The biggest companies from this group include Sanofi (France), Novartis (Switzerland) and GSK (UK).**

The number of biotechnological companies is also increasing. In the last 5 years their number has more than tripled – from 20 in 2007 to 70 in 2013. Almost 40% of these companies are conducting research on new drugs²¹. Mostly, these are the companies with Polish capital, and the value of the carried out projects in 2013 amounted to EUR 77,5 million, out of which EUR 40 m came from public funds within the framework of the Operational Programme Innovative Economy. In addition, research projects in the field of biotechnology is currently conducted by more than 120 research teams in public research centres.

Figure 4. The biggest pharmaceutical companies in Poland in terms of market share in 2013.



Source: *EMIS Intelligence*

Due to the high costs of developing innovative medicines, it is important that cooperation between domestic companies is pursued. For example, Polpharma cooperates with Celon Pharma, that develops insulin. Also a large global pharmaceutical companies are changing their ways to conduct research and development activities. It becomes less common to run a research in own centres (research & development model), rather the companies identify problems to be solved and outsource certain activities into outer partner (search & development model). So it can be expected that in the near future research cooperation will bring about many companies concentrated around market leaders.

²¹ Poland at BIO International Convention 2013, Washington.trade.gov.pl (19.08.2014)

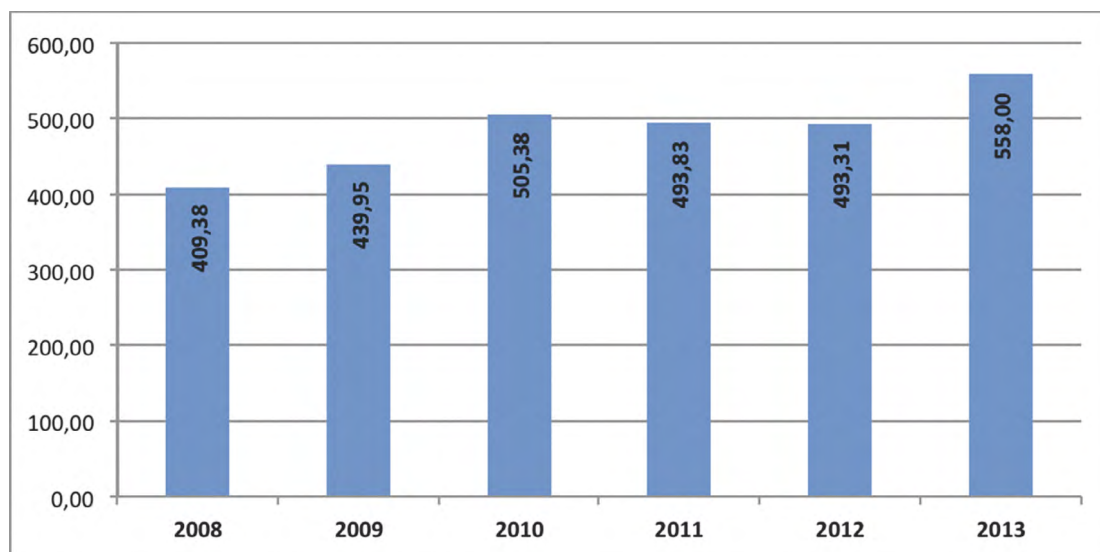
Both companies producing **traditional generic drugs** (such as Celon Pharma Sp. z o.o.) as well as companies **combining biotechnology and pharmacy** (ie. Grupa Adamed, Selvita S.A., Blirt S.A., Celther Polska Sp. z o.o., Stem Cells Spin S.A., Proteon Pharmaceuticals S.A.) are increasingly focusing their activities on the creation of innovative drugs.

Labour market

At the end of 2013, there were 20.4 thousand persons employed in the Polish pharmaceutical industry. The number of persons employed in the Polish pharmaceutical industry accounts for approximately 1% of the total number of people employed in manufacturing²². In comparison, there were 23.0 thousand persons employed in the pharmaceutical sector in 2010²³.

- The declines in employment in the industry are a result of the rationalization of the production and sales processes²⁴.
- In 2013 the average monthly salary in the pharmaceutical industry in Poland reached EUR 1315 (PLN 5513.5). The salary in the pharmaceutical industry is higher by a third than the average monthly salary in the manufacturing sector, which in 2013 amounted to EUR 857 (3591.5 PLN).
- In 2013, the labor productivity in the pharmaceutical sector amounted to EUR 133.1 thousand (PLN 558 thousand) per employee and was 16% higher than the average labor productivity in manufacturing (EUR 114 thousand, PLN 478 thousand).
- Labour productivity in the pharmaceutical sector has increased in the years 2008-2013 by 36.6%.

Figure 4. Labour productivity in Poland in pharmaceutical sector 2008-2013 (PLN thousand)



Source: GUS, 2014.

2.3. Turnover of the sector's foreign trade

In 2013, the exports of the Polish pharmaceutical sector amounted to EUR 2.4 billion (PLN 10 billion), which means an increase of 15.7% as compared to 2012, and the imports amounted to 4.3 billion EUR (PLN 18 billion), which means an increase of 16.2% as compared to 2012. Thus, a trade deficit of EUR 1.9 billion (PLN 8 billion) was recorded.

In recent years the growth of Polish exports followed a strong upward trend.

²² Inputs and the results of the industry in 2013 (Nakłady i wyniki przemysłu w 2013 r.), GUS, 2014.

²³ Inputs and the results of the industry in 2010 (Nakłady i wyniki przemysłu w 2010 r.), GUS, 2011.

²⁴ The development strategy of the domestic pharmaceutical industry, Institute for Market Economics

- In the years 2008-2013 the value of exports of the Polish pharmaceutical sector increased more than two fold.
- We are also observing a process of gradual reduction in the trade deficit of the pharmaceutical sector. In comparison to 2008, the deficit decreased by 3 PLN billion and reached the level of – PLN 8 billion (EUR 1.9 billion) in 2013. The deficit stems primarily from the specificity of the sector. The value of imported into Poland drugs is mainly impacted by the very high price of drugs protected by patents. Enterprises operating in Poland focus purely on producing generic drugs, so it is inevitable to import original drugs. National production of generic pharmaceuticals, due to lower prices, results in the shifting demand from imported products on domestic²⁵.

The dynamics of exports indicates the high competitiveness of the Polish pharmaceutical sector.

- **Between 2008-2013 the value of export of the industry increased more than twofold;**
- The reduction of the negative balance of trade in the pharmaceutical sector can be seen in recent years – compared to 2008 negative balance decreased by PLN 3 billion to PLN 8 billion (EUR 1.9 bn) in 2013;
- Dynamic export growth indicates the high competitiveness of the Polish pharmaceutical sector.

Figure 5. Foreign trade turnover of the Polish pharmaceutical sector between 2008-2013 (in PLN billions)²⁶



Source: *Compilation of the Polish Information and Foreign Investment Agency on the basis of CSO data, 2014.*

- Due to the competitive prices of the Polish generic drugs in comparison with those produced abroad, the export potential of the domestic pharmaceutical industry has not been fully exploited yet.

The majority of the Polish pharmaceutical sector's trade is with the EU member states.

- In terms of value, Polish drugs exports to the EU represent 76.2% of total exports, and the imports constitute 81.3% of total imports.
- Within the EU alone, the biggest number of drugs is exported to Germany (14.2%), France (9.4%) and Spain (8.9%).
- Russia, which accounts for 10.7% of the Polish pharmaceutical sector exports, is the biggest customer from outside the European Union.

²⁵ The importance of the pharmaceutical industry for Polish economy, IBNGR, 2011.

²⁶ At current prices.

- The biggest number of pharmaceutical products imported to Poland comes from Germany (16.3%), UK (13.0%) and France (10.0%), Germany (13.1 %).

Further expansion of domestic enterprises to foreign markets is possible. However, in order to seize this opportunity it is necessary to provide stable and transparent conditions for the functioning of the sector, especially in the legal and administrative dimension.

2.4. Legal regulations relating to the sector

Since May 2004 the Polish pharmaceutical producers are obliged to meet the requirements of the EU and cannot export to other EU markets, without complying with their requirements. Legal acts shall specify in detail, among other things principles of drug registration, storage, sale or manufacture.

In Poland, the issue of drug registration is determined by Pharmaceutical Law Act (from 6th September 2001 (with later amendments) which has implemented EU Directive 2001/03/EC which aims at harmonization of drug registration rules on EU markets.

In accordance with the law, the process of admission of the drug to the market should not exceed 210 days. A marketing authorization is issued for the period of 5 years, but this period may be extended or shortened at the request of the manufacturer. On the Polish market, there could be drugs authorized in the European mode procedures: central (CP) and mutual recognition (MRP).

Currently, there have been revision works on the Pharmaceutical Law, which was accompanied by a debate in the Parliamentary Health Commission on 18th December 2014. The Law's implementation is scheduled for the first quarter of 2015.

The Law's revision is aimed at following amendments:

- The Health Minister will determine the list of products most endangered by the lack of availability;
- The introduction of the obligation to notify the National Pharmaceutical Inspection of intention to export a certain products abroad;

In January 2012 the Reimbursement Act came into force (Journal of Laws No. 122, item. 696, with amendments), whose rules are designed to reduce National Health Fund (NFZ) expenditures on refunded medicines (estimated about PLN 1.5 billion a year, (about EUR 360 million). The main provisions of the Act include:

- The introduction of the limit of expenses for reimbursement up to 17% of public spending on health. In case of exceeding this limit, pharmaceutical companies will be forced to cover half of the cost;
- To determine the official fixed price of retail drugs and constant margins at pharmacies.
- Prices will be negotiated by the Ministry of Health with pharmaceutical companies;
- Determining the wholesale margin at 7% in 2012, 6% in 2013 and 5% in 2014;
- Banning advertising of pharmacies and any incentives for sales of reimbursed drugs.

The Ministry of Health is in the final stages of preparing the amendment to the Reimbursement Act, which will include among others issues such as: the definition of the counterpart and official selling price.

3. FOREIGN INVESTMENT IN THE PHARMACEUTICAL INDUSTRY IN POLAND

At the end of 2013 in the pharmaceutical industry in Poland there were 65 enterprises with foreign capital²⁷:

- 30 entities employing under 9 persons and 35 enterprises employing over 9 people.
- These entities employ 9345 people,
- Core capital of these companies amounted to 2,7 mld PLN (644 mln EUR).

Between 2004-2014 in Poland there were 66 pharmaceutical investment projects localized. It translated into 5373 newly created jobs, and their value amounted to EUR 793 million (PLN 3.3 billion)²⁸.

Among the countries of origins of investment projects in the Polish pharmaceutical industry between 2004-2014, there are the United States (12 projects), United Kingdom (11), and Switzerland (7).

Table 1. The structure of the greenfield investment projects in Poland between 2004-2014

Country	Number of projects	Jobs	Investment outlays (EUR m)
United States	12	391	79.4
Great Britain	11	664	104.1
Switzerland	7	1470	246.4
Germany	6	502	34.2
Japan	4	382	38.4

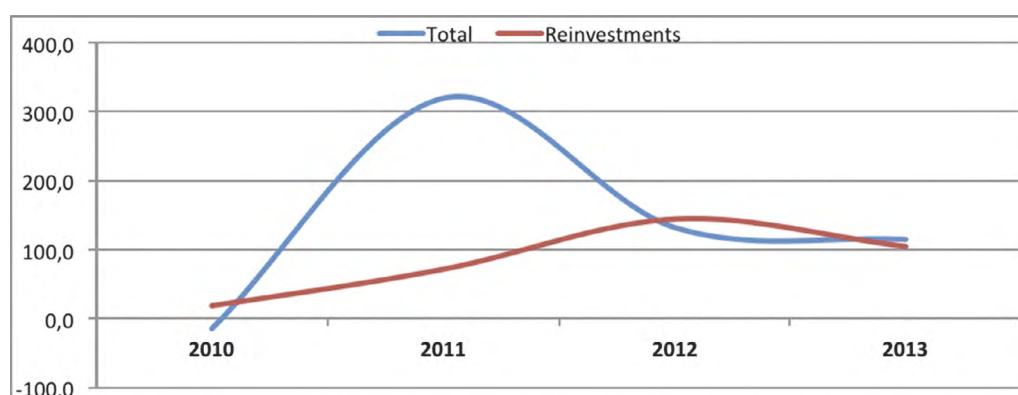
Source: *Elaboration by PAIIZ based on FDImarkets.*

At the end of 2013, **the value of the accumulated foreign direct investment** in the pharmaceutical industry in Poland amounted **EUR 2.21 billion** (PLN 9.25 billion). This stood for 4.6% of the cumulative value of FDI in the industrial manufacturing²⁹.

In 2013 the value of FDI inflow in the pharmaceutical industry in Poland amounted **EUR 114.8 million** (PLN 481 m). Majority of this figure was generated by reinvestments (EUR 104.7 m, PLN 498.7 m).

As of December 2014, Polish Information and Foreign Investment Agency supported 4 investment projects in the pharmaceutical industry, the value of which is EUR 3.5 million (PLN 14.7 million), and the potential employment 630 people.

Figure 6. The inflow of greenfield investment and reinvestments in the Polish pharmaceutical sector between 2010-2013 (in EUR million)



Source: *Elaboration by PAIIZ based on NBP, 2014.*

²⁷ Economic activity of enterprises with foreign capital in 2013, GUS, 2014.

²⁸ FDI Intelligence, 2014.

²⁹ NBP, 2014.

In Poland there can be found manufacturing plants or research and development centres of companies such as:

- **Novartis Group** (consisting of Novartis Poland SP. z o.o., Sandoz Poland SP. z o.o. and Lek S.A.) has a modern factory of generic drugs in Stryków, Distribution and Logistics Centre in Warsaw and the Production-Logistic Centre in Pruszków.
- **GlaxoSmithKline** through the acquisition of Polfa Poznan in 1998, earned an important position on the Polish market. The estimated investment of GSK in Poland amounts to more than EUR 370.5 million (PLN 1.5 billion). The company possesses a business service center in Poznan, specializing in the provision of its services for 273 branches of GSK worldwide.
- **Sanofi Group** employs in Poland about 1000 people. The company possesses a Sanofi-Aventis Production and Distribution Centre in Rzeszów, which is 29 years old and is one of the 112 plants the company operates worldwide.
- **KRKA Poland** is one of the biggest and dynamically developing companies in the pharmaceutical sector in Poland. Today it employs nearly 800 employees and has a modern production facility in Warsaw, producing up to 400 million tablets a year.

Figure 8. The largest foreign investment in the pharmaceutical sector in Poland



Source: *Elaboration by PAliiZ.*

4. INVESTMENT POTENTIAL

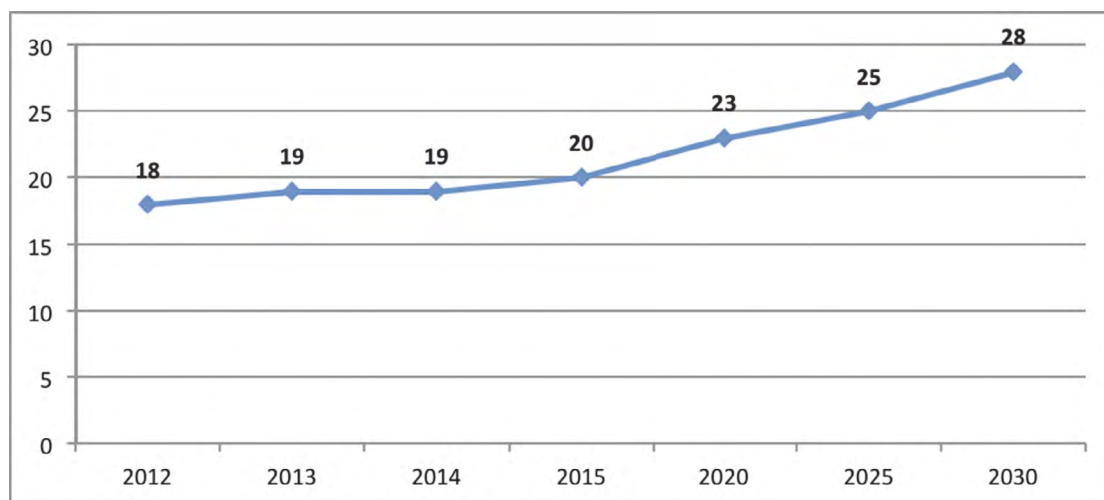
Poland is a country that offers an excellent location both for production, sales and research on world class pharmaceutical products. Decades of development in the Polish pharmaceutical sector are reflected by a modern laboratory and manufacturing base.

Advantage of the Polish pharmaceutical industry lies, above all, in highly qualified staff, more and more modern laboratory and manufacturing base, as well as the relatively low cost of production and competitive prices. Thanks to the so far investments, the production plants operating in Poland are constantly modernised.

Poland is in second place among the countries of Central and Eastern Europe in terms of the attractiveness of investment in the pharmaceutical industry³⁰. In this case the attractiveness is measured by the size of the internal market and its growth potential.

- Polish market is among the 10 biggest pharmaceutical markets in Europe.
- In the longer term the Polish pharmaceutical sector has a higher and more reliable growth prospects than most other sectors of industrial processing in Poland. A factor that will have an impact on the sector is a relatively high health spending in Poland³¹.
- By 2030 forecast expenditure on drugs in Poland will increase by 1/3 i.e. PLN 9 billion (EUR 2.1 billion)³².

Figure 8. Estimated drugs expenditure in Poland (in PLN bn)



Source: PZPF, *Sequence*, 2013.

4.1. Human resources availability

Pharmacy studies are available at 12 higher education institutions in Poland and there is a growing interest in courses related to health care among the Polish students. In 2013, 1295 graduates completed **pharmacy studies**, with the biggest number of graduates found in the Śląskie voivodeship – 160 persons³³.

- The number of graduates of this course has remained at more or less the same level over the past 10 years.³⁴

³⁰ Business Monitor International, 2013.

³¹ EMIS Intelligence.

³² Polski Związek Przemysłu Farmaceutycznego (Polish Association of Pharmaceutical Industry) (PZPF), *Sequence*, 2013.

³³ Graduates of selected fields of study in the 2012/2013 academic year – CSO – April 2014.

³⁴ Zdrowie i ochrona zdrowia w 2012 roku (Health and health care in 2012), CSO.

- In 2013, there were 7671 students pursuing a pharmacy course, with the biggest number of students found in the Śląskie voivodeship – 905.³⁵
- The profession of pharmaceutical technician can be pursued in 218 schools and educational institutions.³⁶

The **significance of biotechnology** is also increasing. This course is available at 36 higher education institutions in Poland.

- Currently 11963 people are enrolled in biotechnology studies in Poland, with the biggest number of students found in the Dolnośląskie voivodeship – 1861 students.³⁷
- In 2013, there were 3710 students pursuing a biotechnology course, with the biggest number of students found in the Śląskie voivodeship – 561.
- **Polish scientists** are another source of highly qualified personnel. More than 8 thousand Polish scientists are conducting **research in the field of biotechnology and medical sciences**. Many of them are interested in direct cooperation with pharmaceutical and/or biotechnological companies.³⁸

4.2. Developed network of clusters

According to PwC studies, on average each innovative pharmaceutical company in Poland is involved in at least 5 projects aimed at building inter-branch coalitions³⁹.

As a result, there is a number of clusters and technology parks functioning within the industry, which provide the infrastructure – and in particular the laboratory space – for the development of innovative biotechnological and pharmacy-related products.

The largest clusters grouping companies and research institutions from both the pharmaceutical and the biotechnological industry include:

1. Life Science Cluster in Kraków

This cluster was founded in 2006 and consists of companies from the pharmaceutical, biotechnological, medical, food and environmental protection industries, as well as universities, research institutes, hospitals, consulting companies, business environment institutions and local authorities. This includes a total of 70 entities, the largest part of which consists of small and medium-sized enterprises.

2. Nutribiomed Cluster

This cluster was created in 2007 and currently consists of 54 entities: 8 higher education institutions, 3 business environment institutions and 43 enterprises. The idea behind this cluster is to create a strong position of Poland in products such as dietary supplements, nutraceuticals and biomedical preparations based on domestic, natural agricultural raw materials and proprietary know-how.

3. Klaster Roślinnych Produktów Leczniczych i Suplementów Diety – Narodowy Instytut Leków (Cluster of Herbal Medicinal Products and Dietary Supplements – National Medicines Institute)

The cluster was established in 2007. Its objective is to strengthen the competitiveness of enterprises manufacturing herbal medicines, herbal medicinal products and dietary supplements. The cluster includes enterprises, public institutions and a vocational school – a total of 17 entities.

³⁵ Students of selected courses in the 2013/2014 winter semester, Ośrodek Przetwarzania Informacji (Information Processing Institute) – March 2014.

³⁶ Centrum Informatyczne Edukacji (Education Information Center), cie.men.gov.pl.

³⁷ Students of selected study courses in the 2013/2014 winter semester, Ośrodek Przetwarzania Informacji (Information Processing Institute) – March 2014.

³⁸ Ibidem.

³⁹ The contribution of the innovative pharmaceutical industry to the development of the Polish economy, PwC, 2011.

4. Mazowiecki Klaster Peptydowy (Mazovian Peptide Cluster)

This cluster is a specialized cooperative association established by the Mossakowski Medical Research Centre of the Polish Academy of Sciences. The cluster brings together universities, research units and enterprises among others- MDiK PAN (coordinator), Warsaw University, USP Life Sciences sp. z o.o. or CELON PHARMA sp. z o.o., – a total of 8 entities.

5. BioEcoChem – Pomorski Klaster BioEkoChemiczny (Pomeranian BioEcoChem Cluster)

The cluster brings together the biotechnological, chemical, pharmaceutical, cosmetics and environmental protection industries. The objective is to create a strong research center in the field of biotechnology, chemistry and pharmacy.

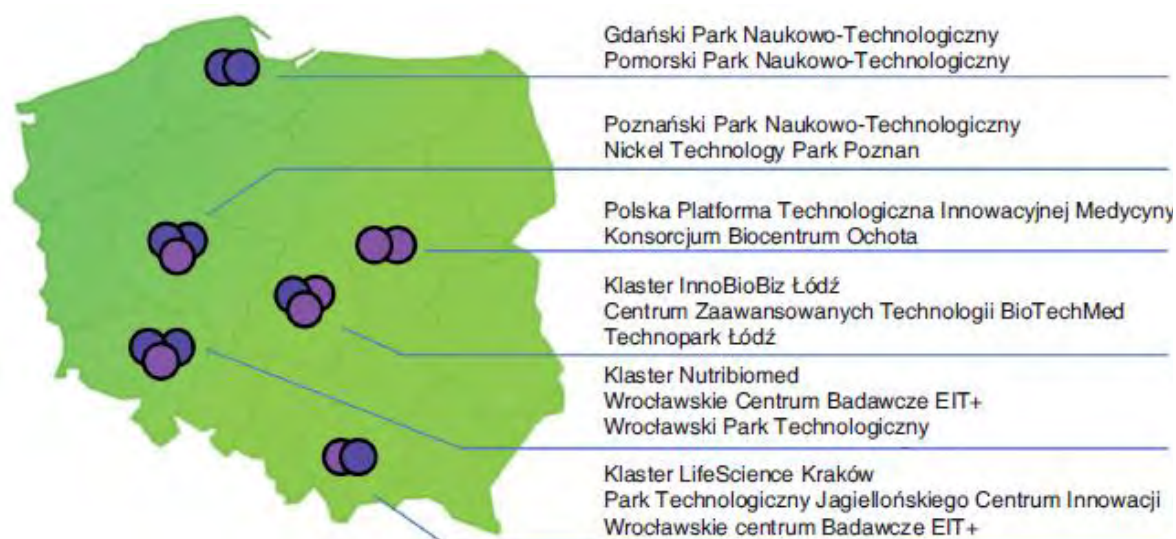
6. Konsorcjum Polskiej Akademii Nauki Biocentrum Ochota (Consortium Of Polish Academy of Sciences Biocentrum Ochota)

The Consortium was created in 2008 on the initiative of the six research institutes of the Polish Academy of Sciences (PAN) acting within the framework of its Warsaw campus. These include: Institute of Biochemistry and Biophysics PAN, Institute of Biomedical Engineering PAN, Institute of Experimental Biology PAN, the Experimental and Clinical Medicine Institute PAN, Institute of Basic Technical Problems PAN and the International Institute of Molecular and Cellular Biology PAN. The primary objective of the Centre is the use of joint research capabilities to carry out extensive research projects out beyond the capabilities of individual members. These projects cover areas of biology, medicine and bioengineering.

7. InnoBioBiz Łódź Clustser

The cluster was set up in 2011 by biotech companies in Łódź and business environment institutions. It includes also Medical University of Łódź and Łódź University. The main objective of the cluster is to create conditions for the development and promotion of innovative bio-business in the region, based on the potential of biotech companies.

Figure. 10. Main clusters and R&D centres of the Polish pharmaceutical industry



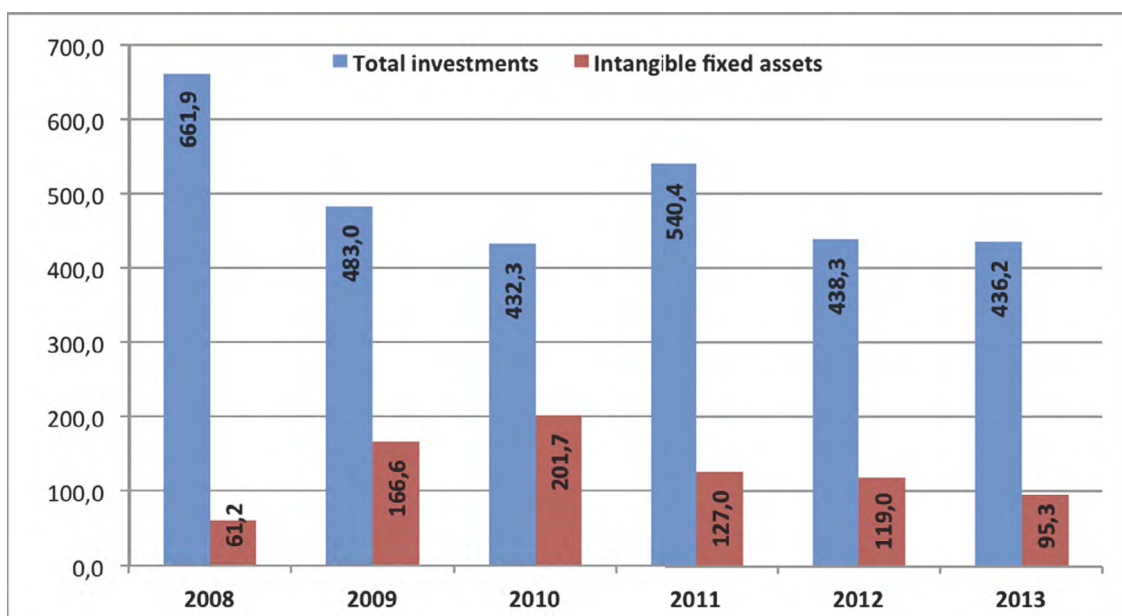
Source: Elaboration by PAliIZ, 2014

4.3. Developed R&D infrastructure

In terms of business expenditure on research and development, biopharmaceuticals are close top.

- Polish drug producers **spending on R&D** constitutes around **13% of its profits**, in turn, the overall investment stands for up to **60% of revenues**. A potentially high level of innovation of the domestic pharmaceutical industry is an extremely important feature from the point of view of the entire Polish economy.
- Expenditure (public and private) on R&D in the pharmaceutical sector in Poland in 2013 amounted to EUR 227 million, which is the highest figure in the region of Central and Eastern Europe, however, far less than for example in Germany (EUR 5.8 bn) and Great Britain (EUR 5.2 bn). In the EU as a whole, the R&D spending in the sector in 2013 amounted to EUR 30 bn⁴⁰.
- High expenditures on R&D are necessary, because the introduction of a new drug on the market generates a cost of about EUR 2.1 billion, and this investment is long term-process from pre-clinical phase to the introduction of the drug on the market may take up to 8-10 years⁴¹.

Figure 11. Investment spending of the pharmaceutical industry enterprises in Poland between 2008-2013 (million PLN)



Source: GUS, 2014.

- Major pharmaceutical companies carry out its operations in the field of R&D for many years:
 - Since 2001 **Adamed** (now Adamed Group) carry out operations in three research programmes – oncology, metabolic and neuro-psychiatric. It develops both biotech and micro-particles drugs, also in cooperation with the scientific community and academia.
 - **Celon Pharma S.A.** belongs to the Group of companies awarded for modern technology and research – in 2013 it was awarded one of the most innovative companies in Poland by INE PAN.
 - **Polpharma in Starogard Gdański** possesses one of the largest R&D centres in Central and Eastern Europe. Polpharma Group has a total of **6 R&D centres**, which employ more than 400 professionals who deliver around 30-40 solutions per year.

In the pharmaceutical sector the innovation investment effects appear later than in other areas of the economy, due to the specificity of the sector and the time consuming process of pre-clinical research and entering a drug onto market. In Poland initial effects of R&D investments in the industry can be seen already. Companies in the industry are developing innovative drugs in different phases, and also intensely cooperate with universities.

⁴⁰ The Pharmaceutical Industry in Figures 2014, EFPIA, 2014.

⁴¹ Tufts Center for the Study of Drug Development, 2014.

It is also worth noting that there was an increasing number of patent applications submitted by Polish research institutions⁴². Positive factors contributing to the increase in the number of scientific research include also an increasing public awareness as to the importance of intellectual property protection in the process of doing research.

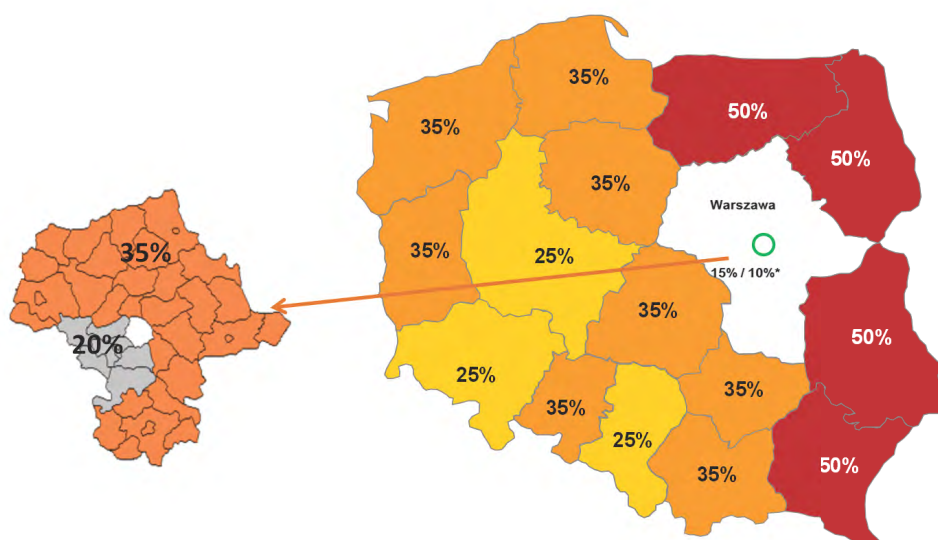
4.4. Attractive investment incentives system⁴³

4.4.1. Regional state aid

The level of State aid in Poland

Regional investment aid is the most important type of public support offered to entrepreneurs working on new investment projects. The maximum level of support for a given investment depends on the location of the investment project and the size of the company. The highest possible level of intensity of regional state aid is available in the Eastern Poland voivodeships, where support threshold of 50% of eligible costs (investment expenditures and 2 years- labour costs) for large businesses is offered.

Figure 12. The maximum levels of regional aid in the new financial perspective (2014-2020) in each voivodeship



Source: *Crido Taxand, 2014 r.*

In the case of small and medium-sized businesses the maximum levels applicable in a given region can be increased by a maximum of 20 p.p. (for micro and small companies) and 10 p.p. (for medium-sized companies).

For “major projects”(of initial investment of eligible costs exceeding EUR 50 million) the state aid is to be calculated due to the following equation:

Maximum amount of regional state aid = $R \times (50\% + 0,5 \times B + 0 \times C)$, where:

- R – intensity of regional state aid in the particular region
- B – the part of eligible costs between EUR 50 million and EUR 100 million
- C – the part of eligible costs above EUR 100 million

Entrepreneurs pursuing new investment projects can take advantage of the possibility of the aid calculated in accordance with the above thresholds using the following instruments:

⁴² Poland at BIO International Convention 2013, Washington.trade.gov.pl (19.08.2014).

⁴³ Detailed information on the new EU perspective can be found in “EU Funds 2014-2020” (“Fundusze UE 2014-2020”) prepared by experts from CridoTaxand: Michał Gwizds, Magdalens Kosewskis-Kwaśny and Szymon Żółciński, C.H. Beck (August 2014)

- government grants,
- grants co-financed by structural funds, in particular to carry out research and development activities in the food sector⁴⁴,
- income tax exemption under the special economic zones,
- tax incentives to acquire new technologies so called technological relief,
- exemption from local taxes, including property taxes.

4.4.2. Government grants

Government grants (for the creation of new jobs and investments) are awarded on the basis of the “Programme for supporting investments of major importance to the Polish economy for the years 2011-2020” focused on investment projects in the following sectors:

- automotive,
- electronics,
- aviation,
- **biotechnology**,
- agri-food,
- shared business services,
- **R&D**.

Apart from these, businesses which are operating in other than above mentioned sectors, might also apply for government grants. Then investment projects should meet the following criteria:

- forming at least 200 new jobs for eligible costs: at least PLN 750 million (EUR 179 million) or
- creating at least 500 jobs for eligible costs at least PLN 500 million (EUR 119 million).

4.4.3. Grants co-financed by structural funds

In the current EU financial perspective, Poland is the largest beneficiary of support from the EU structural funds. In the years 2014-2020 has at its disposal EUR 82,5 billion within the framework of structural support. It is intended, among others into innovative investments, research and development, infrastructure projects, environmental protection, renewable energy sources, the training of staff.

The main priority within the new EU funds is to support R&D, especially in the agri-food sector and biotech available due to the following Operational Programmes:

- Operational Programme Smart Growth
- Operational Programme Infrastructure and Environment
- Regional Operational Programmes

In addition, a **healthy society** was considered to be one of the **5 national smart specializations** defining the relevance of R&D support from EU funds in the pharmaceutical sector in Poland in the years 2014-2020. **Regional smart specializations** in each of the 16 voivodeships are promoting the pharmaceutical sector, strengthening its investment potential.

4.4.4. Income tax exemption in special economic zones

The primary tax incentive is exemption from income tax in one of 14 special economic zones that will remain active until 2026. Each zone has numerous sub-zones in various parts of Poland. In the special economic zones investors may count on the availability of attractive investment lands equipped with the necessary utility infrastructure and comprehensive assistance in legal and administrative procedures related to their project. EUR 100 thousand is the minimum required value of investment expenditures eligible for income tax exemption in SEZ.

⁴⁴ Detailed information in this regard can be found in „Fundusze UE 2014-2020”, Crido Taxand: Michał Gwizda, Magdalena Kosewska-Kwaśny and Szymon Żółciński, C.H. Beck (August 2014).

4.4.5. Technological relief

Relief lies in the possibility of a reduction in the taxable amount of income tax by half of the expenditure incurred on the acquisition of new technology.

4.4.6. Exemption from local taxes

Incentives for entrepreneurs may also be offered by municipalities which have the power to lay down exemptions from taxes and local charges, including property taxes. Conditions for the tax exemption depend on the most common amount of declared investment outlays and/or new jobs created.

Because investment incentives are available in many different programs, and each of them has different terms and conditions to apply, in order to obtain detailed information, we suggest contacting the Polish Information and Foreign Investment Agency.

5. SUMMARY

Global factors, that is the ageing population in developed countries, as well as population growth in developing countries, create a growing demand for pharmaceuticals. In Poland, there are most of the biggest international companies present for many years already. In the sector, there are also vibrant Polish companies operate.

It can be predicted, that a continuation of the positive trend in attracting foreign investment to the sector in Poland will be continued, as well as the development of home-grown companies will be maintained, due to both the demand on the domestic market and export demand that will grow steadily. Further development of the *pharmerging markets* (developing countries) will mainly be based on generic drugs, which creates opportunities for Polish pharmaceutical sector⁴⁵. The pharmaceutical industry, despite the difficulties in previous years, brings a breath of optimism in 2014. Sold production of the sector and expenditure on investments after the third quarter of 2014 increased by 3.4% and 4.5% respectively in comparison with the corresponding period of 2013⁴⁶.

What's more, the return on sales for the pharmaceutical industry after first half of 2014 amounted to 13.2%, while throughout 2013 this value stood at 11.9%. The industry will undoubtedly be supported by the situation in the Polish economy, which despite the crisis in Europe, notes a systematic growth

The pharmaceutical sector in Poland remains one of the most attractive investment areas, due to among others.

- the availability of highly qualified human resources,
- a large internal market and an ageing society,
- strategic localization of Poland,
- as well as the presence of specialized companies involved in logistics and transport.

In addition, the new financial perspective 2014 – 2020 offers a wide range of measures in support of both R&D in the sector, as well as the improvement of professional skills.

⁴⁵ Global Outlook for Medicines Through 2018, IMS Institute, 2014, p. 2.

⁴⁶ Inputs and the results of the industry in I-III quarters 2014., GUS, 2014.

6. INDUSTRY ORGANIZATIONS

Główny Inspektorat Farmaceutyczny (**Main Pharmaceutical Inspectorate**)

Długa Street 38/40,
00-238 Warsaw,
Telephone +48 22 831 42 81
gif@gif.gov.pl
www.gif.gov.pl

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (**Office for Registration of Medicinal Products, Medical Devices and Biocidal Products**)

Ząbkowska Street 41,
03-736 Warsaw
Telephone: +48 22 492 11 00
www.urpl.gov.pl

INDUSTRY ASSOCIATIONS AND CHAMBERS

POLFARMED Polska Izba Przemysłu Farmaceutycznego i Wyrobów **Medycznych (Polish Chamber of Pharmaceutical & Medical Device Industry)**

Łucka Street 2/4/6,
00-845 Warsaw
Telephone +48 22 654 53 52
sekretariat@polfarmed.com.pl
www.polfarmed.pl

Polski Związek Pracodawców Przemysłu Farmaceutycznego (**Polish Association of Pharmaceutical Industry Employers**)

Wiśniowa Street 40b/4,
02-520 Warsaw
Telephone: +48 22 542 40 80
biuro@producencilekow.pl
www.pzppf.com.pl

INFARMA Związek Pracodawców Innowacyjnych Firm Farmaceutycznych (**Employers' Union of Innovative Pharmaceutical Companies**)

Puławska Street 17,
02-515 Warsaw
Telephone: +48 22 852 82 30
biuro@infarma.pl
www.infarma.pl

Written and edited by:
the Economic Information Department

Polish Information and Foreign Investment Agency
ul. Bagatela 12, 00-585 Warsaw
Tel.: 00 48 22 334 98 75
E-mail: post@paiz.gov.pl, invest@paiz.gov.pl

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