



# **The Polish Pharmaceutical market**

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# The Polish Pharmaceutical market



## Introduction

Basic facts about Poland:

- The population of Poland is just over 38.6m.
- The population growth rate amounts to 0.02%.
- The capital city is Warsaw. Other main cities include Krakow, Lodz, Poznan, Gdansk, and Wroclaw.
- Currency: 1 zloty (PLN)=100 groszy. Currency exchange rates €1=PLN 4.697, \$1=PLN 3.8279<sup>1</sup>.
- Main industries include machine building, iron and steel, coal mining, chemicals, shipbuilding, food processing, glass, beverages and textiles.
- Gross domestic product at current prices was €170bn in 2003. This amounted to €4,400 per capita.
- Unemployment reached 20% in 2003.
- Poland have had an unfavourable foreign trade balance where exports amounted to €47.5bn and imports exceeded €60bn
- Top foreign investors include France, the Netherlands, USA, Germany and Italy.

Major country specific features relating to the pharmaceutical market in Poland include the following:

- The pharmaceutical market value (at manufacturer prices) in 2003 amounted to PLN 13bn, which equals to €3bn.
- In 2002 about 8,166 health treatment products were registered in Poland.
- Poland is the second European country when it comes to drug consumption in terms of volume.
- Medicine accounts for about 3% of household expenditures.
- There are about 9,500 pharmacies in Poland.
- Generic drugs dominate the market.
- Four companies (GSK Pharma, Servier, Polpharma and Novartis) account for a quarter of the whole pharmaceutical market.
- Imports of pharmaceuticals increase by 10-15% yearly.

<sup>1</sup> Average exchange rate for the period Jan-Jun 2004, it should however be noted that since June the exchange rate EUR/PLN has decreased. All figures appearing in this white paper, calculated from PLN into EUR are based on average exchange rates for 2003, Q1 2004 and H1 2004 accordingly, which are provided by the National Bank of Poland.

## Overview

The drugs market in the ten CEE countries that joined the European Union this year is about the size of the Canadian market but equals to only 8% of the size of the original fifteen member states. In spite of its relatively small size, the potential is considerable since the economic growth in Central and Eastern European countries has been impressive and has averaged 16% over the past 5 years (as compared with 8% in the EU15).

The two most important markets for the pharmaceutical industry in Eastern Europe, Poland and Hungary, contribute to over 60% of the total value of the new member states' pharmaceuticals markets. These markets have experienced almost 20% growth since 1998.

Drug consumption in Poland is expected to grow as people become increasingly aware of health issues and disease prevention and are more willing to pay for high-quality pharmaceuticals rather than use home-made substitutes. Some forecasts estimate the sales value of pharmaceuticals in Poland will amount to \$4bn in 2005.

The drugs market is not an easy one and despite an increasing convergence with western drugs usage patterns there are still many differences and numerous challenges relating to these industries. Nevertheless there is still plenty of room for competitive companies and those who decide to invest their time, effort and money here can expect attractive rewards.

## The pharmaceutical market in Poland

The pharmaceutical market is one of the most dynamically developing sectors in Poland. A considerable number of the most successful company lists include many representatives of this industry. Names which appear most often are: GlaxoSmithKline, Polfa Kutno, Jelfa, Sanofi-Synthelabo, Polpharma, Bayer, Pfizer Polska, Aventis Pharma, Novo Nordisk and Lek Polska.

The Polish pharmaceutical market is very fragmented with a large number of competing companies. In 2002 there were 328 manufacturers and 15 of them had more than a 1% market share each, together controlling 55% of the total volume and 49% of the value of the market.

According to data published by IMS Global Consulting in September 2003 the five biggest market players in Poland are: British GSK with a market share of 8.1%, Swiss Novartis (6.5%), Polish Polpharma and French Servier (5.4% and 5.1% respectively) and US-based Lilly with its 3.3% market share.

The Polish drugs market at manufacturer prices is valued at PLN 13bn (approximately €3bn), but in retail prices amounts to PLN 17bn (around €4bn). The table below shows the market value of pharmaceuticals for the period of 2001-2003.

	2001	2002	2003
<b>PLN m, manufacturer price level</b>			
- Total pharmaceutical market	11,090	11,570	13,090
- Total non-prescription market	2,830	2,630	2,970
<b>EUR m, manufacturer price level</b>			
- Total pharmaceutical market	3,019	2,998	2,975
- Total non-prescription market	771	681	675
<b>Percentage change over previous year</b>			
- Total pharmaceutical market	+10.7%	+4.3%	+13.1%
- Total non-prescription market	+15.5%	-7.1%	+13.1%
<b>Percentage of total pharmaceutical market</b>			
- Total non-prescription market	25.5%	23.1%	22.7%
<b>Main self-medication product groups in PLN m, manufacturer price level</b>			
- Cough and cold remedies	568	535	673
- Analgesics	362	376	463
- Digestives and intestinal medications	296	304	328
- Circulatory drugs	215	210	223
- Vitamins and minerals	633	578	591

Source: GUS (Central Statistical Office), 2004

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Poles buy prescription drugs most often and this accounts for about 70% of the market. In recent years self-medication has fallen as a share of the total market. In 2003 OTC pharmaceuticals accounted for 22% of the total pharmaceutical market, whilst in 1999 the figure stood at 30%.

The beginning of 2004 was not as successful as was forecast earlier. Drug sales increased by only 2-3%, while previous periods experienced rates amounting to 10% on average (with the exception of 2002), and at the end of 2003 that figure rose to 13%. Manufacturers remain optimistic and market experts estimate that the whole of 2004 should close with a 5-8% growth trend and that this level should remain stable. The reasons for the smaller growth rate are said to be the poor economic situation of the main customer group that consists of old-aged pensioners and disability pensioners as well as confusion with respect to state budget refunded pharmaceuticals, at the beginning of the year. Of all producers present on the Polish market only two companies recorded significant sales drops, the largest drop in sales being 45%. The remaining companies, however, have been successful in maintaining a positive trend.

The majority of the Polish pharmaceutical market consists of generic drugs, as opposed to the EU15 but similarly to the other CEE countries that recently joined the European Union. The share of these products in the market is valued at 70%. Patented drugs have only 1/3 of the market and it is mainly due to large price differentials, which are sometimes as big as 200%.

Price is not the main factor taken into consideration when purchasing drugs. In an OTC Track research conducted by TNS OBOP in 2003, respondents were asked about main factors determining the choice of a drug brand. 64% of respondents claimed that the most important factor was personal experience with a given drug in the past. About 1/3 said that a key determinant was: a doctor's recommendation, a moderate price level, advice given by a pharmacist or advice from a relative. 25% of people interviewed claimed that they also take into consideration: the effectiveness of the drug, the time of reaction or their habits. Only one out of ten considered attractive marketing, Polish origin of the drug, appropriate form or user-friendliness as important factors in making brand choices.

Poland is the second European country, following France, when it comes to drug consumption in terms of volume. The average Pole purchases 31 packets of medicine per year. Poles like the French expect to leave a doctor's consultation with prescription and to get a lot of packs of drugs of different types.

In 2003 the average Pole spent about €55 on pharmaceuticals, which is still less than average expenditures in western EU countries (excluding Luxembourg), amounting to €390. Nevertheless, the demand for drugs in Poland has been rising steadily. It is also worth mentioning that the expenditures on medical services are much below real value, because of a developed “grey economy” in the health business., meaning that payments for medical services are not always recorded.

	Average	employed	Households of farmers	self-employed	pensioners
<b>Total monthly household spending per 1 person in 2003 (PLN)</b>	<b>643.84</b>	<b>673.16</b>	<b>461.2</b>	<b>817.24</b>	<b>697.67</b>
medicine (%)	3.1	1.9	2.7	1.6	5.8
medicine (PLN)	19.96	12.79	12.45	13.08	40.46
<b>medicine (EUR)</b>	<b>4.54</b>	<b>2.91</b>	<b>2.83</b>	<b>2.97</b>	<b>9.20</b>
medical services (%)	1.2	1.2	1.2	1.3	1.4
medical services (PLN)	7.73	8.08	5.53	10.62	9.77
<b>medical services (EUR)</b>	<b>1.76</b>	<b>1.84</b>	<b>1.26</b>	<b>2.41</b>	<b>2.22</b>

Source: GUS (Central Statistical Office), 2004

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## Key pharmacy and hospital statistics for Poland

Drug distribution systems, consisting of wholesalers and pharmacies or other retailers, are important factors of pharmaceutical supplies. Both the wholesale and retail sector are almost fully privatised.

Poland has many pharmaceutical wholesalers, but most of them are very small. In 2002 there were about 543 wholesale outlets, mainly operating on the local market only. During the last couple of years there has been a consolidation of the warehouse market, with capital groups appearing as a result. 75% of the whole market is controlled by 4 largest companies.

Poland has witnessed an increase in the number of pharmacies since 1990 due to an economy-wide privatization process. Poland has the biggest population out of all the new EU member countries, the highest number of pharmacies, as shown in the table below (the second highest is the Czech Republic with 2,189) and the highest number of pharmacists (the second-highest country, Hungary, has three times less). However, when it comes to the number of people per pharmacy, Poland comes in the middle of the list of countries, right after Slovenia (8,027 people per pharmacy), Hungary, the Czech Republic, and Estonia – all three over 4,000 people per pharmacy.

Population	No of community pharmacies	No of people per pharmacy	No of community pharmacists	No of people per pharmacist
38,600,00	9,693	3,992	22,000	1,760

Source: The Pharmaceutical Group of the European Union

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According to the current law every entrepreneur who meets the conditions regarding staffing and premises can become a pharmacy owner. One entity cannot, however, control more than 10% of all of the country’s drug stores.

Pharmacies are the main clients for pharmaceutical companies. Only 10% of the market in terms of volume is sold to hospitals. Because of the poor economic situation of public health institutions in Poland, both manufacturers and importers are very cautious when doing business with them, as they do not pay their suppliers on time.

There are about 22,000 healthcare institutions in Poland. The table below shows the division between the public and private institutions.

State owned				Private			
Stationary healthcare institutions	Clinics	Emergency medical services	Diagnostic and analytical centres	Stationary healthcare centres	Clinics	Emergency medical services	Diagnostic and analytical centres
1,278	3,660	392	1,028	864	12,113	63	2,573

Source: GUS (Central Statistical Office), 2004

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The majority of healthcare institutions (hospitals, sanatoriums and other health care centres for people that require 24-hour-a-day medical attention) and emergency services are in hands of the state. On the contrary, clinics (where patients visit their doctor to get consultation) and various diagnostic and analytical centres are mainly private and their number is growing steadily. Private medicine is growing in Poland, as a result of widespread dissatisfaction with the level of service and quality of the state sector.

## Imports and foreign investment concerning the pharmaceutical market in Poland

According to data published by PAIIZ (The Polish Information and Foreign Investment Agency) the inflow of foreign direct investment in the pharmaceutical and chemical industry in 2003 was \$570m, which constituted 9% of all inward investments and was the second biggest area for all foreign direct investments that year. The total sum of foreign direct investments in this industry amounts to \$2.5bn.

Imports have accounted for a large share of supply for many years, which is confirmed by the Foreign Trade Data Centre. The difference between imports and exports of pharmaceuticals amounted to €1.9bn in 2003.

Imports 2003	Grand total	EU	CEE
Pharmaceutical products in PLN m	9,157.4	6,725.7	843.4
y-o-y change (100)	110.5	113.0	111.7
Pharmaceutical products in EUR m	2,082.3	1,529.3	191.7
Pro-vitamins, vitamins and hormones in PLN m	187.2	94.5	5.4
y-o-y change (100)	112.1	101.1	419.2
Pro-vitamins, vitamins and hormones in EUR m	42.6	21.5	1.2

Source: GUS (Central Statistical Office), 2004

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The table above shows that imports of both pharmaceuticals and vitamins have increased by more than 10% in 2003 as compared with the previous year. The most recent data for the first quarter of 2004 show that imports of pharmaceuticals have grown by nearly 15% in comparison to Q1 2003.

<b>Imports Q1 2004</b>	<b>Grand total</b>	<b>EU</b>	<b>CEE</b>
Pharmaceutical products in PLN m	2,459.9	1,668.7	26.2
<i>p-o-p change (100)</i>	114.7	106.5	135.3
Pharmaceutical products in EUR m	514.8	349.1	5.5

Source: GUS (Central Statistical Office), 2004

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## Drug registration

Starting with the date of entry into the European Union, pharmaceuticals approved by the Council or European Commission in accordance with the so-called centralized procedure do not have to undergo a separate registering procedure in Poland. They are automatically approved on the basis of the Pharmaceutical Law (Article 3 Clause 2) which came into force on 1 May 2004.

The lack of Polish language information on packaging or the lack of an information leaflet in Polish is an obstacle when introducing EU drugs to the Polish market. According to relevant EU regulations, data on packaging and information brochures should be provided in the official language of the country where the drug is sold into. This means that in order to launch the sales of a particular pharmaceutical on the Polish market a label draft and brochure, complete with Polish versions, need to be submitted to the EMEA Agency. Once they are accepted the drug can be marketed in Poland.

Since its entry into the EU, regulations concerning the procedure of mutual recognition have been in force in Poland. The details of those regulations are to be described in an ordinance issued by the Minister of Health.

A simplified approval procedure regarding pharmaceuticals with respect to parallel imports, introduced by the ordinance of the Court of Justice of the European Communities, is a much quicker procedure. In this case the drug should be registered in the country where it is imported from and should have the same active substance, at least the same indications, the same form, strength and way of infusion as a drug approved to be marketed on the Polish market.

Despite the fact that registration procedures have been simplified in theory there are still many obstacles in practice, especially in Polish public offices. In particular foreign companies not familiar with the Polish market may find it hard to find their way around and get through the local bureaucracy, and foreign companies often use consultancies or have their distributor take care of it.



## **Sources:**

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If you would like more information about the pharmaceutical market in Poland or other Central and Eastern European countries or if you are interested in selling in the region please contact:

## **PMR Consulting**

tel.: +48 12 413 88 48

fax: +48 12 413 40 12

[www.pmrconsulting.com](http://www.pmrconsulting.com)

e-mail: [info@pmrconsulting.com](mailto:info@pmrconsulting.com)

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## **About us**

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## Annex: Data about Poland

### Polish Economy: Annual Trends

	2001	2002	2003		Latest 2004	Forecast 2004 2005	
<b>GDP</b>							
GDP at current prices. PLN bn	760.6	781.1	814.7	Jan-Mar	203.7	-	-
GDP real change. y-o-y	1.0%	1.4%	3.8%	Jan-Mar	6.9%	5.5%	5.3%
<b>GDP components. y-o-y</b>							
total consumption	1.7%	2.8%	2.5%	Jan-Mar	3.3%	-	-
private consumption	2.1%	3.3%	3.1%	Jan-Mar	4.0%	4.3%	4.4%
gross fixed capital formation	-8.8%	-5.8%	-0.9%	Jan-Mar	3.5%	6.9%	9.1%
exports	3.1%	4.8%	13.0%	Jan-Mar	-	-	-
imports	-5.3%	2.6%	7.9%	Jan-Mar	-	-	-
<b>Added value to GDP. y-o-y</b>							
industry	-0.3%	-0.2%	7.6%	Jan-Mar	14.5%	-	-
construction	-7.9%	-6.8%	-5.1%	Jan-Mar	-3.9%	-	-
market services	2.8%	3.7%	4.1%	Jan-Mar	5.7%	-	-
<b>Output. y-o-y</b>							
industrial output	0.6%	1.1%	8.7%	Jan-Jun	17.6%	13.8%	11.1%
manufacturing output	0.1%	1.2%	10.5%	Jan-Jun	21.2%	-	-
construction and assembly output	-11.7%	-4.1%	-5.9%	Jan-Jun	-3.2%	-	-
<b>Retail sales. y-o-y real change</b>	0.2%	1.9%	7.9%	Jan-May	14.0%	-	-
<b>Prices. y-o-y</b>							
CPI	5.5%	1.9%	0.8%	Jan-Jun	2.5%	2.8%	3.1%
PPI	1.6%	1.0%	2.6%	Jan-Jun	6.6%	5.8%	3.9%
construction and assembly prices	3.8%	1.2%	-1.1%	Jan-Jun	0.9%	-	-
<b>Salaries in enterprise sector</b>							
y-o-y. real change in gross monthly salaries	1.6%	1.5%	2.0%	Jan-Jun	2.7%	-	-
gross monthly salaries. PLN	2.203	2.277	2.342	Jan-Jun	2.388	-	-
statutory minimum wage. PLN	760.00	760.00	800.00		824.00	-	-
<b>Unemployment. end of period</b>	19.4%	20.0%	20.0%	Jun	19.5%	19.4%	18.3%
<b>Current account balance of payments</b>							
% GDP	-2.9%	-2.6%	-2.0%	Jan-Mar	-1.6%	-2.0%	-2.9%
€ bn	-5.99	-5.40	-3.66	Jan-Mar	-1.67	-	-
<b>Financial indicators (end of period)</b>							
discount rate	14.00%	7.50%	5.75%	Jun	5.75%*	-	-
Lombard rate	15.50%	8.75%	6.75%	Jun	6.75%*	-	-
EUR/PLN	3.5219	4.0202	4.7170	Jun	4.5422	4.6563	4.5100
USD/PLN	3.9863	3.8388	3.7405	Jun	3.7470	3.7763	3.6950
due to the banking system from households. PLN bn	82.7	89.8	102.0	Jun	109.4	-	-
WIG	13.922.16	14.366.65	20.820.07	Jun	23.949.3	-	-
<b>Foreign trade</b>							
exports (€ bn). by GUS	40.4	43.4	47.5	Jan-May	22.2	-	-
imports (€ bn). by GUS	56.2	58.3	60.3	Jan-May	28.0	-	-
exports (€ bn). by NBP balance of payments	46.5	49.3	53.8	Jan-May	24.3	58.4	62.7
imports (€ bn). by NBP balance of payments	55.1	57.0	58.9	Jan-May	26.3	64.5	70.5
<b>FDI. \$ bn. according to PAIZ and PAIIZ</b>	7.1	6.1	6.4	-	-	-	-
<b>Market size</b>							
average monthly per capita income of households. PLN	644	664	681	-	-	-	-
average monthly per capita expenditures of households. PLN	610	625	644	-	-	-	-

\* As of 1 July: 6.25% (discount rate) and 7.25% (Lombard rate)

Sources: BH, BZ WBK, CASE, Dresdner Bank, Gdansk Institute for Market Economics, Pekao SA, PKO BP Societe Generale, WGI

