

# Country Profile

A look at the  
Pharmaceutical Industry in

## POLAND



Produced in collaboration  
with ISPE Poland



THE SOCIETY FOR  
LIFE SCIENCE PROFESSIONALS

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Dear Friends,

The idea of establishing an ISPE Affiliate in Poland was first conceived in 1999. After two years of hard work, which included complying with the intricacies of Polish law, we officially launched the Affiliate to an international audience at the ISPE Amsterdam Conference in December 2001. Over the years, I have come to realize the value of the organization and the importance of bringing together various key participants in the pharmaceutical industry and having a forum for exchanging experiences with global participants. A forum for the collaboration of individuals, industry, government, and academia was and is even more important for the country of Poland that finally became a member of the European Union on 1 May 2004. The Polish pharmaceutical industry is comprised of long-lasting tradition and has made significant contributions to the country as a whole; however, the adoption of the principles proposed and recommended by the Society and its local Affiliates has allowed a global audience to more efficiently and efficaciously implement the principles of Good Manufacturing Practice.

I am convinced that the articles presented in this profile will introduce you to the vast opportunities and contributions of the pharmaceutical industry in Poland. Today, there are more individuals employed in the pharmaceutical industry in Poland than ever before. We are excited and optimistic about the future of the pharmaceutical industry in Poland, but at the same time, we are challenged to compete in this ever-changing, global environment.

After reading the following profile of Poland, should you have any questions or would like to receive more information, please do not hesitate to contact me.

Sincerely Yours,

**Marek Ruzikowski**

Marek Ruzikowski  
Chairman, ISPE Poland



**This new feature in *Pharmaceutical Engineering* is designed so that you can tear it out, three hole drill (if desired), and keep it with other Country Profiles as they are published.**

**Look for the Country Profile on The Netherlands in the July/August issue of *Pharmaceutical Engineering*.**

# Poland - Main Opportunities and Risks in the Industry

by Andrzej Szarmanski

**P**oland, a country with a population of 39-million, a size similar to Spain, is currently one of the most important pharmaceutical markets in Europe. Its size and dynamic growth in terms of sales value provides excellent business opportunities. In 2003, the market growth was one of the highest in Europe reaching 13% and 3.1 billion Euro (\$3.6 billion USD). This article will present the main opportunities and risks of the industry in Poland.

## The EU Enlarged Market

At last! The barriers for making good business are being knocked down. There is no doubt that the new European market will soon become a source of new possibilities and benefits. In 2003, 15% of Poland's pharmaceutical production output was meant for export, but the value of sales on the EU market was absolutely marginal.

In practice, the increased accessibility to the western European markets for the new member states, and in particular for Poland having a strong and large pharmaceutical sector, might mean the "low hanging fruit" within the reach of the business, and also a chance for a long-term development driven by the strengthened export engine.

### The EU Enlarged Market

- 450 million population
- 25 countries
- 21 languages
- market value more than \$120 billion

### The Industry in Poland

- mostly generic products manufactured
- 15% of production value for export
- around 350 manufacturers
- \$1 billion invested over the last eight years
- 23,000 employees

### The Market in Poland

- 13% growth of market value in 2003
- 8,800 products registered
- OTC sales make 50% of total sales
- local industry has 30% of market value
- local industry as 70% of market volume
- top 10 companies have 40% of market value

Table A. Key industry information in Poland.

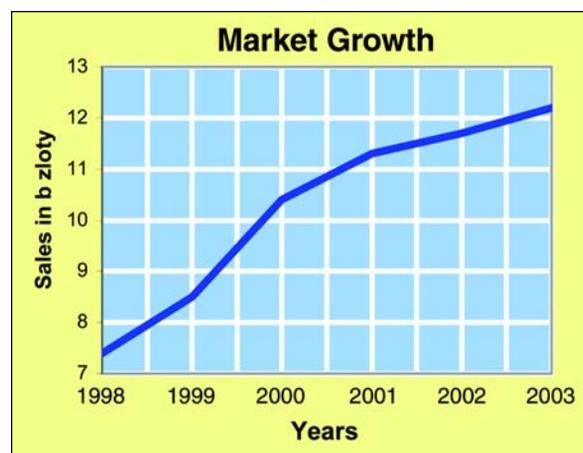


Figure 1. Market growth in Poland.

than 8,000 medicinal products. These companies have four years to update the registration files and to comply with the EU regulations. Some products which will lack sufficient quality, safety, and efficacy data will not be registered. Although demanding, the new regulatory requirements will keep the patients safer than before.

## Growing Competition

The top five players already present on the market include GlaxoSmithKline (GSK), Novartis/Lek, Polpharma, Servier, and Eli Lilly. There is a chance that some other foreign companies will follow the example of GlaxoSmithKline, which established a strong position on the market and in the region of central-eastern Europe by acquisition of a local manufacturer in Poznan. GSK invested around \$400 million in Poland and transferred more than 70 products to the site. Nevertheless, it must be emphasized that in the enlarged European Union, the importance of the site's geographical location might be much lower. In the future, the manufacturing operations may be relocated anywhere where there is assured a good infrastructure, stable tax and judicial system, as well as friendly treatment of investors.

Poland is still able to attract new investors because of the low cost of labor compared to Western Europe; however, keep in mind that labor costs have the potential to increase in the future, and there are other countries that have cheap labor. In addition, pharma-

The industry in Poland manufactures mostly generic products, i.e., products for which the patent has already expired. After accession, it should be much easier to obtain marketing authorization for such products on the EU markets.

There are approximately 350 pharmaceutical manufacturers operating on the Polish market, registering more



Figure 2. Top 5 pharmaceutical companies in Poland. Pharmaceutical manufacturers from Asia are looking forward to improve their position on the Polish market.

The competition will be tougher and tougher, and for companies which will not show a value to the patient, payer, or the regulator, it will mean a struggle to survive.

## Political Interactions

The actions on the edge of politics and business usually pose more risks than opportunities for the business processes. In the case of pharmaceuticals, the state is one of the indirect customers who subsidize a large part of patient expenditures.

The Polish government, certainly in harmony with European trends, has been undertaking various actions regarding reduction of the state expenditures for the healthcare system. First, there has been enormous pressure put on the pharmaceutical companies to reduce drug prices on the reimbursement list. Second, no new medicines have been included on the reimbursement list over the last six years, but at the same

time, some life changing products have been made available in other acceding states.

An unstable and unpredictable legal environment also can create a barrier for investment and development. Recently, frequent changes and re-interpretation of regulations led to the huge dispute between the Polish government and importers of medicines. This unsolved issue re-

### Opportunities

- growth potential of the market
- increase of export opportunities
- the same regulation for 25 member states
- registration of products in EU will be easier
- labor costs are low in Poland
- up-to-date technical infrastructure
- the culture will support new challenges
- products of proven efficacy will be kept on the market

### Risks

- new competitors will enter the market
- few experienced GMP professionals
- other acceding states have also low cost of labor
- government actions to reduce healthcare costs
- affordability of investments to meet the EU safety standards
- other states might have better tax systems and investing environment

Table B. The industry in Poland after accession.

sults in worsening of the situation for investors as well as makes the country a place less attractive for further investment.

Stable, predictable regulations, and transparent information are inevitable for business growth, especially in the pharmaceutical industry which is strongly regulated by governmental decisions.

The government efforts to bring the reimbursement costs down also takes other forms. One way considers merging several large state owned pharmaceutical companies as a way of strengthening the local state owned industry in the tough competition on the local market. It also might be perceived as another method of manufacturing cheap generic products on the market and another instrument of influencing the drug products prices. The new merged company would be one of the major players on the market.

## Good Manufacturing Practice Regulations

All acceding states must comply with the EU GMP regulations on the day of accession. The industry in Poland invested more than \$1 billion over the last eight years in the manufacturing facilities and technical infrastructure to bring them into compliance with the EU regulations.

This is a good message to the patients that the industry is developing new quality standards, and manufacturing safe, effective, and good quality products.

Once the technical challenges are out of the way, companies are able to focus on the business opportunities on the enlarged market.

One of the challenges is certainly to get the return from the investments taking into consideration that the prices of most domestic products are regulated and kept by the government at a very low level.

Implementation of EU GMP requirements in terms of their practical and cost effective application might be a challenge for the industry for the next several years, it also might mean an opportunity for reduction of manufacturing costs.

On the Polish market, due to the relatively short period of GMP implementation, there are not many professionals with practical knowledge and experience; therefore, in many cases, the manufacturers seek for external support or guidance.

## Patent Protection and Data Exclusivity

The patent on a new medicinal product provides 20 years of protection plus the possibility for another five years through a Supplementary Protection Certificate. Regardless of these regulations, the Polish pharmaceutical law from the day of accession provides six years of registered data exclusivity (three years before accession), and this law encompasses products regis-



## ISPE in Poland

by Andrzej Szarmanski

**T**he Poland Affiliate was established in 2001. The organization, although relatively new, having many excellent specialists and managers, makes a good platform for development and cooperation of industry professionals. There have been already several meetings organized by ISPE Poland to promote and facilitate training, professional effectiveness, and links between members. ISPE in Poland as a part of the international organization is open to cooperation with local regulatory authorities which may be particularly valuable after EU enlargement.

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tered back to 1 January 2000. There are plans to extend the exclusivity data protection up to 10 years across Europe which triggers a strong discussion regarding different views.

Bringing a new medicinal product on the market involves huge investments reaching in the hundred million dollar range. The longer new patented products are protected by law, the more chances are for return on investments. This in turn allows for re-investing the revenues into research and potential new drug products, bringing value to the patients and changing their lives.

### The Culture

Change was a close friend of the industry in Poland over the last decade. A reform of the pharmaceutical law, huge investments in the pharmaceutical sector, inflow of foreign investors, and know-how contributed to the culture change in the industry.

After 10 years of continuous changes, resulting change is easier to swallow. Therefore, the advantage and also the opportunity of the Polish industry is that the country is prepared to deal with change management and experienced at doing business in a much more complex environment. Growing competition has already made many of the local manufacturers implement new management techniques, lean manufacturing, and new organizational solutions. As a result, pharmaceutical manufacturers seem to be competing on the enlarged European market, and thriving at it.

### About the Author

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# The Polish Pharmaceutical Market

by Marek Ruzikowski



Continued market growth, wholesale privatization of domestic companies, investment by leading international groups, consolidation occurring in the distribution channels, and major restructuring of the funding of the Polish healthcare system add up to Poland being one of Europe's most dynamic and challenging environments for the pharmaceutical industry.

Poland is one of the largest countries in Middle Eastern Europe totaling approximately 39 million individuals. The total value of the Polish pharmaceutical market in last three years is on the rise. As you can see, in Figure 1, the Polish market is still growing. From 11.3 billion Polish Zloty in 2001 to 13.3 billion Polish Zloty in 2003.

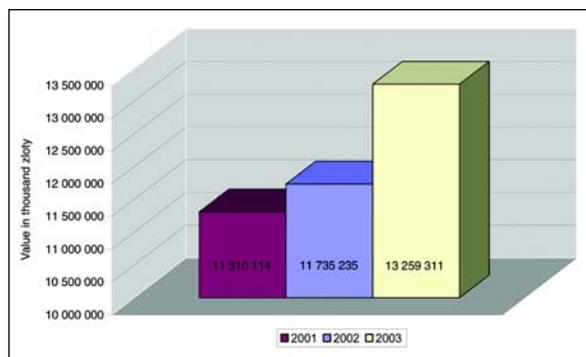


Figure 1. Polish market growth.

All of this product was sold in 10,627 pharmacies. There are about 3.3 staff per pharmacy. The better situation is in the big cities such as Warsaw, Katowice, Gdańsk; the less comfortable situation is in the smaller cities and villages.

Even after the changes in the Polish economy in the last century, the Polish market is still changing. Currently, there are about 600 companies active in the medicines field. In addition to this, there are small private companies that manufacture two or three pharmaceutical products.

The production profile of the Polish pharmaceutical industry differs from that of European standards. A majority of Polish pharmaceutical companies lack sufficient research and business resources to compete with innovative drug producers. They produce mostly generic drugs. As a result, foreign products dominate the Polish market, both in terms of the number of registered pharmaceutical products and the value of sales (the share of imports accounts for around 60 to 70 percent). The value of foreign trade in pharmaceutical products reached \$2 billion in 2001, which represented

an increase of 19 percent or \$318 million compared with the year 2000. Poland's trade balance was negative with the deficit amounting to \$1.6 billion. The value of imports amounted to \$1.8 billion (a rise by 19.1 percent) and the value of exports was \$159 million (a rise by 18.6 percent). Former Soviet Union countries are a traditional market for Polish pharmaceutical products, accounting for around 40-50 percent of the total exports. Regarding Western markets, most Polish drug exports are delivered to two countries – Switzerland (\$19.92 million) and Germany (\$16.1 million). In 2003, the Polish market sold slightly more than 1,219,870 units of medicines.

Please keep in mind that information regarding the value of sale does not mean that all of these products are manufactured in Poland. Specifically, when this information concerns big multinational companies. In case of production, this information does not include sales on exports mainly to the former Soviet Union countries.

The organization structure of the Polish pharmaceutical industry, in particular, the former state facto-

	YEAR/01 Units	YEAR/02 Units	YEAR/03 Units
Selected Market	<b>1,307,918,608</b>	<b>1,203,250,537</b>	<b>1,219,870,434</b>
POLPHARMA S.A.	154,035,593	135,399,102	133,882,490
GSK PHARMA	134,808,773	120,018,775	115,812,957
WARSZAWA ZF PLF	52,585,042	47,533,026	45,618,743
GSK PHARMA RX	48,214,264	45,327,178	43,028,604
PLIVA KRAKOW	46,590,936	40,420,435	41,678,141
JELFA	44,479,179	40,540,766	38,026,805
U.S. PHARMACIA	32,971,839	30,273,509	34,629,614
I.C.N.POLFA RZESZOW	28,938,648	28,504,822	30,444,944
SANOFI-SYNTHELABO	25,897,816	26,768,581	28,380,087
POLFA KUTNO	26,275,365	23,234,673	25,737,338

Table A. Top ten pharmaceutical companies per units produced.

	YEAR/01 Value (z)	YEAR/02 Value (z)	YEAR/03 Value (z)
Selected Market	<b>11,310,144,438</b>	<b>11,735,235,391</b>	<b>13,259,311,340</b>
GSK PHARMA	791,058,236	871,860,151	1,014,730,931
POLPHARMA S.A.	501,550,346	591,834,021	693,674,054
SERVIER	447,498,399	464,172,141	504,670,916
ELI LILLY	267,875,048	339,478,263	475,739,630
NOVARTIS PHARMA	434,926,813	416,748,088	465,740,910
SANOFI-SYNTHELABO	294,432,482	327,462,826	373,284,512
NOVO NORDISK	284,879,588	305,288,337	367,405,964
MERCK SHARP DOHME	303,776,703	319,895,353	331,039,338
ROCHE	232,975,407	253,339,199	328,029,979
JANSSEN CILAG	251,574,979	273,242,430	319,188,530

Table B. Top ten pharmaceutical companies per production value in Polish Zloty.

ries Warsaw Pharmaceutical Works "Polfa," "Polfa" Pabianice, and "Polfa" Tarchomin, is complicated. In the near future, these three companies will be reorganized under one name Polish Pharmaceutical Holding.

### R&D

At this time, there is little innovative drug research taking place in Poland although some pre-approval testing for new products is being conducted. For example, reformulated insulin (developed through biotechnology) is cited as an attempt to expand the innovative research and capacity of the industry, as well as some innovative research taking place at the Drug Institute. The scarcity of innovative research is often explained by the lack of necessary capital and facilities, despite the relative abundance of educated scientists and the sizable internal market. Anecdotal evidence suggests that researchers active in Poland must travel periodically to other countries to use laboratories abroad to support their research.

The recent formation of a biotechnology incubator clearly represents an attempt to use the intellectual capital of Polish researchers. According to industry insiders, a number of potential ideas are waiting for commercialization, but what is needed are capital and partners capable of introducing and exploiting such ideas.

	2001	2002
State healthcare budget (in million Polish Zloty)	4,600.80	3,594.10
Average monthly income per household	2,005.77	2,065.44
Average gross monthly per capita income	644.48	664.21
Average net monthly per capita income	620.47	638.41
Average monthly per capita expenditures	609.72	624.99
Average monthly per capita health-related expenditures	27.58	28.32
<i>of which</i>		
medical devices	19.33	20.39
pharmaceutical products	17.69	18.73
out-patient services	7.67	7.44

Table C. Average per capita healthcare expenditure in Poland in Polish Zloty. (1 USD = 4 Zloty)

The shortage of venture capital funds specializing in biotech and pharmaceutical companies is likely to slow the growth of the native Polish biotech industry. Also needed to foster biotech start-ups are changes to the tax law and licensing of intellectual property rights. It would be very helpful to have governmental initiative to support biotech start-ups, similar to the initiatives undertaken by the governments in many countries, such as Japan, to foster the biotech industry.

### About the Author

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## List of Contacts in Poland

### Medicines and Medical Devices

Ministerstwo Zdrowia  
*Ministry of Health*  
www.mz.gov.pl

### Organs and Units Supervised and Subordinated to Minister of Health

Urząd Rejestracji Produktów Leczniczych,  
Wyrobow Medycznych i Produktow Biobojczych  
*Office for Registration of Medicines, Medical Devices, and Biocides*  
www.urpl.gov.pl

Główny Inspektor Farmaceutyczny  
*Chief Pharmaceutical Inspector*  
www.apteka.biz.pl/giff/

### Veterinary Products

Ministerstwo Rolnictwa i Rozwoju Wsi  
*Ministry of Agriculture*  
www.minrol.gov.pl

### Organs and Units Supervised and Subordinated to Ministry of Agriculture

Główny Lekarz Weterynarii  
*Chief Veterinary Inspection*  
www.wetgiw.gov.pl

### Producers Organization

POLFARMED  
Polska Izba Przemyslu Farmaceutycznego i  
Wyrobow Medycznych  
*Polish Chamber of Pharmaceutical and Medical Devices Industry*  
www.polfarmed.pl

Polski Związek Pracodawców Przemyslu  
Farmaceutycznego  
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