Pharmaceutical sector worldwide, further growth prospects

The current value of the global pharmaceutical industry is ca. USD 1,000 bn (it is expected to be growing less than 10 per cent in the nearest future). The United States (28 per cent of worldwide sales), the European Union (15 per cent) and Japan (12 per cent) are the key global markets for pharmaceutical industry. These three markets make ca. 55 per cent of pharmaceutical product sales volume worldwide. However, they may be gradually losing their significance in the years to come with the tendency of the governments in Western countries to cut down healthcare expenditures, including drug reimbursements. In the nearest future, emerging economies (the so-called pharmerging markets) will be the key driving force for the sector as their governments will be considerably increasing healthcare expenditures. Among these economies, China will be the biggest player. It is already an important market, the significance of which will grow rapidly in the future.

The projections that are being made include society-aging-related (particularly in Europe) generic drug market growth and using biotechnology as drug manufacturing tool as two most important trends for sector growth. In 2012, up to 7 out of 10 global blockbuster drugs will be biotechnological medicines.¹

Description of the pharmaceutical sector in Poland

The past twenty years have seen a number of fundamental changes in the Polish pharmaceutical market, which is one of the oldest industries in our country. Ownership structure of companies has changed with state-owned companies turning into private entities. New regulations such as amended drug sales rules have been implemented. In terms of administration, public healthcare management system has changed (Healthcare Funds were established and then replaced with the National Health Fund (NHF). The sector structure has also changed: we have observed a gradual increase in the number of retail and wholesale pharmacies and subsequent consolidation thereof and the increasing significance of foreign investors operating in the pharmaceutical industry.²

Diagram 1. Polish pharmaceutical market value and dynamics

In the last 10 years the pharmaceutical market in Poland has seen continuous growth, reaching PLN 22.3 bn in 2011. The sales noted impressive increase – by 11% in the comparison to the previous year. In 2010, pharmaceutical industry generated 0.8 per cent of the Polish GDP. Currently Poland is ranked as the biggest medical market in Central Europe (sixth biggest in Europe) with bright outlook for the coming years.

Healthcare expenditures amount to 7.4 per cent of the Polish GDP, which surpasses the average expenditures in the region but is lower than in Western Europe (10%). As much as 68 per cent of the expenditures are covered by the National Health Fund, while families cover 24 per cent. According to the forecast, by 2016 healthcare expenditures in Poland will have increased by ca. 50 per cent to reach PLN 150 bn, and the share of the state in this amount is due to increase³.

Medical market is divided into 2 segments: pharmacies and hospitals. In 2010 86% of medicines in Poland were sold in pharmacies, with prescription drugs (reimbursed or not) making 67% of market value and other drugs sold in pharmacies making 19%. Drugs destined for the hospitals made the remaining 14% of the market value.

² “Jak zmienił się rynek farmaceutyczny w Polsce.” Aptekarz Polski, wrzesień 2011, nr 61/39 online. [The Way the Polish Pharmaceutical Market Has Changed.”, Aptekarz Polski, September 2011, no. 61/39 online].
According to BMI, Poland is becoming more and more attractive investment location for R&D and clinical trials, thanks to a large population of patients and relatively low operational costs. In 2010 the value of the said market was ca. PLN 900 million, which made it the largest such market in Central and Eastern Europe, and in the coming years it is expected to grow by 5 per cent annually according to the forecasts by the analytical company PMR. From 17,000 new trials registered worldwide in 2009, 469 trials (2.5 per cent) were registered in Poland. Our country is ranked 10th worldwide in terms of the number of centres carrying out clinical trials and among the so-called emerging markets (1.176 centres, 1.6 per cent of all clinical trials carried out clinical trials worldwide). There are about 50 centres in Poland, which accept contracts for performance of clinical trials. Some companies such as AstraZeneca have decided to open their own clinical trial centres. Most clinical trials are carried out in oncology and cardiology, but also diabetology and pulmonology.6

Labour market potential in Poland

In the first half of 2012 there were over 21,000 employees in pharmaceutical production sector, which amounted to ca. 0.26 per cent of the total number of employees in Poland. Every third employee was employed in a small or medium-sized company. The estimated total employment rate in the pharmaceutical sector is 31,000 employees with 11,000 of them employed in innovative companies. Retail and wholesale pharmacies offer another 80,000–90,000 workplaces.5 There are about 4,000 employees in the biotechnological sector.

Labour market potential is determined by a large number of students of pharmacy and biotechnology. In 2009/2010 there were more than 8,000 students of pharmacy. Nearly 13,000 students chose to study biotechnology. Pharmacy as a field of study is offered by 12 medical universities in Poland. 39 higher education institutions, including universities, agricultural universities and universities of technology offered biotechnology as a field of study (30 institutions offered PhD studies).6 In 2009/2010 there were over 4,100 biotechnology and pharmacy graduates. The greatest numbers of pharmacy students were reported in Śląskie (12.3 per cent of the total number of pharmacy students) and Lubelskie and Małopolskie Provinces (11.3 per cent in each province). In case of biotechnology (available in 15 provinces), the biggest numbers of students were reported in Śląskie, Dolnośląskie and Łódzkie Provinces (14.3 per cent, 14.0 per cent and 11.9 per cent respectively).11 Except for studies in the Polish language, higher education institutions also introduced biotechnology studies in the English language. Furthermore, 208 colleges in Poland educate pharmaceutical technicians.10

It is estimated that currently there are too many graduates, and this applies particularly to biotechnology as the market growth in Poland is slow. Nonetheless, as regards the latter profile, for many years the number of applicants has been invariably four times bigger than that of the available places.

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8 Wkład innowacyjnego przemysłu farmaceutycznego w rozwój polskiej gospodarki, Raport, PwC 2011.

9 Otwarte centra kontraktowe w Polsce, 2012, s. 54–56. “Drug Manufacturers’ Bet on Poland” (“Dziennik Gazeta Prawna, 21 October 2011”)


Foreign investors have the biggest share in the Polish pharmaceutical market. For the last 20 years they have been opening new sites and taking part in privatisation of existing companies. Germany, France and Great Britain are the main countries investing in the pharmaceutical sector in Poland. The largest enterprises in the Polish market are foreign corporations: Sanofi (France), Novartis (Switzerland) and GSK (UK).

It is also worth noting that business expenditures for B+R projects in Poland increased last year over 800% (from PLN 258 mln to PLN 2.12 bn). Also, public expenses in this field noted a significant increase – Ministry of Science and Higher Education funds together with National Centre of Science and National Centre of Research and Development grants amounted to PLN 1.28 bn.

Foreign investors perceive Poland as a country with high-level knowledge and research potential. A focus on Polish pharma industry on the manufacture of generic medicines creates possibilities for investing in the development of innovative medicines in the pre-clinical phase, which involves relatively lower costs. Manufacturers of traditional medicines (e.g. Adamed Group and Celon Pharma Sp. z o.o.) and companies working across the biotech and pharmaceutical industry (e.g. Selvita S.A., Birit S.A., Celther Polska Sp. z o.o., Stem Cells Spin S.A. and Proteon Pharmaceuticals S.A.) are increasingly focused on the development of new innovative medicines. Poland offers also good conditions for the development and manufacture of biosimilar medicines which are likely to be the future of the pharmaceutical industry.  

Investments and market potential

Poland has one of the lowest annual per capita drug expenditures in Europe amounting to EUR 114 which represents 52% of the European average. Drug prices in Poland are also among the cheapest in Europe (44% of the European average). Consequently, according to research companies, Poland remains a long-term market leader in the pharmaceutical industry and the most attractive market in the CEE. One of the reasons is that Poland has relatively large and aging population which places the country among the top 14 largest global pharmaceutical markets, 6 largest markets in Europe and second largest in the CEE (after Russia). Other important factors include the increasing acceptance of self-medication and the growing number of patients with diabetes and hypertension. It is estimated that despite the market turmoil in 2012 due to the introduction of new reimbursement regulations, the pharmaceutical market is set for a dynamic growth. However, expert forecasts vary considerably as to the expected rate of growth. According to Espicom, Polish pharmaceutical market will grow 9.2 annually in PLN (about 10% in USD) between 2011 and 2016 whereas Datamonitor is forecasting an average annual growth rate of 4.9% between 2010 and 2015. 

Polish pharmaceutical sector has extensive know-how in the manufacture and improvement of generic products which account for 85% of the total market turnover by quantity and 66% by value. According to Business Monitor International (BMI), the market share of generic products in Poland will fall within the next 10 years to about 50% of the total turnover. At the same time, the market is expected to grow from PLN 14.4 bn to PLN 18.5 bn in 2016, i.e. at an annual rate of 5.2 (8.7% in USD) due to domestic demand and budgetary savings in other countries.

Technology parks, clusters and industry groups

According to PwC, each pharmaceutical company takes part in at least 5 projects aimed at building an industry coalition. Therefore, the pharmaceutical industry includes a number of clusters and technological parks providing an infrastructure for development of innovative biotech and pharmaceutical products, particularly laboratory facilities.

Source: PwC

Figure 2. Pharmaceutical and Biotechnology clusters and Science and Technology Parks in Poland

The list of clusters is provided below:

1. Nutribiomed Cluster
2. The Wroclaw Research Centre EIT+ Wroclaw Technology Park
3. The Jagiellonian Centre of Innovation
4. LifeScience Cluster Kraków Technology Park
5. Polish Technology Platform for Innovative Medicine
6. Ostroba Biocentre Consortium
7. The BioTechMed Advanced Technology Centre
8. Technopark Łódź
9. Nutribiomed Cluster
10. The Wrocław Research Centre EIT+ Wroclaw Technology Park
11. The Wroclaw Research Centre EIT+ Wroclaw Technology Park
12. The Wrocław Research Centre EIT+ Wroclaw Technology Park
13. The Jagiellonian Centre of Innovation

The cluster was established in 2007. It has 40 members, including: 6 higher education institutions (e.g. Wrocław University of Environmental and Life Sciences, University of Wrocław, Wrocław Medical University

12. Own materials
18. ibidem, 2012, page 62
23. ibidem pages 5–7 and information obtained from various institutions.
and Poznań University of Life Sciences), 3 business support institutions (including Wrocław Technology Park) and 31 companies.

The main idea behind the cluster is to combine innovative knowledge-based economy with development of biomedical technology to manufacture food supplements, nutraceuticals and products for pharmaceu
tical use. Activities of the cluster are also aimed at improving food preservation technologies and creating modern bioplastic packages. The cluster covers the area of Lower Silesia, southwest and central Poland.

2. LifeScience Cluster Kraków

Established in 2006 on the initiative of the Jagiellonian University, LifeScience Cluster Kraków comprises several dozen institutions, including 21 enterprises, 15 health institutions, 5 science and research institutes (including the Institute of Pharmacology of the Polish Academy of Sciences), 6 higher education institutions, 19 business environment institutions and 5 institutions representing local and state authorities in the region. The objectives of the cluster include supporting entrepreneurship and innovation in the area of life science and creating conditions for successful commercialization of research.

3. Polish Technology Platform for Innovative Medicine (PTPIM)

PTPIM was created in 2003. It comprises 20 entities, mainly enterprises engaged in conducting and financing research projects on new medicines, medical technologies, modernisation of medical equipment and innovations for the medical market. The main goal of the cluster is to support development of innovative pharmaceutical solutions and improve competitiveness of the pharmaceutical sector in Poland.

4. The BioTechMed Advanced Technology Centre

BioTechMedCentre is a consortium of entities, mainly R&D and business environment institutions, including the Centre of Molecular and Macromolecular Studies and the Institute for Medical Biology of the Polish Academy of Sciences. The Centre holds 14 patents and 4 patent applications. It is committed to conducting joint long-term R&D and research and implementation projects for developing new technologies and services in areas related to protection and improvement of human health and environmental protection using advances in biotechnology, technology and medical sciences. Research projects conducted within the consortium cover areas of medical biology, chemical biology, medical chemistry, virology as well as life and pharmaceutical sciences.

5. Ochota Biocentre Consortium of the Polish Academy of Sciences

The Consortium was founded in 2008 on the initiative of 6 research institutes of the Polish Academy of Sciences operating in the Ochota Campus in Warsaw. The founders include: Institute of Biochemistry and Biophysics, Institute of Biocybernetics and Biomedical Engineering, Nencki Institute of Experimental Biology, Mossakowski Medical Research Centre, Institute of Fundamental Technological Research and Institute of Computer Science. The objective of the consortium is to create conditions for development of innovative biotechnology companies in the region, based on the potential of biotech companies.

Contact details of all technological parks, clusters, consortiums and other industry groups are available in section “Contact details of main institutions”.

Investment incentives

Enterprises implementing new investments in Poland may apply for various forms of support as part of the so called regional aid, including non-repayable grants (state or co-financed by the EU) and tax exemptions (CIT exemption in Special Economic Zones and local tax exemptions).

Investors planning investments in strategic sectors (including biotechnology sector) may apply for two types of government support for creation of new jobs and/or support for new investment as part of the “Program for supporting investment of strategic importance for Polish economy 2011–2020”. Grants are paid proportional to the degree of implementation of commitments specified in a contract between the investor and the Ministry of Economy.

Large part of the grants co-financed by the EU structural funds have already been used. One year prior to the end of the 2007–2013 budget, over 80% of the available funds have been allocated. The remaining funds are still available e.g. for investors implementing R&D projects. New round of structural funds will be available in the next financial perspective 2014–2010.

Special Economic Zones

Special Economic Zones (SEZs) are separate areas designated for conduct of economic activities on preferential terms. Businesses operating in SEZs may enjoy income and property tax exemptions in municipali
palities which have adopted a relevant resolution. They are also offered attractive investment plots with all necessary infrastructure as well as assistance in legal and administrative procedures related to their project.

Various investment incentives are also available on the municipality level, as municipalities have the power to offer exemptions for local taxes and charges, including property tax exemption.

Specific regulations relating to the sector

From May 2004, Polish pharmaceutical companies must comply with EU pharmaceutical regulations and are only permitted to export their products to other EU in accordance with such regulations.

Drug registration process in Poland is regulated by the Pharmaceutical Law implementing Directive 2001/83/EC which aims to harmonise drug registration regulations across the EU markets. According to the law, drug registration process in Poland should not take more than 210 days. In Poland, the administrative authority competent for regulatory affairs is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Warsaw (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych) under the authority of the Minister of Health.

A new drug reimbursement law effective since January 2012 has brought about significant changes to the Polish pharmaceutical market, with new provisions aiming to reduce drug reimbursement expenditures of the National Health Fund (estimated to ca. 1.5 bn PLN annually) which is equal to about 360 m EUR.

The main provisions of the Act:

- set a ceiling on reimbursement expenditure amounting to 17% of the total public healthcare expenditure. Where this limit is exceeded, pharmaceutical companies shall be responsible to pay back 50% of the overspend above the 17% limit;
- introduce fixed, official retail prices and margin for reimbursed medicines in pharmacies. Prices will be negotiated by the Minister of Health with pharmaceutical companies;
- introduce a wholesale margin of 7%, 6% and 5% for 2012, 2013 and 2014 respectively;
- set an advertising ban on pharmacies and a ban on discounts relating to reimbursed drugs.

Testimonial

“The year the Servier Group celebrated our 20 year presence in Poland. With our successful operations comes the opportunity to invest in education, R&D and since 1997, in our industrial manufacturing operations at Anpharm S.A. in Warsaw. These operations have enabled us to serve the domestic and regional markets with our innovative medicine.

In Poland we are delighted to have a well-educated, highly qualified workforce with relevant industrial experience in the pharmaceutical and life science sectors. As an investor we have had positive experiences executing capital investment projects. The availability of the required skilled in designers, contractors and with good support from our local authorities has contributed enormously to our success in these projects.

Over the last 15 years we have continued to expand our operations as demonstrated in 2011 with an investment in a new line dedicated to cardiovascular products for the local and regional markets. This brings to 135 M PLN the total invested in our manufacturing operations alone which employ up to 180 staff and service providers. Overall, the Group has invested 620 M PLN in Poland since 1992 and currently employs 720 people in manufacturing, R&D and promotion”.

Colm Murphy, Production Site Director, Servier Group (Anpharm SA)
Important institutions and contacts

TRADE ASSOCIATIONS AND CHAMBERS

Polish Chamber of Pharmaceutical Industry and Medical Devices (POLFARMED)
Łucka 2/4, 00-845 Warszawa
Tel.: +48 22 654 53 52
sekretariat@polfarmed.com.pl
www.polfarmed.pl

Polish Union of Employers in Pharmaceutical Industry
Wiśniowa 60A/4, 02-520 Warszawa
Tel.: +48 22 542 40 80
biuro@producentchelpekow.pl
www.puppt.com.pl

Employers’ Union of Innovative Pharmaceutical Companies (INFARMA)
Puławska 17, 02-515 Warszawa
Tel.: +48 22 852 82 30
biuro@infarma.pl
www.infarma.pl

Polish Council for Supplements and Nutritional Foods
Chłodna 64, 00-872 Warszawa
Phone: +48 22 620 29 34
info@krso.org.pl
www.krso.org.pl

Polish Federation of Biotechnology
Instytut Biochemii Technicznej Politechniki Łódzkiej Stefanowskiego 4/10, 90-924 Łódź
Tel.: +48 42 631 34 29
www.fibp.pl.lodz.pl

Natural Heritage Association (Ecosystem)
Krakowskie Przedmieście 66, 00-950 Warszawa
Tel.: +48 22 828 70 02+48 22 828 80 11
www.dziedzictwonatury.pl

BioTechnolog.pl
Legionowa 2/49, 20-048 Lublin
Tel.: +48 608 304 379
http://www.biotechnolog.pl

CLUSTERS AND CONSORTIUMS

Nutribiomed Cluster
Wrocławski Park Technologiczny
Klecińska 125, 54-413 Wrocław
Tel.: +48 71 798 58 08
www.nutribiomed.pl

LifeScience Cluster Kraków
Bobrzyńskiego 14, 30-348 Kraków
Tel.: +48 12 297 46 05
www.lifescience.pl

Polish Technology Platform for Innovative Medicine (PPTIM)
Wolska 88, 01-141 Warszawa
Tel.: +48 22 321 51 00
www.innowacyjnamedycyna.pl

The BioTechMed Advanced Technology Centre
Politechnika Łódzka
Stefanowskiego 1/15, 90-924 Łódź
Tel.: +48 42 631 32 66
www.biotechmed.pl

Ochota Biocentre Consortium
Instytut Medycyny Dodatkowej i Klinicznej im. M. Mossakowskiego PAN
Pawiińskiego 5, 02-106 Warszawa
Tel.: +48 22 668 52 50
www.biocentrumochota.gov.pl

InnoBioBiz Cluster Łódź
Biuro Analiz i Strategii Uniwersytetu Medycznego
w Łodzi
Koziuszk 4, 90-419 Łódź
makog.gurdala@umed.lodz.pl

TECHNOLOGY PARKS

Technology Park at the Jagiellonian Centre of Innovation
LifeScience Park
Bobrzyńskiego 1, 30-348 Kraków
Tel.: +48 12 297 46 00
www.jci.pl

The Wrocław Research Centre (WRC EIT+)
Stablowicka 147, 54-066 Wrocław
Tel.: +48 71 720 16 01
biuro@eitplus.pl

Wroclaw Technology Park
54-424 Wrocław
Tel.: +48 71 798 58 00
www.technologpark.pl

Poznań Science & Technology Park
Rudej 46, 61-812 Poznań
Tel.: +48 61 82 79 700
www.pptm.poznan.pl

Nickel Technology Park Poznań (NTPP)
Krzemowa 1, Złotniki
62-002 Suchy Las
Tel.: +48 61 65 85 499
www.ntpp.pl

Gdańsk Science & Technology Park
Trzy Lipy 3, 80-172 Gdańsk
Tel.: +48 58 739 61 17
www.gnpp.pl

Pomeranian Science and Technology Park (PPNT)
Zwycięstwa 96, 81-451 Gdańsk
Tel.: +48 58 735 11 42
www.pnpp.pl

TechnoPark Łódź
Łódzki Regionalny Park Nauki i Technologii
Sp. z o.o.
Dubois 114/116, 90-465 Łódź
Tel.: +48 42 684 44 44
www.technopark.lodz.pl