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The Expected Effects of the EU Accession on the Pharmaceutical Industry in Poland

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Table of Contents

<i>Table of Contents</i>	2
1. Introduction	3
2. General characteristics of the sector	4
2.1 Production	4
2.2 Distribution	4
3. The impact of integration on the pharmaceutical sector in Poland	6
3.1 The pace of the sector's development	6
Domestic production	6
Market size	7
The effect of integration	8
3.2 Foreign trade	9
Competitiveness of Polish producers	10
Development investments	11
Effect of integration	11
3.3 Foreign investment	14
The effects of integration	15
3.4 Labour market	15
The effect of integration	16
3.5 The sphere of institutional regulations	17
The Pharmaceutical Law of September 6, 2001	17
The Law on the Office for Registration of Medical, Medicinal and Biocidal Products	17
The Law on Prices of July 5, 2001	18
The Law on industrial property	18
3.6 Market competition level	18
The effect of integration	20
3.7 Government policy towards the pharmaceutical sector	21
4. Summary	24
SWOT Analysis	26
References:	27
Annex 1. Key pharmaceuticals' producers in Poland (2002)	28
Annex 2. Key pharmaceuticals' distributors in Poland (2002)	29

1. Introduction

The Polish market for medicaments is one of the largest and most attractive in Central and Eastern Europe. Poland accounts for almost 35 percent of trade in pharmaceuticals in that part of Europe. In 2001, almost 1.3 billion packs of medicaments worth €3.1 billion were sold in Poland. This was partly due to rapid expansion of the pharmaceutical industry in Poland, which has been among the fastest growing sectors of the Polish economy.

Integration with the European Union will be a great challenge for the entire economy. It would be difficult to find a sector or a branch not being affected by that process. Integration means that it is necessary to take up actions that would allow operation of Polish enterprises on the single European market. These are multi-level actions starting with indispensable legislative changes to align Polish legislation with Community law, and ending with the improvement of companies' competitiveness, which is required to be able to survive on the market.

The Polish pharmaceutical sector faces, first of all, the necessity to adjust to organisation and legal requirements of the European Union. Consequently, legal acts harmonising provisions of the Polish and EU law have been transposed to the Polish legislation. An overview of major legislative changes and their impact on the pharmaceutical sector can be found later in this report.

Furthermore, the present report also provides an assessment of the possible impact of integration on the pharmaceutical sector in many areas of its operation, starting from its impact on the pace of the sector development, through its effect on foreign trade and foreign investment inflow, and ending with the government policy. The report also contains an assessment of opportunities and threats concerning the pharmaceutical industry and the market for medicaments in Poland in the light of integration with the European Union.

The information contained in the "Strategy for the pharmaceutical industry until 2005", adopted by the Polish government on October 1, 2002, has served *inter alia*, as a source of reference for this report.

2. General characteristics of the sector

2.1 Production

The pharmaceutical industry is a part of group 24.4 according to the NACE Classification. The group is made up of two classes:

- Manufacture of basic pharmaceutical products (24.41), which covers, inter alia, manufacture of medically active substances and blood transfusion
- manufacture of medicaments of pharmaceutical preparations (24.42), which covers, inter alia, manufacture of medicaments, antisera and vaccines, chemical contraceptive preparations, adhesive dressings, catgut and similar materials; first-aid boxes.

In Poland medicaments are produced by 66 firms jointly employing above 22,500 persons (these data relate to operators employing more than 49 persons). Apart from that, there are several dozen small, private plants manufacturing mostly OTC¹ medicaments. Subsidiaries of foreign pharmaceutical companies, such as Lek-Poland, Solco-Basel, Rhone-Poulenc-Rorer and Schwarz-Pharma are operating in Poland as well.

The pharmaceutical industry also covers:

- scientific and research institutes (e.g. the Drug Institute - *Instytut Leków*);
- 10 herbal medicines plants (Herbapol);
- 14 chemical and pharmaceutical co-operatives;
- 3 manufacturers of veterinary preparations (Biowet);
- 3 manufacturers of antisera and vaccines (Biomed).

2.2 Distribution

The Polish distribution market for pharmaceuticals consists of three parts. The first of them is the so-called pre-wholesale, with pre-wholesale distributors acting as intermediaries between manufacturers of medicaments and wholesale warehouses as well as hospitals. Companies established in the early 1990s, dealing with pre-wholesale trade originated mostly from importers of a group of medicaments and serviced many manufacturers. Apart from them, pre-wholesale market is penetrated by small companies specialised in serving specific manufacturers.

The second part of the distribution market is made up of wholesale warehouses, whose number in Poland is estimated at about 400. This group shows considerable variations in the scope of operations, involving local, supra-regional and nation-wide warehouses. Wholesale warehouses are the actual provider of medicaments for pharmacies and hospitals. Pharmacies, accounting for almost 90 percent of trade in pharmaceuticals are the major buyers of medicaments from wholesalers, with hospitals accounting for the remaining part.

Pharmacies are the third link in the medicaments distribution chain. There are more than 9,500 pharmacies in Poland, which means that the number of inhabitants per pharmacy is approx. 4,000. Hence, the density of the network of pharmacies does not differ significantly from the European Union average, totally roughly 3,300 customers per pharmacy.

¹ OTC (over the counter) – medicaments, which can be sold by pharmacies without prescription.

According to CENTRAL STATISTICAL OFFICE estimates, in the year 2000, an average Pole spent \$45 on medicaments, which constituted one eighth of the German spending. However, such a considerable difference is the case only in terms of value, as the quantity of medicaments sold in Poland is not lower than that sold in Western Europe. This is due to the fact that despite their increase in recent years the prices for medicaments in Poland still account for less than a quarter of respective prices in the European Union countries, being at the same time approx. 30 percent lower than the prices in the Visegrad Group countries.

3. The impact of integration on the pharmaceutical sector in Poland

3.1 The pace of the sector's development

Domestic production

According to estimates based on the results of the first six months of the year, in 2002 the revenues of the pharmaceutical industry in Poland exceeded €1.8 billion, which was about €100 million more than in 2001, and almost €500 million more than in 2000 (Fig. 1).

Fig. 1. Total revenues of pharmaceuticals manufacturers in Poland
(current prices in € billion at an average Central Bank exchange rate)



Source: Own calculations based on the CENTRAL STATISTICAL OFFICE data

Revenues of the pharmaceutical industry have been increasing steadily since the early 1990s, and in this respect that sector is among the fastest growing ones. Nevertheless, the quick rise in revenues of medicaments' manufacturers results partly from a significant increase in prices for pharmaceuticals in Poland. Since 1998, the price index for medicaments in Poland has been surpassing the inflation index, but over the last two years the growth rate of pharmaceuticals prices slowed down substantially (Table 1).

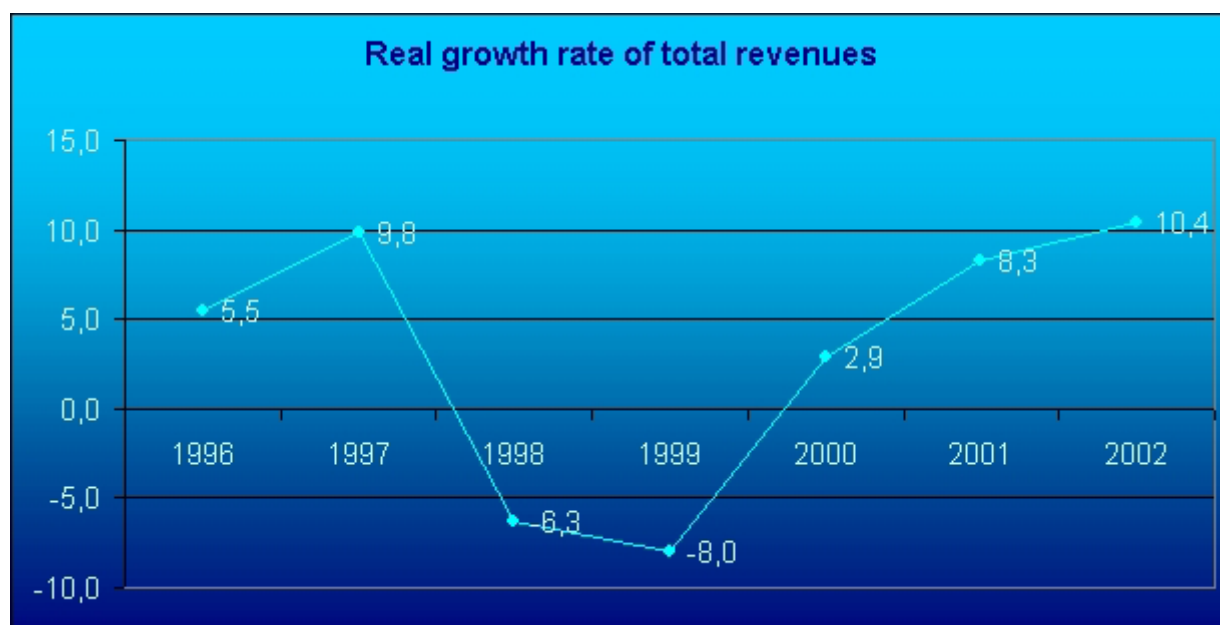
Table 1. Pharmaceutical price index in Poland and inflation
(previous year = 100)

	1996	1997	1998	1999	2000	2001	2002
Price index for medicaments	121.7	114.9	116.3	115.6	112.6	107.5	105.9
CPI	119.9	114.9	111.8	107.3	110.1	105.5	101.9

Source: CENTRAL STATISTICAL OFFICE

According to estimates, in 2002 the real growth rate of revenues of medicaments' manufacturers, adjusted for price growth, amounted to 10.4 percent, which was by more than two percentage points higher than in the previous year. In the second half of the 1990s, only the years 1998 – 1999 saw a real decline in the revenues of pharmaceuticals' manufacturers (Fig. 2).

**Fig. 2. Real growth rate of total revenues of pharmaceuticals' manufacturers
in Poland (percent; constant prices in PLN)**



Source: Own calculations based on CENTRAL STATISTICAL OFFICE data

Market size

The size of the Polish market for medicaments in 2002 is estimated at PLN 11.7 billion, i.e. ca. €3.1 billion². That value covers domestic manufacturers' sales and imports, which accounted for some 65 percent of sales in terms value. Considering quantity, imported medicaments accounted for about 30 percent of sales, but their prices were, on average almost four times higher.

In the period 1998 – 2001, the value of pharmaceuticals' sales on the Polish market had been growing steadily. This, however, constituted growth mostly in terms of value, enable largely by an increase in medicaments' prices. The data provided by IMS Health company, which has been monitoring the market indicate that during that time the number of packs of medicaments sold in Poland increased by slightly more than 2 percent, while the value of sales soared by above 55 percent. Estimates for the year 2002 point to a fall of about 100 million pieces in the number of packs of medicaments sold in Poland and to a slight decline in the market value expressed in euro. The value of sales at current prices in PLN grew by approx. 3.5 percent in 2002.

Table 2. Size of the Polish pharmaceutical market

	1998	1999	2000	2001	2002
Volume	1.28	1.32	1.32	1.31	1.20
(billion packs)					
Value	1.9	2.0	2.6	3.1	3.0
(€ billion)					

Source: IMS Health; estimates for 2002

The above data cover exclusively wholesale trade sales of medicaments. Between 300 and 400 million packs of pharmaceuticals are sold outside wholesale trade. Hence, the entire size of the Polish pharmaceutical

² IMS Health data.

market, taking into account also sales outside wholesale trade, ranges between 1.5 and 1.6 billion packs, with its value estimated at €3.7 billion.

The effect of integration

Poland's integration with the European Union should not affect development trends in the Polish pharmaceutical sector to a major extent. Unless unexpected accidental shocks occur (e.g. a deep economic crisis), a further dynamic growth of the sector should be expected.

To some extent, integration with the European Union should speed up that upturn. This will be the consequence of several mechanisms. First, integration will accelerate the growth rate of the entire Polish economy, which will result in a faster rise of real incomes of the population. This growth will stimulate demand for medicaments, especially OTC ones, which are characterised by a higher price elasticity of demand compared to that of medicaments sold on prescription.

Second, integration with the European Union will contribute to accelerated modernisation and restructuring of manufacturing plants, which will be partly associated with increased involvement of foreign investors. This will bring about a rise in the efficiency of company operation and will allow improved market offer of pharmaceutical companies. This process should also result in increased demand for certain kinds of pharmaceutical products.

Third, integration with the European Union will indirectly contribute to a surge in exports of Polish medicaments, especially to the EU markets. A rise in foreign demand will be another factor speeding up the sector's expansion.

Both the market and the entire pharmaceutical sector in Poland face good development prospects. According to World Bank forecasts, the average annual growth of the pharmaceutical market in Poland in 2003 – 2005 will be between 8 and 9 percent, and the value of per capita sales of medicaments will grow at that time by above 50 percent.

Even more optimistic forecasts are presented by IMS Health. According to their analysts, by 2004 the sales of medicaments in Poland should soar by an average annual rate of 14.5 percent. In 2004, Poland will still remain the largest pharmaceutical market in Central and Eastern Europe, and its value may reach \$4.5 billion that year.

Summing up, it should be emphasised, that Poland's integration with the European Union offers numerous opportunities for the Polish pharmaceutical industry. Nevertheless, the integration itself will not be a breakthrough, but only the culmination of processes which have been occurring in the sector for many years.

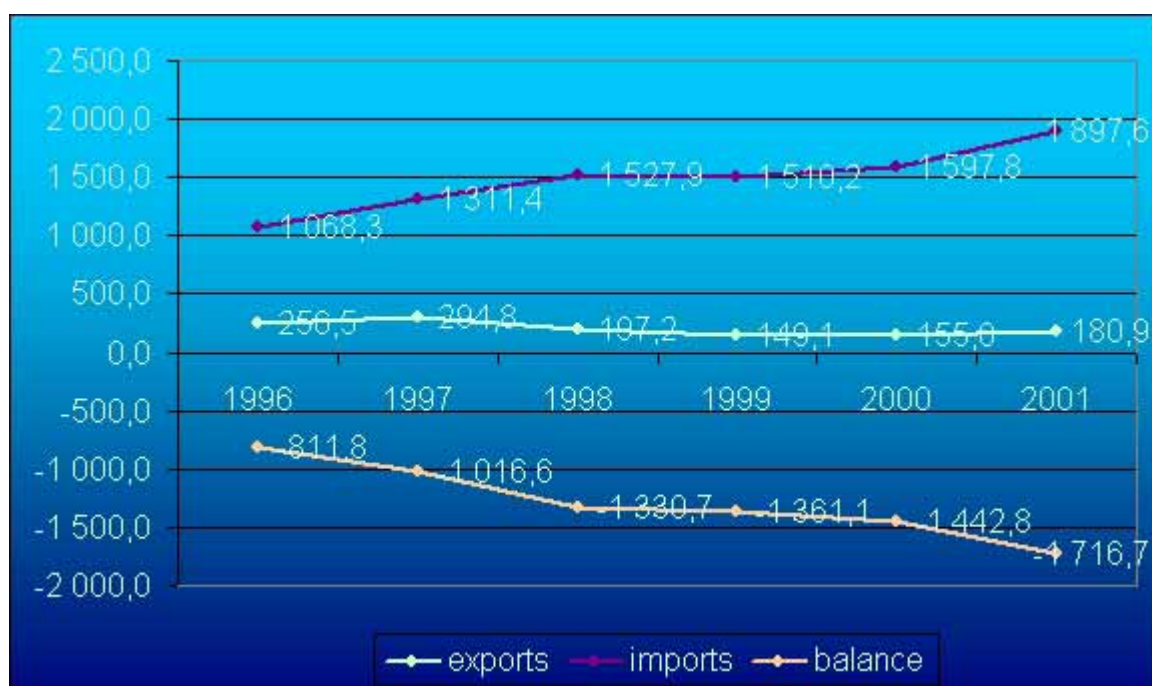
On the other hand, one cannot expect positive effects of integration for the pharmaceutical to occur immediately following Poland's accession to the European Union. As in the case of the entire economy, advantages will appear in the long-term perspective. For the European integration to become a strong incentive for the development of Polish pharmaceuticals, an appropriate healthcare policy of the government will be required in the future. Namely, the pharmaceutical industry in Poland is one of the sectors of the economy which is particularly sensitive to institutional regulations associated with politics. In view of failed systemic solutions, the chance created by Poland's integration with the European Union may not be fully utilised by the Polish pharmaceutical sector.

3.2 Foreign trade

Poland is a net importer of medicaments as well as pharmaceutical and medicinal products. In 2001, imports of these products totalled almost \$1.9 billion, while their exports amounted to only \$180 million. Consequently, the trade balance closed with a deficit of above \$1.7 billion.

Since 1996, the trade deficit in pharmaceuticals has been growing (Fig. 4). Over five years the deficit more than doubled recovered from slightly more than \$800 million in 1996. During that time the value of exports dropped by some 30 percent, while that of imports shot up by almost 80 percent.

Fig. 3. Poland's exports, imports and balance of trade in pharmaceuticals
(\$ million)



Source: CENTRAL STATISTICAL OFFICE

The commodity composition of Poland's foreign trade in pharmaceuticals is dominated by medicaments, including veterinary ones. In 2001 they accounted for above 85 percent of imports (\$1.6 billion) and almost 75 percent of exports (\$130 million). The remaining part, i.e. 15 percent and 25 percent of imports and exports, respectively consisted of other medicinal and pharmaceutical products. Since 1996, the commodity composition of exports has been more or less stable, while in imports the share of medicaments went up significantly from 79 percent in 1996. Hence, over five years that share increased by 6 percentage points.

The commodity composition of Poland's trade in pharmaceuticals is different for exports and imports. Poland imports medicaments and pharmaceutical products mostly from advanced economies. In 2001, France and Germany, the two major suppliers of those products, accounted for 18 percent and 15 percent of Polish imports, respectively. Switzerland with an 8 % share is ranked third. We should also mention three more countries: the United Kingdom, the Netherlands and Italy, each of them having a 7% share in Polish imports .

At the same time, Russia is the major importer of medicaments from Poland. In 2001, that country accounted for almost 35 percent of Polish exports of pharmaceuticals. Germany, with a 12-percent share was ranked second, and Lithuania with a 10% share was number 3. Among importers of pharmaceutical products from Poland the following ranks are occupied by Ukraine, the Czech Republic, Latvia, Hungary and Belarus.

Competitiveness of Polish producers

Medicaments produced in Poland are almost exclusively generic, i.e. duplicative ones. Polish producers do not have funds to carry out scientific research and develop original medicaments. Nevertheless, they provide a broad product range. From the therapeutic point of view, domestic companies manufacture medicaments fulfilling requirements for treatment of all diseases.

In 1999 – 2001, approximately 350 new products were introduced, which is associated, among other things, with the anticipated necessity to withdraw more than 100 preparations from the circulation in the coming years due to their low profitability, licence expiration or introduction of new procedures in connection with registration of medicaments in line with the European Union requirements.

In recent years OTC medicaments have won a special place in manufacturers' offers. No official prices are applicable to such preparations, which enables their producers to obtain higher return on their sales. Domestic manufacturers introduced many doubled products to the market. The reason for that is the lack of co-operation between works in the field of new medicaments research and development projects. This leads to mounting competition among domestic producers.

Polish pharmaceutical works meet European standards. The technological lines in use satisfy the conditions existing on international markets, which have been laid down in GMP principles³. Nevertheless, the required validation process has not been completed for a major proportion of production lines in Polish pharmaceutical works, and this is why some 70 percent of the installed lines do not have a formal GMP certificate.

The fact that Poland is not a party to the PIC/S agreement⁴ and that quality certificates issued by the National Pharmaceutical Inspection are not recognised by countries bound by that agreement has a negative impact on the competitiveness of Polish companies as well.

Furthermore, the competitiveness of Polish producers of medicaments is adversely affected by the domination of Chinese and Indian sources of supply for medicinal substances. Some of these suppliers do not meet GMP requirements and in the near future will have to be eliminated from the Polish pharmaceutical sector.

However, the competitiveness of pharmaceuticals' producers is largely determined by prices of their products. At present, the prices for Polish-made medicaments are approximately four times lower in comparison to imported medicaments. Although that difference has diminished in recent years it still remains substantial.

Table 3. Average prices of domestic and imported medicaments in Poland (€)

	1996	1997	1998	1999	2000	2001
Average price of domestic medicaments	0.56	0.61	0.71	0.80	0.95	1.24
Average price of imported medicaments	2.47	3.25	3.76	3.57	4.37	4.82
Price ratio: foreign to domestic	4.4	5.3	5.3	4.5	4.6	3.9

Source: Drug Institute

³ GMP (Good Manufacturing Practice) – is that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation (MA) or product specification.

⁴ PIC/s (Pharmaceutical Inspection Cooperation Scheme)

In view of the above data it should be pointed out that Polish producers of pharmaceuticals can be competitive. Lower prices for domestically-produced medicaments result primarily from the fact that most of them are generic medicaments, which are usually much cheaper than a major proportion of innovative imported medicaments.

Development investments

Development investments in the Polish pharmaceutical sector contribute to improvement of international competitiveness. The value of investment outlays had been growing steadily until to later decline in 2000 and 2001 (Table 2). In 2001, the value of total investment outlays in the pharmaceutical industry amounted to nearly €105 million, almost half of which was accounted for by acquisitions.

Table 4. Value of investment outlays in Poland's production of pharmaceuticals (€ million)

	1996	1997	1998	1999	2000	2001
Investment outlays	125	127	139	165	135	105

Source: Own calculations based on CENTRAL STATISTICAL OFFICE statistics

Intensive processes of restructuring and modernisation of the pharmaceutical industry comprised, among others, activities associated with production quality adjustments to GMP requirements, and solving environmental protection issues. As a result, the Polish pharmaceutical sector has won many new production departments with state-of-the-art technological lines.

Investment in the pharmaceutical industry has resulted in expansion of production capacities in the field of ready-made pharmaceutical forms, accompanied at the same time by many cases of doubling capacities of domestic companies, and their insufficient utilisation. Consequently, the capacity utilisation ratio of production departments in most enterprises does not exceed 50 percent.

It should be stressed, however, that intensive investment in the pharmaceutical industry, with considerable involvement of foreign investors, has contributed to a substantial modernisation of production in Polish plants, allowing for a large scale application of state-of-the-art technologies, and, consequently, for quality improvement of pharmaceutical products manufactured in Poland.

Effect of integration

Integration with the European Union will speed up further modernisation of the pharmaceutical industry in Poland. That process will be partly enforced by intensifying competition on the sector. This will also be facilitated by growing involvement of foreign investors in the Polish market.

Among other things, investment processes will be aimed at:

- adjustment to GMP standards of those Polish plants which do not yet fulfil these requirements, to be achieved, inter alia, through improvement of the production infrastructure in companies,
- adjustment of testing and clinical laboratories to GLP⁵ GCP⁶ requirements

Development of an own research base is one of strategic goals of investment processes in the Polish pharmaceutical sector following integration with the European Union. Thanks to that, Polish producers of medicaments will be able to get involved in innovative processes in pharmaceuticals on a larger scale than before.

This does not mean that integration with the European Union will transform the Polish pharmaceutical sector from the one dominated by generic companies into one occupied by innovative firms. On the other hand, in the future it can be expected that, as is the case in the world with such firms, Polish producers of generic medicaments will get involved more actively in the following areas:

- new technologies of synthesis of known medicinal substances,
- new technologies of classical and improved forms of medicaments.

New technologies of synthesis provide opportunities to use cheaper raw materials, enhance efficiency and safety of processes, to reduce environmental hazards, reduce labour-intensity of syntheses, and improve product quality. On the other hand, works on new technologies for known medicaments are indispensable to develop products characterised, e.g. by extended release, or easier application by patients.

The above-mentioned investment activities of Polish producers of medicaments are already quite conspicuous, and integration with the European Union should speed them up. As a result, an improvement of international competitiveness of the Polish pharmaceutical sector is to be expected.

Higher competitiveness will give rise to new trends in international trade. A gradual improvement of the balance of trade in pharmaceuticals can be awaited, mostly as a consequence of a rise in exports. Better quality of the domestic offer should also render it possible to replace a part of currently imported medicaments with Polish-made ones.

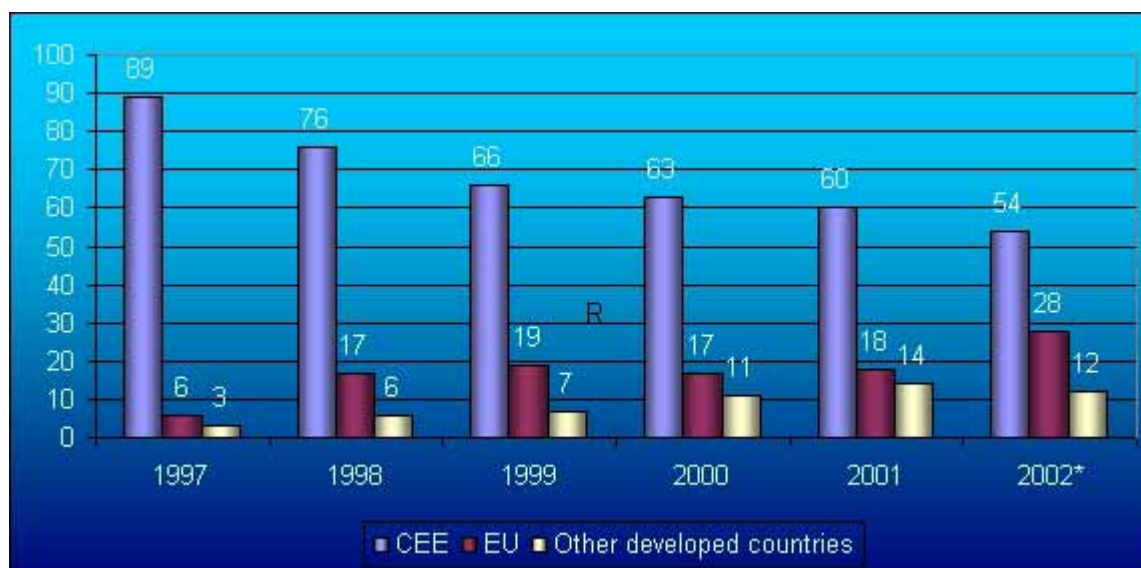
Furthermore, the exporting capacities of Polish producers are limited, first of all, by the fact that the fulfillment of GDP conditions by these producers is not confirmed in legal regulations. This situation is to change with Poland's accession to the European Union and with joining the PIC/S agreement.

Integration with the European Union means not only a gradual increase in exporting capacities of the Polish pharmaceutical industry, but also changes in the geographical composition of international trade. Although the countries of Central and Eastern Europe still remain the largest importers of Polish pharmaceutical products, their share clearly declined in the second half of the 1990s. At the same time, the European Union's share in Polish exports of these products has been growing (Fig. 4).

⁵ GLP – Good Laboratory Practice – embodies a set of principles that provides a framework within which pre-clinical trials of new medicinal products are planned, performed, monitored, recorded, reported and archived.

⁶ GCP – Good Clinical Practice – a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Fig. 4. Geographical composition of Polish exports of pharm. products (percent)



Source: CENTRAL STATISTICAL OFFICE

Integration with the European Union should intensify the above phenomenon, and in several years time the European Union is likely to become the largest importer of Polish medicaments. This is a welcome development for Polish exporters of medicaments, as Western European markets provide opportunities to obtain high profits, and consolidation on those markets may ensure stable revenues for producers.

As a conclusion, it should be stated that Poland's integration with the European Union will have a favourable effect on trends in foreign trade pharmaceutical products. Faster growth of exports can be expected, along with a reduction of trade deficit in the analysed commodity group (although Poland will surely remain net importer of pharmaceutical products). Favourable changes should also involve the geographical composition of trade, with the role of European Union countries becoming increasingly relevant.

The above phenomena will be feasible thanks to the improved competitiveness of Polish pharmaceutical producers. The greater international competitiveness may only be achieved by continuing investment processes, especially towards expansion of the research base, which will allow a broader scale of works on development of generic medicaments.

3.3 Foreign investment

The inflow of foreign investment to the pharmaceutical sector is involved with the process of ownership transformations taking place there. The sector's privatisation process has been going on since 1994. A major part of large privatisation schemes has been completed with involvement of foreign investors. As of June 30, 2002, the total value of ten major foreign investment projects in the pharmaceutical sector amounted to almost \$800 million (Table 3)

Table 5. Ten major foreign investments in the pharmaceutical sector
(as of June 30, 2002)

Investor	Equity and loans (million USD)	Commitments	Country of origin	Investment location
GlaxoSmithKline	369.9	35.0	United Kingdom	Polfa Poznań
Pliva	154.0	16.0	Croatia	Pliva Kraków
ICN Pharmaceuticals	51.0	35.9	USA	ICN Polfa Rzeszów
Robert Lewis	40.0	n.a.	USA	Laboratorium Funkcjonowania Osocza)
KRKA	25.0	n.a.	Slovenia	KRKA Poland sp. z o.o.
Byk Gulden	22.7	n.a.	Germany	Byk Roland Poland sp. z o.o.
Novartis	18.0	17.8	Switzerland	Novartis Poland sp. z o.o.
Sanofi-Synthelabo SA	15.3	n.a.	France	Sanofi-Synthelabo sp. z o.o.
Lek Ljubljana	10.0	27.0	Slovenia	Lek Poland sp. z o.o.
BASF AG	10.0	2.5	Germany	Polfa Kutno

Source: Polish Agency for Foreign Investment

Foreign investment has a positive effect on development of the pharmaceutical sector in Poland. The presence of foreign investors in the Polish pharmaceutical sector represents not only capital transfer needed for modernisation of production plants, but also transfer of modern technologies and so-called *know how*. Companies with foreign participation have better opportunities for modernisation and development, research, introduction of new medicaments, and large-scale clinical tests.

Foreign investors' activities in the Polish pharmaceutical sector are not limited to the field of production, as they are also involved in distribution. Examples of foreign companies present in that segment include the takeover, of Ziola Polskie wholesale warehouses by Germany's Phoenix corporation, 1992, or the takeover of ORFE wholesale warehouses by Holland's OPF company. Nevertheless, no major foreign investor has entered the Polish market since 1999.

The effects of integration

Poland's integration with the European Union may contribute to a rise in foreign investors' interest in the Polish pharmaceutical sector. First, this is indicated by good development prospects of the Polish market (presented earlier in this report), which already is the largest pharmaceutical market in Central and Eastern Europe. Such a big and fast-growing market guarantees interest on the part of foreign investors.

Second, Poland's accession to the European Union will improve Poland's worthiness and will diminish investment risk associated with capital repatriation from Poland. Membership of the European Union will increase the broad-sense economic stability of Poland.

Third, Poland's integration with the European Union may contribute to an intensified interest of foreign investors in the Polish pharmaceuticals distribution market. This segment of Poland's market has been undergoing dynamic transformations, especially of an ownership nature, but the involvement of foreign investors in these changes has been very limited so far. Hence, it can be assumed that Poland's accession to the European Union will be the ultimate incentive for global medicaments distribution giants to take interest in the Polish market.

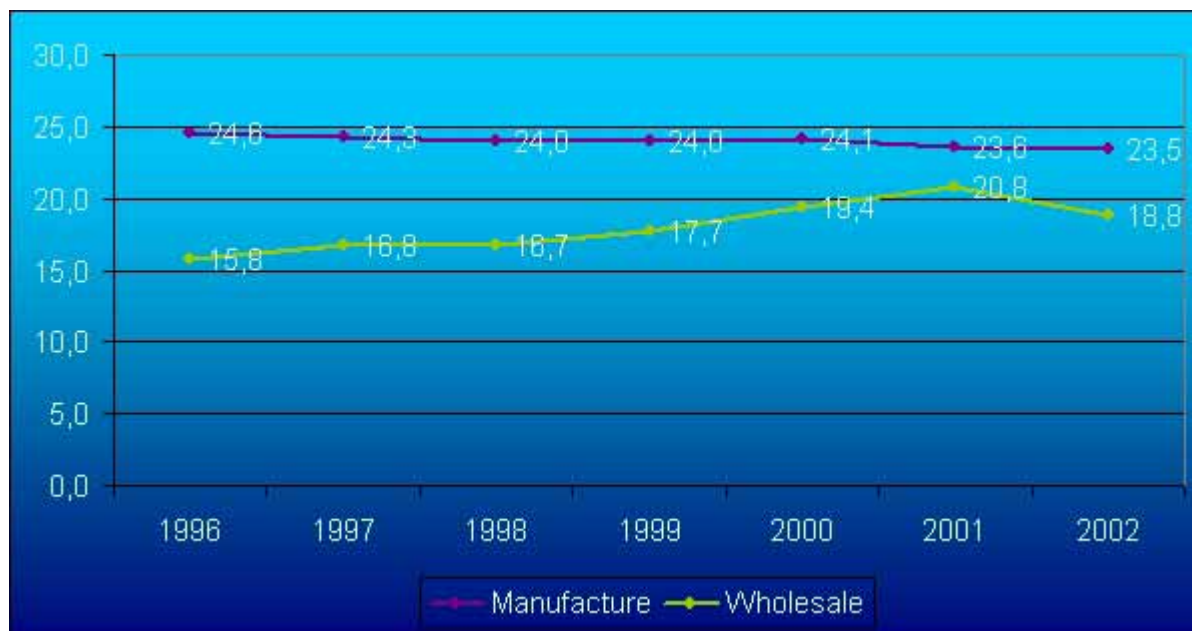
Summing up, considerable significance of foreign investment for development of the Polish pharmaceutical sector in the 1990s should be emphasized once again. Integration with the European Union should result in a further inflow of foreign direct investment to that sector, which will be one of crucial factors of the speed and directions of its further development.

3.4 Labour market

Unlike the Polish economy as a whole, the labour market situation in the pharmaceutical sector is relatively stable. In the second half of the 1990s employment in the production segment amounted to approximately 24,000 persons. In 2001- 2002 the level of employment fell slightly to 23,500 persons at the end of 2002.

More substantial changes in the level of employment took place in the wholesale trade in pharmaceuticals. In 1996 – 2001, employment rose from, less than 16,000 to almost 21,000 persons. This process was, first of all, a consequence of the growing number of companies operating on the market. According to provisional estimates, that trend was reversed in 2002, with employment dropping by almost 10 percent, as a result of the progress of consolidation processes in the sector and the generally bad labour market situation.

Fig. 5. Employment in the pharmaceutical sector in the years 1996 – 2002 (thous. persons)



Source: CENTRAL STATISTICAL OFFICE

The relatively stable level of employment coupled with a rise in the level of production in the second half of the 1990s indicate increasing labour productivity in manufacture of medicaments in Poland. The rise labour productivity was possible thanks to modernisation works and introduction of advanced methods of production. The inflow of state-of-the-art technologies to Poland, along with foreign investment, was another factor of improvement of the efficiency of pharmaceutical products' manufacture.

The effect of integration

Integration with the European Union should not have any major impact on the level of employment in the Polish pharmaceutical sector. Two factors acting in opposite directions will contribute to stabilisation of employment. The first of them is represented by the anticipated fast development of the pharmaceuticals market in Poland, implying a rise in domestic production. This factor will give rise to an upturn in the sector's employment. Another factor, acting in the opposite direction, will be further increase in the efficiency of production and labour productivity.

As a result of these two factors, the level of employment should be relatively stable, as was the case in the second half of the 1990s???. Temporary fluctuations of the number of those employed in the sector are obviously possible due to temporary changes in the strength of the mentioned factors, but in the long run employment should remain stable.

On the other hand, job losses can be expected in the coming years in the distribution sector, especially with regards to wholesale distribution. Integration with the European Union will speed up consolidation processes in that segment of the sector, which will surely contribute to the restructuring of employment. The entry of foreign investors into the wholesale market pharmaceuticals in Poland should also improve the operation efficiency of domestic firms, this way allowing cut employment. Finally, it seems that the rise in employment in that part of the sector recorded in the late 1990s (nineties) may be offset within the next couple of years.

3.5 The sphere of institutional regulations

The basic legal acts adjusting the Polish legislation of the pharmaceutical sector to the EU regulations was adopted in 2001. The adoption of these solutions provides opportunities for more effective operation of Polish pharmaceutical firms under conditions of a single European market. Five new legal acts and their significance for the operation of the sector are presented below.

The Pharmaceutical Law of September 6, 2001

The Pharmaceutical Law introduces radical changes into pharmaceutical legislation and provides for a number of new solutions. The scope of the new law covers such areas as bringing new medicaments into circulation, manufacture of medicinal products and their advertising, as well as operation of pharmaceutical wholesale warehouses and pharmacies.

Not only harmonised national systems of bringing into circulation, but also the procedure of mutual recognition of national approvals and a procedure providing for a single Community approval of the release for circulation are applicable in the European Union.

From the point of view of Polish producers, determination of the date bringing these regulations into force was of key significance so that producers could prepare to meet new requirements. Under provisions of the new Pharmaceutical Law, the permits relating to the registration of medicaments in Poland will remain in force until December 31, 2008.

Poland has also been granted a transitional period in the field of supplementing registration documents of pharmaceutical products. Domestic manufacturers are obliged to supplement these documents, in particular chemical and pharmaceutical ones. Supplements may also relate to studies of the form of medicaments, experts' reports or reference data. The cost of supplementing registration records for a single medicament is estimated at about €75,000.

Another significant issue is posed by the so-called data exclusive rights, concerning mostly generic medicaments. Original medicaments are protected by patents, and bringing duplicative medicaments is possible only upon expiration of patent rights. The procedure of bringing generic medicaments into circulation is usually simplified, as it is not necessary to carry out some tests thanks to possible referral to tests relating to the original medicament. Interests of the owners of generic medicaments are protected by means of granting them for a specified period of time, data exclusive rights, which means that other producers must not refer to the results of tests presented by them. In practice, that prohibition is equivalent to granting exclusive market rights.

In the Polish Pharmaceutical Law, implementation of the regulation concerning data exclusive rights has been postponed until accession to the European Union, which is favourable from the point of view of subjects of the Polish Pharmaceutical Law, and the healthcare system operation. The data exclusive rights regulation which has been effective in Poland, providing for a three-year exclusive period, enables Polish producers to prepare for the EU rules.

The Law on the Office for Registration of Medical, Medicinal and Biocidal Products

Pursuant to the law, a new, central government administration body has been established, namely the President of the Office for Registration of Medical, Medicinal and Biocidal Products, whose task will be to evaluate quality, efficiency and safety of these products.

The Law on Prices of July 5, 2001

The Law is to provide statutory guarantees for the freedom for price setting, and for its protection against administrative restrictions. Furthermore, it guarantees protection of interests of entrepreneurs and buyers, which may be threatened in case of abuse of the freedom to set prices and protection of consumers against unfair market practices.

The Law introduces new principles of pricing of pharmaceutical and medicinal products manufactured in Poland and entering the Polish customs area, financed partly or entirely from public funds. The above-mentioned regulations are aimed at implementation of the Council Directive 89/105 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

The Law on industrial property

The law provides for a 20-year patent protection of chemical compounds (active substances of medicaments) and for pharmaceutical products. This way, the rules applicable to the above issue have been harmonised with those binding in the European Union.

The law introduces provisions being favourable for the domestic pharmaceutical industry as regards permits for conducting experiments indispensable to obtain data for registration of medicaments prior to expiration of the patent protection.

Summing up, it should be stated that Polish law has been fully aligned with the EU regulations relating to the pharmaceutical sector. This will put Polish producers on the same footing with the EU entrepreneurs. Equal opportunities are bound to improve the competitive position of Polish companies, but will surely not solve all the problems associated with competition. Adoption of the EU regulations, being much better developed than those previously binding in Poland, will improve the operation of Poland's pharmaceutical sector, and contribute to better efficiency of Polish companies in the future.

3.6 Market competition level

Systemic transformation initiated in 1989 brought about gradual reshaping of the market and the entire pharmaceutical sector in Poland. Among other things, that phenomenon found its reflection in the healthcare system reform, privatisation of state-owned enterprises operating in the sector, emergence of new private companies or entry of big international corporations into the Polish market.

These processes brought about "marketisation" of Polish pharmaceuticals and increased level of market competition. With the number of consumers remaining virtually unchanged, the growing number of market actors was bound to result in tightened competition within the sector.

In the Poland's medicaments' production sector there are 66 enterprises employing above 49 persons and some 30 enterprises employing between 9 and 49 persons. The leading producers are 15 plants of the former POLFA Holding. Smaller manufacturers operating in the sector are specialised, primarily in production of OTC medicaments.

Over the last couple of years the competition among domestic manufacturers of pharmaceuticals intensified sharply. The reason for that is, in the first place, doubling product offer of pharmaceutical firms. This is, among others, due to lack of co-operation between research laboratories of particular plants, which is particularly conspicuous in the OTC medicaments segment.

Similar changes have occurred in the medicaments distribution sector. By the end of the 1980s the wholesale and retail trade in pharmaceuticals was monopolised 17 state-owned enterprises grouped in CEFARM, originally a Centre for Supply of Pharmaceutical Enterprises, which was later transformed into a holding.

Transformations in the distribution sector also involved privatisation of state-owned enterprises, but the process of starting private companies from scratch was of more relevance here than in the case of the production sector. At the same time, foreign investors played a less significant role.

At present, there are some 400 private wholesale pharmaceutical warehouses operating on the market. Most of them, are small companies of a local or regional range of operation.. There are also several big commercial companies, which have achieved their strong market position mostly by means of mergers and acquisitions processes. The four largest ones, which determine the shape of the Polish pharmaceuticals distribution market are the following:

- Polska Grupa Farmaceutyczna SA
- Farmacol SA
- Prosper SA
- ORFE SA

In Poland, the competition among wholesale warehouses has been clearly intensifying in recent years. This is due to the large number wholesale warehouses compared to that of retail sale outlets (pharmacies). Poland belongs to the group of European countries with the highest number of wholesale warehouses relative to the number of both customers and suppliers (Table 4).

Table 6. Number of operators in the pharmaceutical sector in selected European countries

	Wholesale warehouses	Producers	Pharmacies
United Kingdom	14	109	12 200
Germany	17	464	20 000
France	21	285	22 400
Spain	86	240	18 100
Greece	165	59	7 300
Italy	160	243	15 900
Poland	400	95	9 800

Source: "Strategy for the pharmaceutical industry until 2005" – a government document

The level of competition on the Polish pharmaceutical market is also subject to changes in the so-called pre-wholesale market. At present, all major distributors of medicaments operate in that sector, playing a role of an intermediary between producers of medicaments and wholesale warehouses. The pre-wholesale market was created in the early 1990s by the largest firms importing pharmaceutical products, which in this way entered the distribution market.

The significance of that segment declined considerably in recent years. This is mostly a consequence of the sector's consolidation, as the leading groups of distributors provide themselves their local branches and dependent operators, so they in fact act as pre-wholesalers for those operators. As a result, being aware of a demise of the pre-wholesale market, most companies restrict their activities on it, at the same time focusing on wholesale. This way the competition among traditional wholesalers becomes more intensive.

On Poland's retail market the level of competition is similar to that recorded in European countries. In Poland there are almost 10,000 pharmacies, which means that the number of inhabitants per pharmacy is about 4,000, on average. The density of the network of pharmacies in Poland corresponds with European standards.

The Polish pharmaceutical market concentration level is much lower than in the world. In 2002, the ten largest firms accounted for less than 40 percent of sales in value terms, while in the world that figure is about 75 percent. At the same time, in terms of the volume of sales the ten largest firms account for 45 percent of sales. Over the last couple of years, the concentration level went up in terms of the value of sales, at the same time declining in terms of the volume of sales (Table 5).

Table 7. Polish medicaments market concentration in 1998 and 2002

(percent)

	By value of sales		By volume of sales	
	1998	2002	1998	2002
5 largest firms	22.6	25.3	39.7	32.8
10 largest firms	36.8	38.7	50.5	45.1
15 largest firms	47.0	50.1	60.4	55.2
20 largest firms	57.3	58.7	66.6	63.3

Source: CASE – Doradcy Ltd.

The effect of integration

Substantial changes on the Polish pharmaceutical market are to be expected in the nearest future. First of all, consolidation of pharmaceutical wholesale warehouses will continue, as their number is currently too high compared to European standards. This will mean a fall in the number of business operators dealing with wholesale trade in medicaments. The pharmaceutical wholesale market will evolve towards a model typical of Western European countries, where this segment of trade is dominated by not more than 5 nationwide wholesale suppliers.

Poland's integration with the European Union will speed up that process. It is likely that Poland's entry into structures of the Single European Market will contribute to growing interest of major European distributors in the Polish pharmaceutical market. The presence of foreign investors in the medicaments distribution sector has been only marginal so far.

The involvement of European giants in the distribution market will be a catalyst for the Polish market consolidation. First of all, one should reckon with a takeover of smaller wholesale warehouses by operators currently dominating the market. The largest wholesalers will use all possible means to increase their market shares, which will surely contribute to improvement of their investment attractiveness.

On the market of pharmacies no radical change can be expected in the nearest future. Recently, the number of pharmacies in Poland has increased sharply as a result of controversial regulations provided for by the new Pharmaceutical Law. Under its provisions, only pharmacists are now authorised to open pharmacies. This resulted in an avalanche of applications for permits to run pharmacies, filed by persons wanting to start up a business before the new provisions enter into force. This means that now the number of pharmacies will not grow rapidly. Furthermore, it can be assumed that some of the newly opened pharmacies will not survive on the market.

The continuing process of transformation of the pharmaceutical sector should also intensify in the field of production. There are still five large fully state-owned plants operating in the sector, which formerly belonged to the POLFA holding. Hence, one should expect their privatization in the future, which may involve participation of foreign investors.

Integration with the European Union will speed up the transfer of global trends in the pharmaceutical sector to Poland. This is why progressing consolidation of firms can be expected in the production sector as well. Until now this concerned especially innovative companies, but now the consolidation trend is also present in the sector of generic companies.

Consolidation of producers in the pharmaceutical sector is primarily aimed at:

- attainment of an appropriate scale of production, optimising economic efficiency,
- concentration of marketing efforts and improvement of sales effectiveness,
- possibility of obtaining own active substances (inside the group).

Measurable benefits from consolidation are reflected, first of all, in the reduction of costs of production, cuts in marketing and advertising spending, as well as in increasing the number marketing channels. Furthermore, consolidation allows firms to intensify their activities in the field of scientific research.

Summing up it should be stated that integration with the European Union will speed up the process of consolidation in Polish pharmaceuticals, contribute to increased involvement of foreign investors in the Polish market and facilitate dissemination of global market trends in Poland. As a result, market competition is likely to intensify. The possible fall in the number of operators (especially in wholesale distribution) will be offset by the fact of European giants stepping up their competitive struggle on the Polish market.

3.7 Government policy towards the pharmaceutical sector

In its document: "Strategy for the pharmaceutical industry until 2005" adopted in October 2002, the Polish government laid down the activities to support the functioning of development of the Polish pharmaceutical sector. The proposed activities are to secure appropriate functioning and development of the sector, improvement of competitiveness, adjustment to the European Union requirements, and further reduction of the adverse environmental impact of pharmaceutical plants.

The basic objectives of systemic activities of the Polish government towards the pharmaceutical sector in the coming years include:

- adjustment of industry to requirements resulting from integration with the European Union,
- further restructuring and privatisation,
- improvement of competitiveness of companies ,
- modernisation of production and expansion of the exporting capacity ,
- securing fair competition on the domestic market,
- improvement of co-operation with enterprises.

Within the framework of adjustment of the pharmaceutical sector to the European Union requirements the following tasks have been assumed:

- drafting of implementing regulations to the Pharmaceutical Law, *inter alia* concerning registration records, GMP, GLP and GCP, so that relevant legal provisions (consistent with Community law) could really work,
- establishment of the Registration Office in connection with implementation of the Pharmaceutical Law and the law on the Registration Office.

Within the framework of the **programme of restructuring and privatisation of the sector** the following tasks have been assumed:

- further restructuring and privatisation of state-owned enterprises and taking up activities in the field of consolidation of pharmaceutical firms,
- restructuring and privatisation of research and development units of the pharmaceutical industry involving, among other things, preparation of laboratories to fulfil GLP requirements, with special reference to better utilisation of the research potential of those units, towards research into new generic medicaments and new forms of medicaments,
- evaluation of fulfillment of commitments assumed by strategic investors in pharmaceutical plants privatization contracts .

The following tasks have been imposed within the framework of **increasing the sector's competitiveness**:

- elaboration of „The Drug policy of the State“ – a document setting out guidelines for changes aimed at securing the population access to medicaments on the most favourable conditions as well as optimisation of pharmacotherapy,
- joining the PIC/S system
- support for pharmaceutical firms in the field of innovativeness through: aid in seeking studies, partners and capital for launching production of certain chemical substances, which are used as raw materials for production of generic medicaments, and through support for development of innovative medicaments (these tasks will be implemented with utilisation of budget funds, as well as aid funds from the 5th and 6th Community Framework Programme of Research),
- implementation of environmental protection objectives through: support for investment in environmental protection, appropriate adjustment of economic instruments in the field of environmental protection towards their increased ecological efficiency, and transformation of ecological funds into financing instruments consistent with principles and criteria of public aid applicable in the European Union.

Within the framework of **modernisation of production and of increasing export potential** the following tasks have been adopted:

- diversification of the market offer of medicaments through placing on the market new pharmaceutical preparations, new generic medicaments, new forms of medicinal products, as well as through increasing the scope of applications for pharmaceutical medicaments,
- introduction of instruments having their impact on development of export production through: implementation of appropriate financial instruments, re-financing with budget funds of the participation of Polish firms in foreign fairs and exhibitions, increasing the involvement of Polish business and commercial missions abroad in promotion of domestic pharmaceutical products, strengthening of the position of Polish trademarks, creation of direct distribution networks, development of on-line marketing,
- compiling a list of medicaments (by therapeutic groups) recommended for treatments of patients, the production of which should be launched in Poland,
- adjustment of the pharmaceutical industry to new legal requirements through, *inter alia*: preparation of registration documents for preparations declared for registration and extension of validity of registration certificates, implementation of GLP and GCP in bio-equivalence and bio-accessibility studies.

Within the framework of **securing fair competition on the domestic market**, the following task has been assumed:

- large-scale utilisation of tariff regulations relating to duty-free imports of semi-products and raw materials for production of medicaments involving, in the first place, setting tariff quotas on certain goods imported for the pharmaceutical industry,

Within the framework of **improving co-operation with enterprises** the following task has been assumed:

- training and dissemination of information relating to legal acts binding in Poland and in the European Union, including the admissible state aid for enterprises,
- intensification of activities and relevance of non-governmental economic organizations, reflected in increased involvement of centres lobbying for the Polish pharmaceutical industry to promote its products in accordance with principles and standards applicable in the European Union.

Some of the tasks mentioned within the framework of the Polish government policy towards the pharmaceutical industry have already been partly implemented. The implementation deadlines for the remaining ones may vary, some of them even go beyond the deadlines set in the government strategy (e.g. supplementing registration documents of pharmaceutical products is scheduled for completion by the year 2008). Some tasks have no precisely formulated implementation deadlines and are to be implemented successively.

Relevant ministers (i.e. those appropriate for healthcare, the State Treasury, economy, environmental protection) are responsible for implementation of most tasks specified in the strategy. Some of the tasks are also to be taken up by entrepreneurs. Apart from formal alignment with the European Union requirements we can mention here e.g. diversification of the sales offer.

The state budget carries the burden of financing most tasks set forth in the strategy. Some tasks can be co-financed with aid funds of the European Union, while other should also be co-financed with enterprises' own funds (e.g. export promotion activities), or should be fully financed by enterprises (e.g. lobbying).

4. Summary

The Polish pharmaceutical sector has been still growing. This refers to both the market size, measured by the value or volume of sales of medicaments, and the situation of enterprises. Per capita sales of medicaments in Poland are lower than in the European Union countries, and pharmaceutical enterprises are still undergoing a period of restructuring and modernisation.

Hence, the pharmaceutical sector has been undergoing a transitional period. Ownership transformation processes are in progress, involving privatization of state-owned enterprises (especially in the sector of production of medicaments), and consolidation of companies (especially in the distribution sector).

Many of these processes have been going on irrespective of Poland's integration with the European Union and are a part of the systemic transition which has been continuing in Poland since 1989. In many ways, transitions in the pharmaceutical sector are similar to those recorded in other sectors of industry.

Nevertheless, integration with the European Union is, in a way, a catalyst for these changes, as in view of prospects for accession many processes are faster gaining momentum. This refers, in the first place, to modernisation of pharmaceutical firms, which are being restructured in order to face competition on the common European market. The prospects for integration also speed up privatization processes and contribute to increased interest of foreign investors in the Polish market.

Since for many years the pharmaceutical sector has, in a way, been partly transforming with the European integration in mind, the integration itself will not have a decisive impact on the changing situation of the sector. After Poland's accession some processes may accelerate, while other will continue at their pre-accession rate .

The phenomena which to a lesser or greater extent may affect Poland's accession to the European Union are, first of all, the following:

- acceleration of the sector's development due to increased sales of medicaments, which, in turn, may be the effect of faster economic growth and increase in the purchasing power of household incomes;
- growth of medicaments' exports due to improvement of competitiveness of Polish enterprises, resulting from further modernisation and restructuring;
- change of the geographical composition of exports, involving reorientation of export sales from eastern markets to the European Union markets;
- increased activity of foreign investors on the Polish market reflected in taking up investments by new entities, and in the intensification of investment activities by operators already involved in the Polish market;
- tightening competition in the Polish pharmaceutical sector as a result of intensified processes of consolidation and increased activity of foreign investors.

The above-mentioned factors will contribute to greater efficiency of the pharmaceutical sector in Poland. In the long run, opportunities for faster market growth in connection with enhanced of economic effectiveness are bound to allow for improvement of the situation of domestic producers and distributors of medicaments.

It should be remembered, however, that the situation of pharmaceutical industry companies depends largely on the drug policy of the State, as well as on the principles governing the broad-sense healthcare system. The impact of those factors on the pharmaceutical sector's situation is relatively easy to predict due to the fact

that an effective healthcare system has not been established in Poland so far, and works on its formula are still in progress. This means that the institutional environment of the pharmaceutical sector has changed and it is now hard to predict how its future changes would affect that sector.

Finally, it is worth pointing out that although Poland has not yet become a Member State of the European Union, the pharmaceutical sector has already been benefiting from the future membership. They result from adjustment of the Polish legislation relating to the sector to the *acquis*. Thanks to implementation of European regulations, the Polish Pharmaceutical Law has become more transparent, and Polish enterprises have been put on an equal footing with their EU competitors.

SWOT Analysis

Strengths:

- large internal market,
- high level of technological advancement of pharmaceutical works,
- high level of foreign investment in the segment of production,

Weaknesses:

- Poland not being a member of PIC/S
- shortage of funds for scientific research,
- very slight share of innovative medicaments in production,
- fragmentation of the wholesale distribution sector,

Opportunities:

- rise in demand for medicaments thanks to higher household incomes after accession to the EU,
- export growth,
- reorientation of exports towards European Union countries,
- intensification of studies new medicaments and new forms of medicaments thanks to involvement of foreign investors in this field,
- consolidation of wholesale distribution firms and inflow of foreign capital to that segment,

Threats:

- slowdown of further privatization of the sector,
- reduction of funds for research and development,

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Annex 1. Key pharmaceuticals' producers in Poland (2002)

	Company	Main Property	Revenues (mln PLN)*	Gross profit (mln PLN)*	Employment
1	GlaxoSmithKline Pharmaceuticals SA Poznan	foreign	1 193,1	147,4	1 538
2	Polpharma SA Starogard Gd.	polish private	865,8	na	na
3	Sanofi-Synthelabo sp. z o.o. Warsaw	foreign	404,0	47,5	413
4	Polfa WZF SA Warsaw	state	290,4	53,9	1 417
5	Jelfa SA Jelenia Góra	polish private	261,9	38,6	na
6	Polfa Kutno S.A.	polish private	220,4	34,0	na
7	Polfa Pabianice	State-owned	164,3	20,6	894

Source: "The List 500", Gazeta Bankowa, 25.04.2003

*In 2002 1Euro = 3,86 PLN

Annex 2. Key pharmaceuticals' distributors in Poland (2002)

	Company	Main Property	Revenues (mln PLN)*	Gross profit (mln PLN)*	Employment
1	Polska Grupa Farmaceutyczna SA Łódź	Polish private	3 300,3	34,8	bd
2	Farmacol SA Katowice	Polish private	2 417,2	50,8	1 869
3	Prosper SA Warsaw	Polish private	1 376,5	10,2	bd
4	Orfe SA Warsaw	Foreign	1 173,7	10,8	224
5	Torfarm SA Toruń	Polish private	779,5	5,0	340
6	Apofarm Group sp. z o.o. Kielce	Polish private	698,6	4,0	74
7	Hurtap SA Łęczyca	Polish private	363,0	5,3	256
8	Profarm sp. z o.o. Warsaw	Polish private	285,6	13,3	111
9	Silfarm sp. z o.o. Katowice	Polish private	266,5	11,8	283
10	Urtica sp. z o.o. Wrocław	Polish private	265,7	1,4	75
11	KRKA Polska sp. z o.o. Warsaw	Foreign	253,9	5,9	246
12	Cefarm PZF Białystok	State-owned	208,9	9,9	525
13	Optima Farma SA	Polish private	146,7	2,5	109
14	Podkarpacka Hurtownia Aptekarska sp. z o.o. Rzeszów	polish private	131,8	4,8	97

Source: "The List 500", Gazeta Bankowa, 25.04.2003

*In 2002 1Euro = 3,86 PLN