

Prospects of the biotechnology industry development in Poland

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Abstract

Background:

The dominant sector of the biotechnology industry in Poland and worldwide is the medical biotechnology sector, therefore, along with its development (creation of new technologies), there was a need to formulate appropriate legal acts regulating the activity of various enterprises on the biotechnology market as well as initiatives and institutions financing this development. The aim of the study was to assess the current state and direction of development of the biotechnology industry in Poland against the global sector.

Methods:

The conducted research was based on the analysis of statistical data of the Central Statistical Office (CSO) covering the time horizon 2011 - 2017.

Results:

The analysis of CSO reports indicated that the biotechnology market in Poland is constantly developing and highly expansive. In the years 2011-2017, the number of biotechnological enterprises in the country increased from 91 to 188 and the number of employees in the sector in this period increased from 1972 in 2011 to 3321 in 2017. However, the Polish biotechnology sector, compared to the sector of Western European countries, is a young market, which is only just moving towards the maturity phase (product/branch life cycle).

Conclusion:

Both in Poland and worldwide, the dominant sector of the biotechnology industry is medical biotechnology. A characteristic feature of this sector is its high innovativeness, which combines business with research and development activities, and it employs a relatively large number of highly qualified people and educated professionals. With the expansion of the market and the development of new technologies, the need has arisen to

formulate appropriate legal acts regulating the activity of various companies on the market, which directly affect the pace and direction of development of this industry globally.

Introduction

Every year in Poland, new specialized companies and companies conducting research and development activities are established. In this area a very dynamic growth is recorded. Currently, Poland is dominated by small enterprises, employing up to 49 people, but every year since 2011, on average 3 new large companies appear on the market. This trend is probably caused by the global trend of relocating research and development centres of pharmaceutical and biotechnological concerns to the countries of Central and Eastern Europe or liquidating such centres and replacing them with outsourcing offered by external companies, which are most often located in Central and Eastern Europe and Asia. The basis and driving force of any economy are primarily small and medium-sized enterprises, which can benefit from the transfer of technology and knowledge acquired from the giants of the sector, which in turn, can lead to their much faster development. In addition, in order to enhance the emerged opportunity for development, it is suggested that smaller companies should establish close cooperation with the academic community.^[1,2]

The analysis of statistical data published by CSO indicates that the Polish biotechnology market is a dynamically developing and expansive sector. The largest sub-sector is the area of medical biotechnology (80.2% of entities registered in Poland), which deals mainly with the production of innovative medicines, health care and research and development (R&D) activities in this area.^[3] Among the entities operating in Poland one can distinguish state entities (usually academic units) and private companies. The public institutions constitute less than 41% of the registered entities.^[3] The situation of the biotechnology sector is similar in other European Union countries. In the United Kingdom (UK), the "Core Biopharma" and "Core Med Tech" sectors include companies involved in the discovery, development and marketing of medicines and medical devices. The "Core Med Tech" sector employs the largest number of people in the whole biotechnology industry (97600 people, which accounts for 39% of all employees in the biopharmaceutical sector). The whole biopharmaceutical sector in the UK records the highest capital turnover, amounting to £33.4 billion, or 45% of the industry in 2018.^[4]

In 2016, Deloitte, in cooperation with the National Centre for Research and Development and Life Science Business Consulting, published a report entitled "The role of the European Union in the development of the European Research Area". "Biotechnology in Poland. Industry point of view.". The report was based on the results of a survey conducted among companies operating in the biotechnology sector in Poland. The aim of the survey was to assess the condition of the biotechnology market and present a forecast for the next years. The Polish biotechnology market, despite being relatively young, plays an important role in building the Polish innovative knowledge-based economy. The immaturity of the market is confirmed by the tendency of companies in the sector to concentrate their activities on research and creating a prototype, instead of taking specific development initiatives. Nevertheless, over 70% of respondents positively perceive the current business conditions for the activity of biotechnological companies in Poland as moderate, good or very good.^[5] The biggest obstacle and problem identified by the researchers turned out to be the access to capital for enterprises and complicated procedures in the process of applying for government or European funding. Financial resources are necessary for the biotechnology sector to start maturing and to start the next stage of its transformation.

The aim of this study was to analyse, describe and evaluate the market of the biotechnology industry in Poland both now and in the wider time horizon on the basis of statistical market data analysis and scientific literature.

Materials and Methods

Analysis of Central Statistical Office data

The analysis of statistical data published in the reports of the CSO on the condition and status of the biotechnology industry in Poland. The analysis collected and described issues covering the time horizon 2011-2017, specifying such areas as: the number, type and size of biotechnological enterprises, the number of people employed in the sector and internal expenditures incurred by biotechnological enterprises.

Results

Central Statistical Office report for the years 2011-2017

Over the years 2011-2017 we can observe a clear development and expansion of the biotechnology industry in Poland. The number of enterprises in field of biotechnology (BF) has increased in Poland by 206.6% - from 91 in

2011 to 188 in 2017 (Fig. 1). The largest number of new enterprises was registered in 2013 and 2015, 32 and 34 respectively. Among all the companies there is also an increase in the number of entities specialising in the field of biotechnology (BFS) and entities, including enterprises, conducting R&D activities in biotechnology field - BFRD. In 2011, there were only 31 specialised enterprises on the Polish market, while in 2017 the number was 111 (on average 14 new enterprises each year). Also a clear trend is visible in the field of research and development - within 6 years the number of enterprises increased almost 2.5 times, from 54 to 123 BFRD. The statistics clearly show an upward trend in each area of the industry.

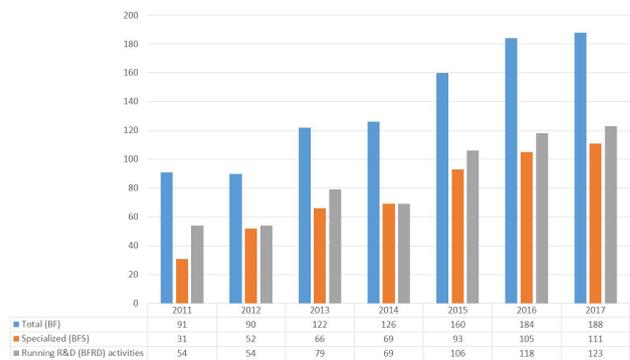


Fig 1. Biotechnological enterprises operating in the field of biotechnology (2011-2017) (based on CSO reports).

The change in the size structure of biotechnology companies is becoming increasingly evident (Fig. 2). In our domestic market, the ratio of small, medium and large companies is clearly changing. Although the number of companies increases annually, small and medium-sized enterprises continue to dominate the Polish market of the biotechnology industry. In 2011, there were 1.77 medium-size enterprises and 4.15 small enterprises per large enterprise. In 2017 this ratio is changing and there are 1.42 and 3.64 medium and large enterprises per one large enterprise respectively

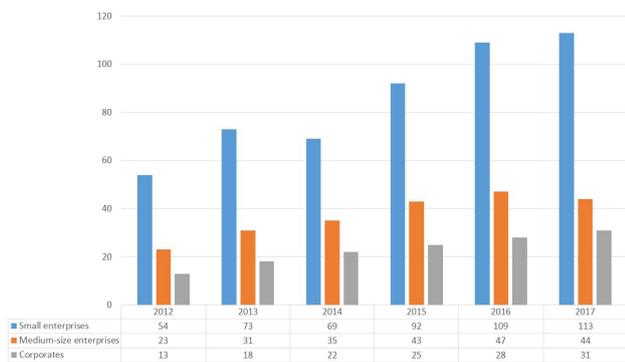


Fig 2. Size of enterprises in the field of biotechnology (based on CSO reports).

Another important indicator of the development of the biotechnology industry in Poland is the number of people working in enterprises (Fig. 3). In 2011, there were 1972 people employed in the biotechnology sector. This number increased over the following years, until 2015, when a decrease of 231 employees was recorded. Since then, the number of people working in the field of biotechnology has been growing and amounted to 3321 in 2017. A very dynamic and continuous increase in the number of employees can be observed in activities focused on research and development. From 2011 to 2017 this number more than tripled, from 396 to 1375 persons.

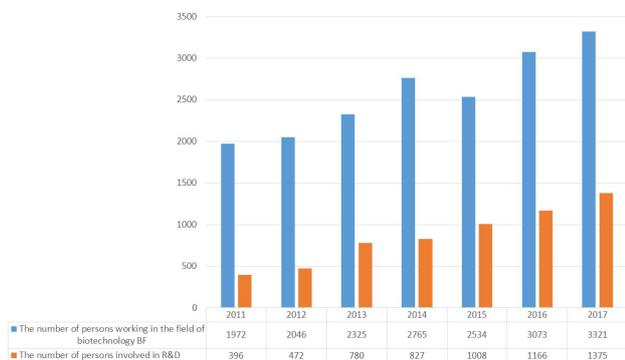


Fig 3. Those working in the field of biotechnology in enterprises (based on CSO reports).

In 2014, internal expenditures incurred by enterprises exceeded PLN 800 million. This is almost twice as much as in 2013 and 2012 (Fig. 4). The enterprises spent most in 2015. Internal expenditures then amounted to almost one billion PLN. In subsequent years, this amount decreased, maintaining the level of 2015 and amounted to PLN 761.1 million and PLN 825.8 million in 2016 and 2017 respectively. All this indicates that companies are willing to invest in the field of biotechnology, seeing the potential and opportunity for development.

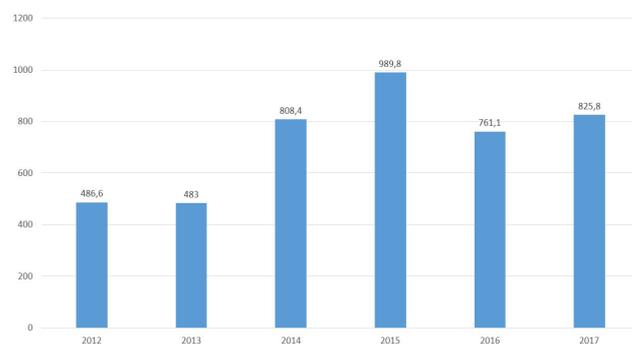


Fig 4. Internal expenditure incurred by enterprises on activities in the field of biotechnology (in MLN PLN) (based on CSO reports).

Discussion

The most successful Polish companies dealing with medical biotechnology include Selvita, Oncoarendi Therapeutics, Adamed, Medicalgorithmics, Synectik, Bioton, Nanogroup, Polish Stem Cells Bank (PSCB), Scope Fluidics and Celon Pharma. Selvita is running several innovative projects and the most advanced and flagship ones are the works on SEL24 and SEL120 molecules for the treatment of acute myelogenous leukaemia.^[6, 7] Oncoarendi Therapeutics is also conducting research on innovative drugs. Out of the 34 mln PLN allocated for research on the OATD-01 molecule used in the treatment of respiratory diseases and being in the first stage of clinical trials, the company managed to obtain 21 million from public grants.^[8] In turn, Adamed focuses on the development of its two departments - oncology and neuropsychiatry. In these areas, its innovative molecules, such as the selective MDM2 protein inhibitor with potential use in the treatment of sarcomas, lymphomas and leukaemia and the double specific ligand targeting 5-HT₆ and 5HT_{2A} serotonin receptors that can be used in the therapy of mental disorders, are currently undergoing a preclinical research phase.^[9] In another area of biotechnology it conducts research on Medicalgorithmics. The company is developing its ECG TechBot telemedical technology, which is to be used to fully automate the verification and interpretation of heart echo results. This project has received over 6 million PLN of funding from NCBiR.^[10] Synectik company also conducts research in the field of cardiology. Its globally innovative radiopharmaceutical, which is in the second phase of clinical trials, is to improve the diagnosis of coronary artery disease using positron computed tomography.^[11] Bioton, as the oldest Polish biotechnological company registered on the Polish stock exchange, is a well-known producer of human insulin. The hormones of this company are exported not only to other European countries but also to Asian markets.^[12] PSCB tries to create an innovative drug for peo-

ple suffering from atrophic lateral sclerosis. The research on ATMP based on mesenchymal cells of Wharton jelly is currently underway. Subsequent stages of clinical trials are to include at least 100 patients and end in 5 years' time from now at the earliest. Celon Pharma has in its portfolio as many as 12 innovative research projects, of which the most advanced is the study on esketamine in the treatment of drug-resistant depression currently in the second phase of the clinical trials. Half of the funds (PLN 12 million) needed for Phase II of clinical trials were obtained by Celon from the funds of the National Centre for Research and Development).^[13]

The area of R&D in biotechnology is very capital intensive. Recognition of the biotechnology sector by the Polish government as a priority sector makes it easier for enterprises to apply for public funding for R&D projects on which biotechnology units spend the most funds.^[14] The existing and newly established biotechnological companies may apply for financial support from the government or the European Union. The amount of co-financing is determined on the basis of analysis of the number of new jobs created or the amount of financial outlays that a given entity has incurred for the investment. In the case of scientific research, the funds are usually provided by the National Centre for Research and Development.^[1] The enterprises and other entities operating in the field of biotechnology very often see in their R&D activities an additional source of profit because they see business benefits in them. The money spent is intended to pay for itself in the future. However, entrepreneurs are often not aware that their activities qualify as R&D works. The investments in future development, testing, prototyping are only some of the terms used by the unaware entrepreneurs. Meanwhile, the research projects are carried out through the development of innovative technologies or development of the new production processes.^[15] In Europe, the UK is the leader when it comes to raising funds and making money from biotechnology. The British biotechnology companies in 2017 earned more than twice as much (£234 million) as in 2016 (£105 million). In addition, these companies have raised £515 million in venture capital funds and £452 million in further funding. Additionally, in Europe, the UK has the largest number of medicinal products in clinical development (15 products in Phase III of clinical trials) or pre-clinical (351 products).^[16] In recent years, the UK government has also introduced favourable tax regimes for biotechnology investors, including R&D tax reliefs and the launch of a government-supported partnership known as Biomedical Catalyst.^[16]

With the expansion and growth of the biotechnology sector, in addition to increasing financial resources, the demand for human resources is also going up, especially for highly qualified specialists. Since 2011, the number

of employees in the sector in Poland has increased from 1972 to 3321 persons. For comparison, 3840 people were involved in a related sector of nanotechnology in 2017 in Poland.^[3] Additionally, in the group of industrial enterprises active in innovation in the years 2015-2017, the enterprises involved in the production of pharmaceutical products took first place. The CSO report entitled "Innovative activity of the enterprises in the years 2015-2017" indicates that as much as 57.7% of such enterprises implement innovative solutions. Further places in the ranking were taken by entities producing computers, electronic and optical products (52.9%) and entities engaged in mining of hard coal and lignite (50%).^[17] In the case of service companies, most of the companies active in innovation are operating in the insurance, reinsurance and pension funds sector - 73.1% of the sector's entities. Fewer than 70.5% of the companies providing services in the field of scientific research and development works, i.e. also biotechnological companies, implement measures increasing the level of innovation of their services.^[17]

The biotechnology sector is also classified as a high technology sector. According to the statistical data, in Poland, in 2017, this sector employed 3% of all people working in the Polish economy. Such a result places Poland among such European countries as Romania (3%), Cyprus (3.1%) and Portugal (2.9%). The highest result was recorded for Ireland (8.4%) and Switzerland (6.3%), while the lowest rate of employees in high technology sectors in the total number of people employed in the national economy was recorded for Turkey (1.1%).^[18] In Great Britain, between 2009 and 2018 an increase by 17400 persons being in employment in the biopharmaceutical industry was observed in the sector.^[4] According to Eurostat statistics, the percentage of people employed in high and medium technologically advanced industries and knowledge-based sectors in the years 2008 - 2016 increased by about 3 percentage points, from less than 42.9% to 45.8% of all employees.^[19] In 2016, in various EU countries, the percentage of people employed in these areas ranged from 27.8% to 57.6%. Taking into account only the high- and medium-technology sectors, the highest share of people employed in them was observed in the Czech Republic (11.5%), Slovakia (10.8%) and Germany (9.8%). In terms of persons employed in knowledge-based industries, the highest results were recorded in Sweden and Luxembourg, representing 53.2% and 51.5% of the total employment, respectively.^[19] The Eurostat report states that in the whole of Europe, the R&D sector, including both enterprises and government institutions as well as higher education units and private non-profit organizations, involved 1.2% of the EU population in 2015, which translates into over 2.8 million jobs.^[19]

Europe remains a strong region for biotechnology, with Cambridge in the UK as the leading centre. Switzerland is

also considered to be one of the strongest biotechnology centres on the continent, due to its educational and research environment for highly skilled workers, its liberal business environment and access to venture capital. Liv Minder, Director of Investment Promotion at Swiss Global Enterprise, said that the Swiss Parliament asked the government to develop a proposal for a "future fund" that would include "pension funds investing venture capital in promising economic sectors, including biotechnology".^[20] In Denmark, despite restrictions in raising funds from venture capital, the country has a strong advantage in terms of technology transfer, which "imitates the American system as far as the patent rights of universities are concerned", claims Jannik Grodt Schmidt, Investment Manager of Invest in Denmark.^[20] The Medicon Valley, a bi-national cluster covering the Oresund region in eastern Denmark and southern Sweden, is an area where 350 biotechnology, medical and pharmaceutical companies with local R&D centres and world-class life science universities are located. Novo Nordisk, LEO Pharma, Baxter Gambro and Lundbeck are among the largest companies located there. The Medicon Valley website informs that the region attracts 90% of Scandinavian life science graduates and has 6,000 PhD students as well as it employs 40,000 people in life science.^[20]

Easier access to capital would allow to change the market profile from research and prototyping to commercialization of innovative products. However, the changes in this area require actions of the legislators, which would allow enterprises to develop far-reaching development strategies. Despite these difficulties, already more than 75% of the surveyed companies are planning to sell their business, technology or sign license agreements with larger corporations.^[5] Only slightly more than 15% of the companies declare that they are currently in the phase of launching their product on the market but the vast majority of them plan and want to start making money from their innovations in the future.^[5] A great opportunity for development of Polish biotechnological enterprises is seen in cooperation with the academic centres. However, over 90% of companies participating in the survey perceive such cooperation as negative or only moderately positive.^[5] In order to accelerate the development of the sector, this problem would need to be analysed in more depth in order to identify its reasons.

Additionally, the experts stress the need to implement the "Open Innovation" model on the Polish market.^[5] It assumes the cooperation of individuals with the environment in order to make the best possible use of available technologies, know-how and human resources, as none of the entities is able to employ all the best specialists in a given field. Such a model of action effectively allows not only to reduce the risk taken by innovative activities but also to gain access to new sources of financing, optimise

resources and increase the development potential.^[5] This type of cooperation in Western Europe is very common and brings measurable benefits. Close cooperation between universities, hospitals and industry has made Denmark a world leader in biotechnology research and innovation. In fact, the Medicon Valley in Denmark is the third largest centre, after the one established in France and Germany, where the most commercially available drugs are produced.^[21-23] "The biotechnology cluster in Denmark clearly shows the importance of communication between scientists in laboratories, industrial scientists and clinicians in hospitals", writes Dr Rasmus Beedholm-Ebsen.^[21]

Conclusions

In summary, analysis of Polish and foreign statistical reports and literature suggest that the medical biotechnology sector is a dynamically developing sector, and the increasing demand for innovative treatment methods is driving the development of this market branch. The analysis of statistical reports of the CSO indicates that the Polish market of biotechnological drugs is an emerging market and still at an early stage of development. Foreign, international pharmaceutical corporations, which operate in the Polish medical biotechnology sector, have a large share in its development.

Authors declare none potential conflicts of interest.

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