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The Expected Effects of the EU Accession on the Pharmaceutical Industry in the Slovak Republic

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Growth effects of EU accession

The pharmaceutical industry faces significantly lower sensitivity to cyclical development than other sectors, such as the automotive or metallurgy industries. The demand for drugs is more stable, reliable and less elastic than for luxury goods, with a positive long-term outlook with an ageing population. The Slovak pharmaceutical industry should benefit from increased demand for cheaper, generic drugs as the burden of providing health care to an older population becomes unbearable not only in Central European countries, but in the EU member states as well. Domestic consumption of drugs will be spurred by increased purchasing power of Slovaks as wages gradually converge to EU levels. Badly needed market features in the healthcare system have been lacking for a long time, but the new liberal minister of healthcare Rudolf Zajac is ready to introduce them. However, austerity measures may hamper increased demand.

The pharmaceutical industry accounted for just under 1% of sales in industry as a whole –

The share of sales of pharmaceutical companies in overall industrial sales in Slovakia were on the decline in the second half of the 1990s. While sales of pharmaceutical producers in Slovakia represented 1.45% of industrial sales in 1997, by 2001 this share had fallen to 0.9%. This is the consequence of a faster growth in booming manufacturing sectors bolstered by FDI inflow (i.e. automotive, electronics or rubber and plastics) than in pharmaceuticals. Within the chemical industry (production of chemicals, chemical products and fibers), pharmaceutical production retains an important position, representing almost one fifth of sales and employment.

Table 1

Standing of pharmaceutical production in the chemical industry in 2001

SKK m, %

	pharmaceutical industry	chemical industry*	% share
number of companies	9	61	-
sales	10,142	53,830	18.8%
y/y change (%)	+16.7%	+9.6%	-
employees	3,932	19,042	20.6%
y/y change (%)	-7.3%	-3.8%	-
average wage (SKK)	17,515	16,113	108.7%
y/y change (%)	+12.1%	+11.9%	-

* production of chemicals, chemical products and chemical fibers, OKEC 24

Source: Statistics Office SR, Symsite Research

– with its share declining

The importance of pharmaceutical production in Slovakia is declining, in spite of a strong 17% y/y growth in sales to Sk 10.1bn in 2001. The growth of the sector was supported in particular by good results of the key pharmaceutical company Slovakofarma, which enjoyed a 22% y/y growth in sales in 2001. The number of employees in the pharmaceutical sector is steadily falling – in 2001 it was under 4,000 employees, which is 7% down on the previous year. Restructuring and consolidation of the sector not only led to a drop in employment and increase in productivity in the sector, but also in a growth in profit. In 2001 pharmaceutical producers in Slovakia increased their profit by 90% to Sk 668m with a positive outlook in 2002. In 1H 2002,

companies in the Slovak Republic dealing in the production of pharmaceutical products recorded a further 12% y/y increase in sales to Sk 5.141bn. The value of exported production represented Sk 3.546bn, which is 26% more than seen in the first half of the preceding year.

Table 2

Selected indicators of the pharmaceutical industry in Slovakia

financial indicators excepting wages in SKK thsnd

	1998	1999	2000	2001	1H/2002
number of companies	9	11	12	9	11
average number of employees	4,850	4,527	4,241	3,932	3,838
average wage (SKK)	12,619	13,578	15,619	17,515	19,392
sales	7,673,452	8,254,022	8,693,573	10,141,815	5,141,347
receivables	2,759,251	3,206,503	3,056,374	3,250,276	3,162,023
receivable turnover (in days)	131	142	128	117	113
payables	2,305,032	2,160,765	2,551,704	2,204,197	1,815,457
payable turnover (in days)	110	96	107	79	65
pre-tax income	-1,282	249,715	353,405	667,992	759,393

Source: Statistics Office SR

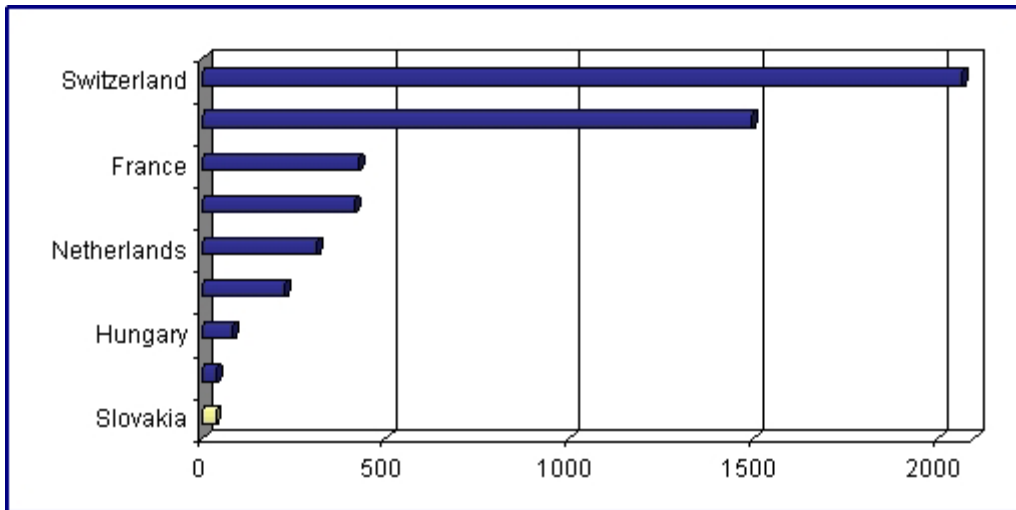
Receivables of companies in the pharmaceutical industry rose y/y by 6% to Sk 3.25bn to the end of December 2001, which is substantially less than the 17% sales growth. Pharmaceutical producers have pressurized distributors in the past year and shortened the turnover period for receivables. The receivable days fell in 2001 by 9% y/y to 117 days with 113 days in the first half of 2002. The payable days of pharmaceutical producers was shortened by even more in 2001, falling by a quarter y/y to an average of 79 days (65 days in 1H/2002).

The pharmaceutical industry remains one of the best performing sectors in many EU countries, with regular double-digit returns. Pharmaceutical production plays a considerably greater role in terms of volume, research and development spending, employment or trade balance in the EU (mainly Germany, Ireland, Great Britain, France) than in the Slovak Republic. In several Western Europe countries the pharmaceutical sector is one of the top five net exporters among industries. The Slovak Republic produces less than one tenth of the pharmaceuticals per capita than Belgium. Compared with the Czech Republic pharmaceutical production per capita is roughly on the same level – EUR 38 /p.c. (graph 1.1).

Graph 1

Pharmaceutical production in selected European countries in 2000

EUR/per capita



Source: EFPIA, Symsite Research

Taking into account the importance and status of Slovak pharmaceutical production either within the national economy or in the European context, the pharmaceutical industry in Slovakia plays a limited role. Moreover, foreign direct investments (FDI) is the key driving force of manufacturing industries not only in Slovakia, but in other CEE countries as well, paying just a little attention to Slovak pharmaceutical production up to the present (for more on FDI see 'The effect of accession on FDI inflow').

Pharmaceutical production in Slovakia is based on four companies

Output of the pharmaceutical industry in Slovakia comes from four key companies—Slovakofarma, Biotika, Hoechst-Biotika and Imuna. Hlohovec-based Slovakofarma is a key producer of pharmaceuticals in Slovakia, accounting for as much as three quarters of all sales in the sector in 2001. Sk 1bn threshold in sales has been surpassed also by Hoechst-Biotika and Biotika, while Imuna is still struggling. In addition to these four companies, the rest of the industry is made up of small local companies whose influence on the development of the sector is negligible. These companies mostly focus on OTC drugs and nutritional preparations (Biomin, Unimed Pharma, Pharmagal, Salviafarm).

Table 3

Largest companies in the Slovak pharmaceutical industry in terms of sales in 2001

sales in SKK thousand

producer	2001	% change	employees	note
Slovakofarma, a.s., Hlohovec	7,743.0	+21.8%	1,494	acquired by Warburg Pincus (US investment fund) in early 2003
Hoechst-Biotika, s.r.o., Martin	1,749.3	+25.8%	310	interest of Aventis to get rid of its investment in joint venture;
Biotika, a.s., Slovenska Lupca	1,581.0	+14.3%	1,077	currently holding talks with Aventis to buy majority stake in joint venture Hoechst-Biotika
Imuna, state enterprise, Sarisske Michalany	95.2	-44.6%	454	new domestic owner as of November 2002

Source: companies, Symsite Research

The new acquirer of Slovakofarma, an American investment fund Warburg Pincus (the deal is not closed entirely yet—the statement of Antimonopoly authority is on the way) will help the company to find and exploit market potential in the West. To succeed in an integrated EU market the companies must be able to secure technological innovation of generic drugs by prompt response to the patented drug expirations. The investments into R&D made by pharmaceutical producers (represented by Association of Pharmaceutical Producers SR) oscillate around 4% of the sales. The largest spenders on R&D in Slovakia are Slovakofarma and its subsidiary VULM (Drug Research Institute in Modra), where research is carried out for Slovakofarma. Hoechst-Biotika under the control of pharmaceutical giant Aventis has focused exclusively on production, keeping R&D activities in the West. Biotika will need to strengthen investments in research and innovation. In the mid-term the R&D expenditures by Slovak pharmaceutical companies (mostly Slovakofarma and Biotika) will increase their share on sales slightly.

Table 4

Expenditures on research and development of domestic pharmaceutical producers

	1997	1998	1999	2000	2001
SKK million	214	268	268	315	368
% of sales	3.1%	4.0%	3.6%	4.1%	4.2%

Source: AFV SR — Association of pharmaceutical producers SR

Slovakofarma

Slovakofarma, the largest pharmaceutical company in Slovakia, produces generic drugs, cosmetic preparations and chemical substances. The year 2001 was successful in terms of turnover growth, with Slovakofarma seeing a sharp 22% increase in sales to Sk 7.743bn (including sales of a Czech drug distributor ZP Medica). Total sales in the Czech Republic, the most important market for Slovakofarma, rose in 2001 by a remarkable 23.3% to Sk 4.440bn (some 58% of which however are sales of goods through ZP Medica). Exports to other markets increased in 2001 by as much as 43% to Sk 1.483bn, accounting for 19.1% of consolidated sales of Slovakofarma (16.3% in 2000). The three largest of these markets are Russia, Germany and Poland, constituting a total of 8% of all sales. A 12% drop in sales was seen by Slovakofarma on the German market in 2001 (Sk 129m), while Poland recorded a 120% y/y growth to Sk 184m (especially thanks to expansion with the drug pentoxifylin).

Table 5

Territorial structure of sales of Slovakofarma 1999-2001
SKK m

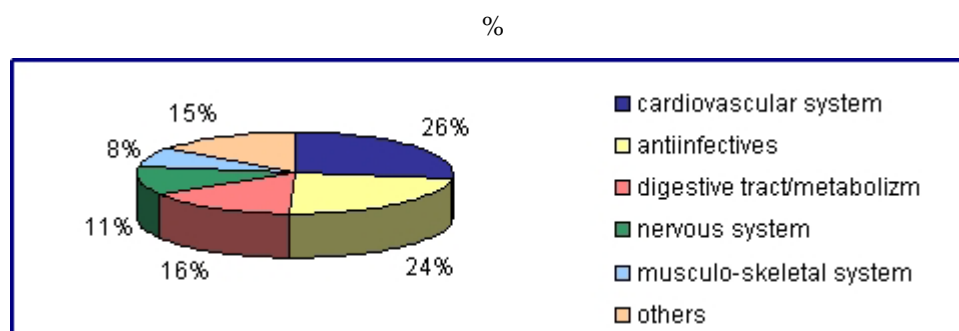
	1999	2000	2001
Total sales	5,986	6,357	7,743
Slovakia	1,696	1,720	1,820
Czech Republic	3,404	3,601	4,440
Export to other countries	886	1,036	1,483
Russia	192	270	284
Germany	149	147	129
Poland	70	83	184
Ukraine	69	81	89
Bulgaria	45	63	89
Hungary	58	49	67
Egypt	9	29	13
India	25	25	48
Lithuania	29	19	31
other territories	225	270	317

Source: Slovakofarma

The core pharmaceutical products include cardiovascular drugs (26% of overall sales of drugs in Slovakia in 2001), anti-infectious preparations (24%), drugs for the digestive tract and metabolism (16%), and for the nervous (11%) and musculoskeletal systems (8%). According to SUKL data, the OTC preparation accounted for 28% of the sales in the domestic market (SKK 362 million at maximum prices set by the Ministry of Finance). In 2001 Slovakofarma spent a total of Sk 212m on research and development, which was 10.4% more than the preceding year.

Graph 2

Structure of sales in the Slovak Republic by therapeutic groups in 2001



Source: SUKL, graph by Symsite Research

In 2002 the sales of Slovakofarma's production reached Sk 4.62bn (without sales of sold ZP Medica) according to the preliminary results. Some 40% were exports to Czech Republic (1% y/y growth). The other export territories accounted for 28% (Sk 1.3bn) of production in 2002. Slovakofarma is aiming for a gradual reduction in the level of dependence on Czech and Slovak markets by concentrating more on sales growth elsewhere. Nevertheless its operations in both the countries remain of key importance. The sales in Slovak market amounted to Sk 1.56bn, a drop of 5% caused by the cancellation of non-core fuel components production.

Biotika

Biotika is the second largest Slovak pharmaceutical company in terms of sales volume. The main production program of Biotika is the production of penicillin and antibiotics and their associated substances. Biotika also produces vitamins and hormonal medicinal preparations and from 1992 veterinary products (premixes of feed additives and medicated feed preparations). With a 26% y/y sales growth in finished products to Sk 1.36bn in 2001 the company exported as much as 84% of production (compared with around 75% in 2000). After several years of operating in the red, Biotika saw an after-tax profit of Sk 39.5m on overall sales Sk 1,594m in 2001. Loan restructuring together with improved access to resources via leasing and factoring significantly improved the economics of Biotika in 2001. The company re-invested Sk 46.2m, mainly into measures for increasing the cost-efficiency of production and for environmental protection.

Table 6

Selected economic indicators of Biotika 1997-2001

	SKK m, %				
	1997	1998	1999	2000	2001
sales	1,442	1,282	1,406	1,403	1,594
sales growth (%)	-1.1	-11.1	9.7	-0.2	13.6
net profit	-132.3	-19.9	-196.6	-93.0	39.5
Operating income	-39.9	-84.5	-26.7	79.5	144.6
Average number of employees	1,427	1,275	1,182	1,096	1,061

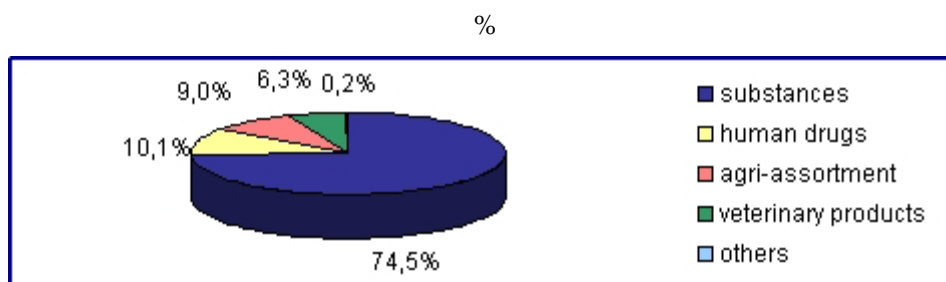
Source: Biotika, Symsite Research

The most important production item of Biotika continues to be substances. Sales of Penicillin V and Penicillin G accounted for 84% of all sales of substances in 2001, whereby sales profited most from a growth in sales prices on foreign markets, revived after a drop in 1999. The share of substances in overall production

of Biotika rose from 48% in 1998 to as much as 74% in 2001 (Graph 3). Conversely, the share of agri-products fell sharply from 26% in 1998 to less than 9% in 2001. Human drugs saw a drop in its share of the sales structure of Biotika from 18% in 1998 to 10% in 2001. The company invested 3.5% of turnover (Sk 55m) into the research and development of new preparations in 2001. Biotika increased its profit during the first nine months of 2002 by 118% y/y to Sk 101m on sales up 10.4% to Sk 1.233bn.

Graph 3

Sales structure of Biotika by individual products in 2001



Source: Biotika

Hoechst-Biotika

The joint venture of Aventis and Biotika is the third largest pharmaceutical company in terms of sales and the only producer of original drugs, under the license of Aventis, in Slovakia. The product portfolio of the HBM operation in Slovakia is augmented by Aventis with imported drugs from other European production operations of Aventis. The company's own production accounts for 70% of sales, with trade activities (import of Aventis goods) making up around 30%. None of the drugs are intended for the market of OTC preparations. During its time in Slovakia the company has already invested around Sk 1bn. At the end of 2001 Aventis announced its intention to sell off its share in the joint venture.

Table 7

Selected economic indicators of Hoechst-Biotika in the period 1997-2001

SKK m

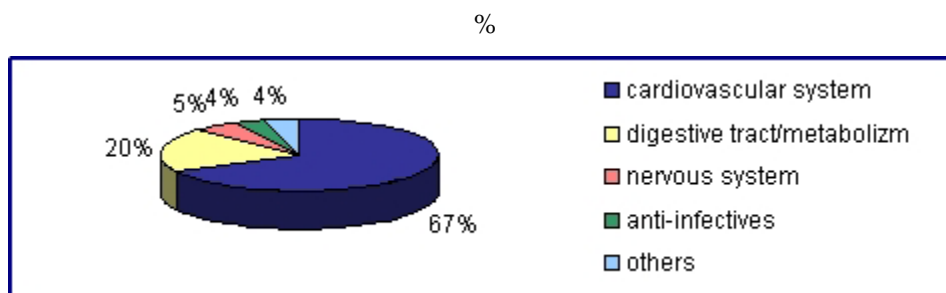
	1997	1998	1999	2000	2001
sales	711,550	866,516	1,077,938	1,390,480	1,749,284
sales growth	12.1	21.8	24.4	29.0	25.8
pre-tax profit	110	4,616	54,893	39,356	132,937
Operating income	56.6	120,3	119,4	118,3	205,7
Average number of employees	297	293	295	308	310

Source: Hoechst-Biotika

Two thirds of sales by Hoechst-Biotika generated in Slovakia in 2001 were preparations for the cardiovascular system (Sk 364m according to SUKL data) and one fifth of sales are from drugs for the digestive tracts and metabolism (Sk 109m). From the range of cardiovascular drugs the most sold in Slovakia are preparations acting on the rennin-angiotensin system - ACE inhibitor Tritace, which is also the highest selling HBM drug in the Slovak Republic.

Graph 4

Sales structure of Hoechst-Biotika in Slovak market by therapeutic groups in 2001



Source: SUKL, graph by Symsite Research

Hoechst Biotika recorded a turnover of Sk 1.5bn last year and a record high profit of Sk 162m resulting mostly from a favorable exchange rate with the Czech crown (sales in the Czech Republic represented 50% of overall sales). Hoechst Biotika exports 55-57% of its production. The firm's investments totaled Sk 25m in 2002.

Imuna

Imuna is the only producer of blood derivatives, infusion solutions and vaccines in Slovakia until 2002 under state ownership. At the end of 2002 the new owner purchased Imuna's property in liquidation, the order for which the court imposed on Imuna at the beginning of 2002. Representatives of the new owner of Imuna plan to invest around Sk 0.5bn in the company and to gradually double the capacity of production of dietetic and nutrient media. Representatives of Imuna Pharm Holding – the new owner – expect the share of Imuna on the Slovak market of infusion substances to increase from the current 16% to 80% following the planned investments in the company. The production of blood derivatives at Imuna still do not meet the norms of good manufacturing practice (GMP) despite a government guarantee for a loan worth DM 44m (Sk 835m) for production modernization in summer 1998. However, this important investment was halted. The doubts are whether needed investments are carried out before EU enlargement to meet GMP standards.

The major part of Imuna's production is placed on the domestic market (around 88% in 2001), while just 12% is exported (mainly to the Czech Republic). In 2001 sales of Imuna on the Slovak market fell y/y by 40% to Sk 58.2m. Plasma substitutes and perfusion substances represented 79% (Sk 46.3m in 2001) of total sales of the company, with another 12% comprising immunosera and immunoglobulins. In terms of reimbursements, as much as 87% of sales comprised goods bound to requisition orders for hospitals. Overall sales fell by more than a half to Sk 72.8m in 2001 and a further drop was also seen during 2002.

Table 8

Selected indicators of the company Imuna

	SKK thsnd			
	1998	1999	2000	2001
total sales	200.0	173.3	171.7	72.8
export	25.5	25.4	22.7	13.1
indebtedness	72.6	80.1	95.0	n
gross profit/loss	-102.2	-58.3	-91.7	n
employees	595	550	539	454

Source: Imuna, Trend

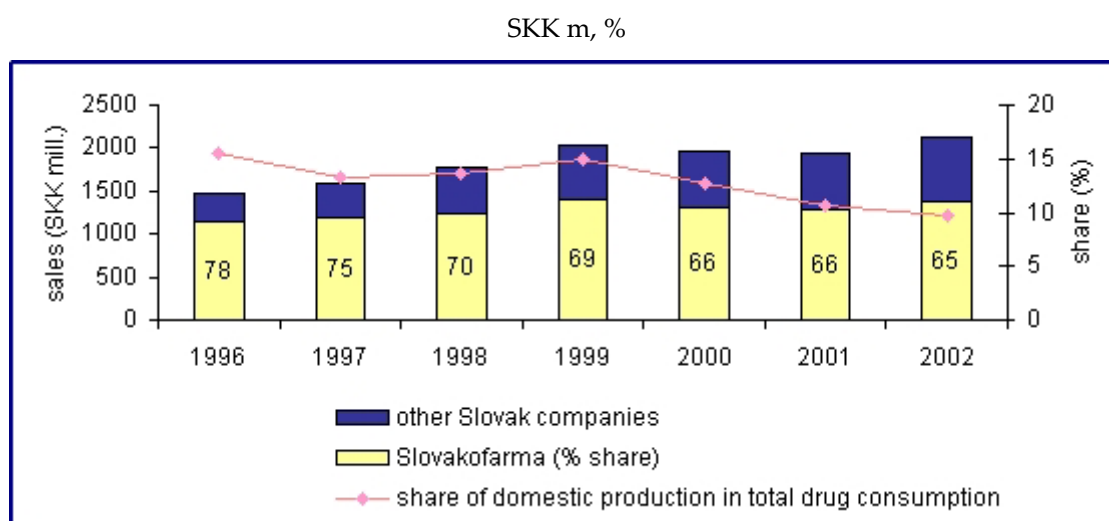
Sales

are concentrated on the domestic and Czech markets—

According to data from the drug testing office SUKL, in 2002 domestic producers covered just under 10% of domestic demand for drugs, which is the lowest value to date. This one tenth coverage of drug consumption by domestic producers is the lowest among the surrounding countries, with Hungary and Poland both covering about one third of their requirements, and the Czech Republic one fifth. In terms of the number of sold units, domestic producers had a higher share of the market - 26%. This proves the low average price of, mostly generic, drugs produced domestically. Slovak pharmaceutical producers strengthened their position in the supply of drugs to foreign markets in 2001 (chiefly to Czech R., Hungary, East Europe), whereby sales from exports amounted to as much as two thirds of all sales in 1H 2002. The countries of the former eastern block have a great potential of economic growth, which is also reflected in the growth of the pharmaceutical market. The growth in the consumption of drugs in these countries is particularly boosted by the endeavor of these countries to deal with the neglected pharmacological care of citizens from the insufficiently effective from the socialism era.

Graph 5

Development of sales and share of Slovak producers on domestic market



Source: SUKL, Symsite Research

—but with growing competition

Competition to domestic pharmaceutical producers comes not only in the shape of generic producers from Central and East Europe, but above all from the large multi-national corporations - producers of original drugs. Global producers of original drugs have been conquering the Eastern markets since the beginning of the 1990s, following liberalization of foreign trade with pharmaceuticals. The TOP 20 pharmaceutical companies in 1996 (in terms of financial volume of sales) sold 60% of generics and the rest original drugs. Six years later, the share of generics has fallen to almost half that value to around 35% (for more information see 'EU accession effects on market structures').

Compared to markets of other European countries, the Slovak pharmaceutical market with its USD 328m turnover is rather small. Consumption of drugs per capita in Slovakia remains one of the lowest among neighboring countries. In 2000, the average Slovak citizen consumed drugs worth USD 61 in production prices, which is (according to IMS data) three times less than the situation in Western Europe (USD 185). The average Slovak citizen consumes drugs worth just two thirds of the value consumed by the average citizen in the Czech Republic. According to calculations by Symsite Research (based on SUKL data), in 2001 the average Slovak citizen consumed drugs worth USD 70.

The drug consumption is low but increases after considering the price level and purchase power

Comparison of consumption that takes into account the purchasing power of the population is in many regards a more accurate criterion, as it considers different price levels in different countries (so-called purchasing power parity or PPP). Although the OECD calculates PPP for the whole economy - i.e. for all products and services, and not only for drugs - this comparison may at least partially assist in creating a more accurate comparison of drug consumption per capita (prices of drugs in Slovakia are generally lower than the EU or the Czech Republic, the same applies to prices of the majority of goods and services). When calculating using PPP, the lagging behind of all V4 countries is substantially less. Consumption of drugs per capita in PPP terms is approximately the same in Slovakia as in Hungary, reaching nearly 90% of the level experienced in the Netherlands. In the V4 region, the Czech Republic enjoys the highest consumption of drugs per capita (USD 279). As Slovakia has one of the youngest populations in Europe, the consumption of drugs should naturally be lower. On the other hand, the generally higher sickness rate of Slovaks tends to compensate such drug savings as a result of the shorter lifespan of Slovaks. Although in 1999 and 2000 there was a decline in drug consumption in terms of USD per capita, due to a weakening of the Slovak crown, if calculated in PPP terms, the consumption of drugs in fact rose during this period (Graph 6).

Table 9

Consumption of drugs in selected countries in 2000

USD m, USD/per capita

Region/Country	Consumption	USD/per capita	USD/per capita in PPP*
Czech Republic	995	97	279
Hungary**	875	87	210
Slovakia	328	61	200
Netherlands	3,034	191	226
Denmark	1,435	269	260
Switzerland	2,990	416	376
Sweden	2,201	248	239

* PPP – using purchasing power parity (on the basis of OECD estimates of purchasing power and comparison of price levels)

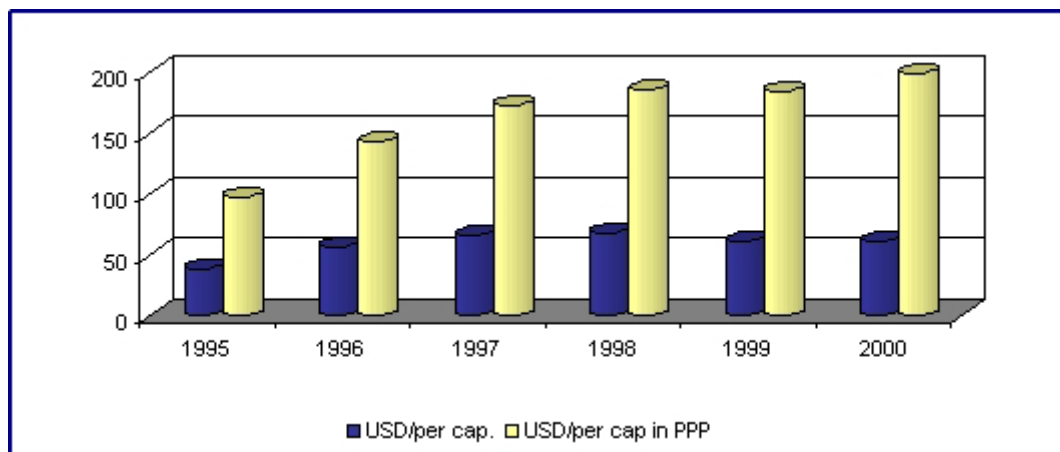
** 1999

Source: OECD Health Database 2002, Symsite Research

Graph 6

Consumption of drugs in Slovakia in nominal and PPP terms

USD/per capita



Source: OECD Health Data 2002, Symsite Research

Drug expenditures are high, although their consumption is under pressure from a number of factors

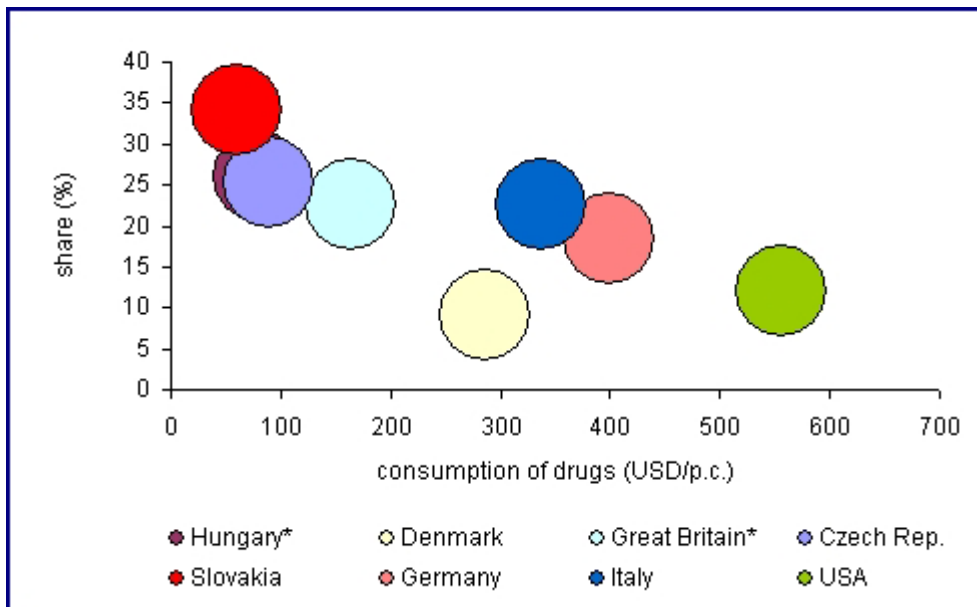
High drug expenditures are considered by almost all entities involved in the healthcare system (except for pharmaceutical companies) as one of the key factors threatening its financial stability in terms of public expenditures. More than one third of all expenses in the healthcare system are spent on the consumption of drugs, compared with 10% to 25% in more developed Western European countries. However, in nominal terms, the consumption of drugs in Slovakia at USD 61 per capita (in production prices) is one of the lowest among the countries of Eastern Europe. A higher share of drug expenses is natural to a certain extent however, due to the low price of local healthcare and labor costs (this is characteristic for all V4 countries). At the same time, the majority of drugs used in therapy come from abroad and so their prices are on a par with world prices. The fact that Slovakia consumes relatively more generics than the countries of Western

Europe, i.e. in general less expensive drugs (although differences are steadily diminishing), only supports the thesis about high drug expenses in Slovakia.

Graph 7

Consumption of drugs per capita compared to drug expenditures (% of total healthcare expenditures)

%; USD per capita; 2000, unless indicated otherwise



* 1997

Source: OECD Health Data 2002, Symsite Research

Sales of drugs in 2001 and 2002 accelerated

According to SUKL data, in 2002 the consumption of drugs in Slovakia reached Sk 21.5bn (in prices of Ministry of Finance). Compared with 2001 this represents an increase of almost 18%, similar growth was seen a year earlier. In nominal USD terms, the y/y growth of drug consumption in 2002 was even higher (+26%) because of the gradual appreciation of Slovak crown against USD. The drug consumption in USD terms stagnated in the period 1997 to 2001 due to the weakening of SKK against the American dollar. After the declines in 1999 and 2000, the number of sold units in 2001 rose again y/y by nearly 4% to 157.2m units and by another 1.5% in 2002 to 159.6m units. Resources of health insurance companies are therefore under heavy pressure, as during the first Dzurinda government in 1998-2002 the Healthcare Ministry failed to adopt fundamental reform measures that would have led to a reduction in inefficient and needless drug consumption.

Table 10

Consumption of drugs in Slovakia 1996-2002

SKK bn, USD m, million units

Consumption in	1997	1998	1999	2000	2001	2002*
SKK bn	11.9	12.9	13.6	15.3	18.3	21.5
Growth index	126.6	108.4	105.4	112.5	119.0	117.7
USD m	354	366	328	331	378	477
Growth index	115.7	103.4	89.6	100.1	114.2	126.2
EUR m	-	-	308	358	423	502
Growth index	-	-	-	116.2	118.1	118.7
Units (m)	168.5	166.2	162.7	151.6	157.2	159.6
Growth index	104.5	98.6	97.9	93.2	103.7	101.5

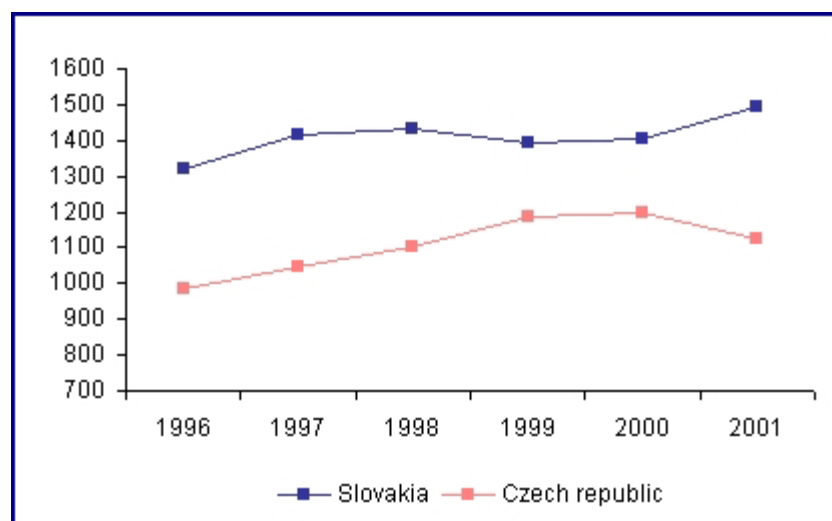
*preliminary

Source: SUKL, Symsite Research

Consumption in terms of DDD higher in Slovakia than in the Czech Republic

Consumption of drugs in DDD terms (daily defined dose – concept expressing standard daily dose of a drug determined for the treatment of the respective disease; special volume measure of consumption) per 1,000 inhabitants per day rose in 2001 in Slovakia by 6% y/y to 1,493 DDD/1,000 inhabitants/day. Compared with the Czech Republic (1,125 DDD) this number is nearly one third higher (see Graph 8), i.e. drug therapy is more efficient in the Czech Republic. With the escalating pressure of health insurers on prescribing doctors the stronger emphasis on efficiency and pharmaco-economics is to take place. Together with awaited austerity measures in drug policy (for more information see 'EU accession effects on short-term policy measures and regulatory framework') this should contribute to making pharmacological care more efficient.

Graph 8

Consumption of drugs in DDD per 1,000 inhabitants/day in Slovakia and Czech Republic

Source: SUKL in SR and CR, calculations and graph by Symsite Research

The highest share of drug consumption in Slovakia in 2001 from the 14 main ATC groups was recorded in the cardiovascular system (22%), corresponding to the fact that approximately 55% of deaths in Slovakia are caused by circulatory system diseases. The division of the consumption of drugs according to ATC groups is similar in the Czech and Slovak republics and does not significantly differ from the division used in the EU countries (Table 11). The drug range sold by Slovakofarma on the domestic market corresponds with drug consumption in relative terms. The four largest therapeutic groups consumed in Slovakia are those that are largest within the structure of Slovakofarma's domestic sales (cardiovascular, digestive tract/metabolism, nervous system and antinfectives). On the other hand, Hoechst-Biotika specializes in the cardiovascular segment—the largest therapeutic group consumed by Czech, Slovak or European patients. The development of the drug range of both companies in the middle run will be more a result of adapting the business strategy by new owners rather than changes in drug consumption.

Table 11

Share of ATC groups in drug consumption in Slovakia, the Czech Republic and EU countries

%, financial volume, 2001, 2000 in the case of EU countries

Therapeutic drug area	SR*	CR	EU
A digestive tract / metabolism	12 (16)	13	14
B blood and haemopoietic organs	6 (7)	8	5
C cardiovascular system	22 (13)	20	20
G urogenital system	5 (3)	6	5
J systemic antiinfective	12 (19)	9	11
M musculoskeletal system	6 (7)	6	5
N central nervous system	13 (12)	12	14
R respiratory system	9 (10)	9	9
Other	15 (13)	17	17

* numbers in brackets indicate the share of the given ATC group in total drug consumption in 1995

Source: SUKL SR, SUKL CR, IMS Health, calculations by Symsite Research

With the gradual alignment of Slovakia's demography and health status towards the standards in current EU members, the participation of therapeutic categories of drugs will come closer to the EU average. Although the gap between the ATC shares in Slovak Republic and the EU average will continue to narrow, some specific discrepancies amongst individual countries will remain. Demography and health status of Slovakia is significantly shaped by the minorities—Hungarians and Romas—when compared with the more nationally homogenous Czech Republic for example. Thus, higher prevalence of circulatory system diseases amongst Hungarians increases cardiovascular drug consumption. One of the most important social-economic factors influencing the structure of pharmaceuticals consumption will be the success of healthcare reform. Implementation of stronger market principles into the healthcare system would also result in the remedy of a distorted pharmaceutical market. The current drug market is distorted by redundant and unfounded drug consumption because of low co-payments as well as bad prescription habits of Slovak doctors from the economic point of view.

Table 12

Forces driving the Slovak pharmaceutical market in the near future

Driving Forces		
Factors	to converge to EU	to keep national features
Social - Demographic	ageing decreasing fertility and natural addition improving nutrition quality	health status of Hungarian and Roma minorities weak adaptation of eating habits and healthy lifestyle in some regions (East)
Economic	improved accessibility of drugs successful healthcare reform with market principles implemented	lower purchasing power state drug policy - strategy for drug reimbursement by health insurers

Source: Symsite Research

Over-the-counter (OTC) drugs

Sales of OTC drugs stagnate—

The market of OTC drugs in Slovakia remains deformed by many drugs that are partially or fully reimbursed by health insurance companies. OTC drugs put constant pressure on public finances, although their significance should be the reverse. OTC preparations are subject to the regime of maximum prices in Slovakia, although in the majority of EU countries their prices are liberalized. Despite a continuing and relatively high coverage rate of OTC drugs by compulsory health insurance, sales of OTC drugs in Slovakia have stagnated according to SUKL data. During the last few years, the Ministry of Health decided to move drugs not covered by insurance companies to the category of OTC, for example certain antihemorrhagics substances, vitamins, or the popular pain-killer, Ibuprofen, made by Leciva.

The share of OTC drugs of total sales declined from nearly 20% in 1996 to 11% in 2002. In Western Europe, the share of OTC preparations in the total drug consumption ranges between 10-30% with governments increasingly transferring prescription drugs to the category of OTC drugs due to increased public expenditure (Rx to OTC switching). A decline was recorded also in sold units, with a 38% slump in 2001. After the decline in 1998 and 1999 the sales of OTC drugs rose in 2000 by a mere 1%. A year later this increased to 6% in financial terms to Sk 2.3bn also thanks to an increase in real wages in the population. The preliminary data for 2002 reveal only a slight 4% increase in OTC market. Low purchasing power as well as a low level of awareness, together with the still present illusion of a free-of-charge healthcare system, are among the biggest obstacles facing greater development of the OTC preparations market. The condition of the OTC market will affect Slovakofarma's performance to a significant degree as its 28% of sales in Slovakia in 2001 were OTC drugs (mostly Vitamin E, Anopyrin, Acylpyrin and others). Slovakofarma is the second largest firm in terms of OTC drug sales in Slovakia. Expanding the OTC market may spur Slovakofarma's sales both at home and abroad. Moreover, once merged with Leciva (which is the number one in the Slovak OTC market) quite positive middle term outlook for the OTC market will favor both companies. The remaining three crucial local pharmaceutical producers do not concentrate on the OTC market and no radical change in such an approach is seen in the future.

Table 13

Historical consumption of OTC drugs in Slovakia

SKK m, thsnd units, USD m, %

Consumption in	1997	1998	1999	2000	2001	2002*
SKK m	2,327	2,245	2,149	2,170	2,307	2,396
Growth index	119.7	96.5	95.7	101.0	106.3	103.8
Share on total consumption	19.6	17.4	15.8	14.2	12.6	11.1
USD m	69.2	63.7	51.9	47.0	47.7	53.0
Growth index	109.2	92.1	81.5	90.5	101.6	111.2
in units (m)	76.4	69.6	67.4	60.4	60.4	58.7
Growth index	102.5	91.2	96.9	89.5	100.1	97.1
Share on total consumption	45.3	41.9	41.5	39.8	38.4	36.8

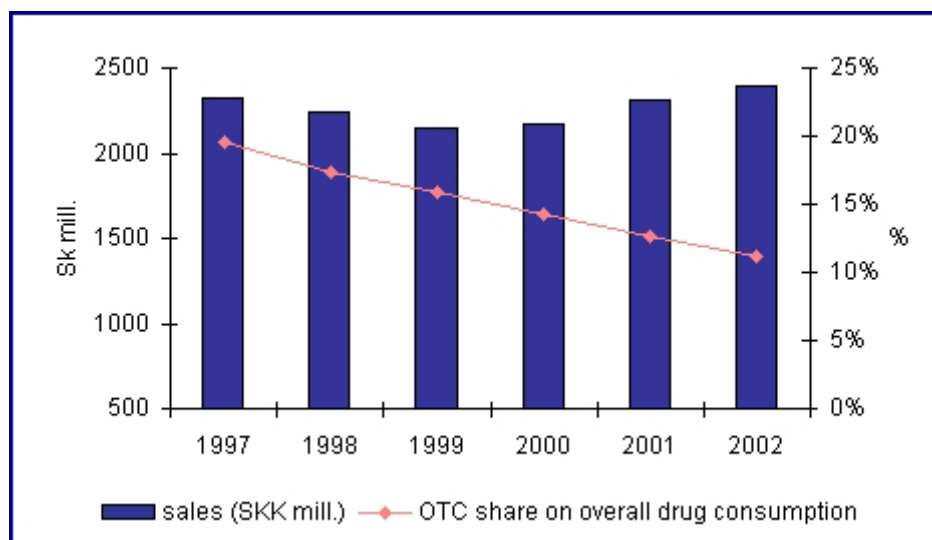
* preliminary data

Source: SUKL/MCR, calculations by Symsite Research

Graph 9

Historical consumption of OTC drugs in Slovakia

SKK m, %



note - data for 2002 are preliminary

Source: SUKL, graph by Symsite Research

—also thanks to efforts by MH SR to lower coverage in the form of health insurance

Stagnation in the consumption of OTC drugs is also affected by the intense effort of the state to lower reimbursements by insurance companies for OTC drugs, mainly through the categorization tool. In 2002, sales of fully covered OTC drugs rose by 9% to Sk 267m. The share of OTC drugs not covered by health insurance companies (with full co-payment by patients) slightly decreased. We project the significance of

OTC drugs not covered by health insurance companies to increase in the coming years, “heavily supported” by reform measures of the new Health Minister, Rudolf Zajac. On the basis of data from AESGP (Association of European self-medication industry) member organizations and calculations by *Symsite Research*, Slovakia has the lowest consumption of OTC drugs among all V4 countries - only EUR 12.5 per capita.

Table 14
Consumption of OTC drugs* in 2001 in selected countries

EUR m, EUR/per capita, %

Country	OTC market	Consumption per capita	Share on total consumption
V4 total	1,458	23.8	20%
Czech Republic**	171	16.7	15%
Hungary	174	17.4	14%
Poland	1,054	27.3	24%
Slovakia	68	12.5	11%
European Union***	22,829	60.1	19%
Austria	292	35.9	9%
Great Britain	3,905	65.2	27%

* consumption of OTC drugs available without prescription in end public prices (including VAT)

** 2000

*** average (except for Luxemburg)

Source: AESGP (Association of European Self-Medication Industry), calculations by *Symsite Research*

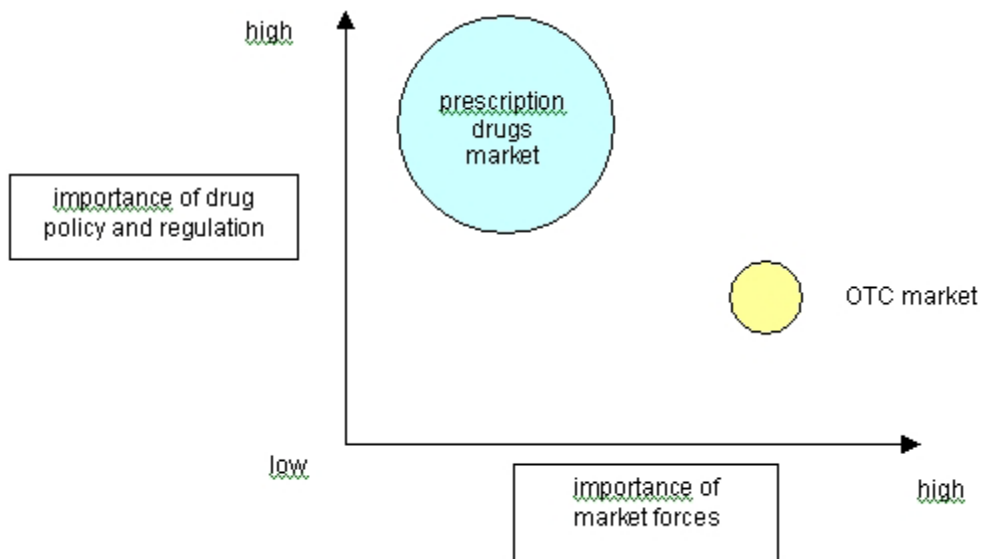
Outlook

Local market shaped by reforms

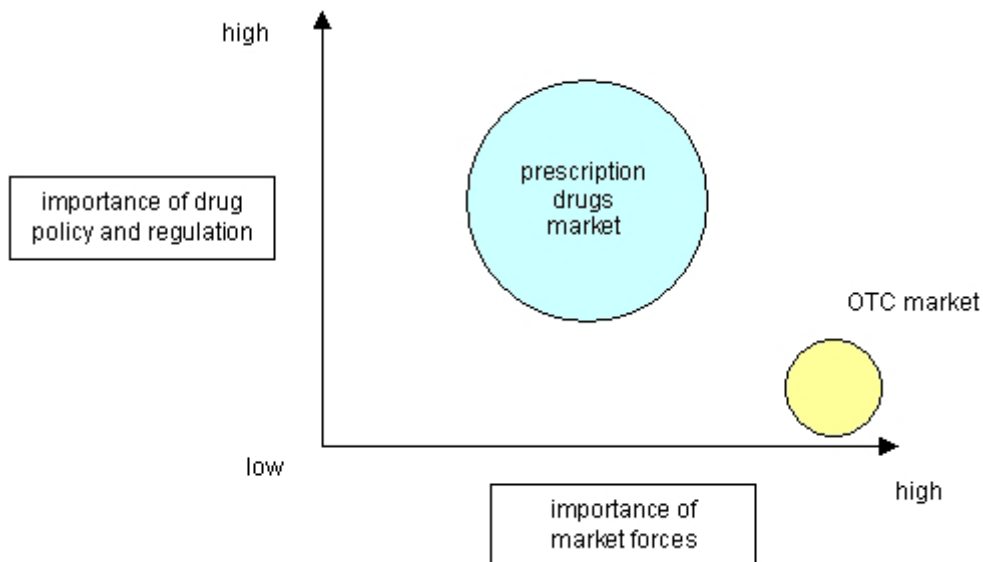
Within the market of drugs prescribed by doctors the relevance of measures taken as part of the drug policy of Health Ministry is higher than in the OTC market. The prescription market is influenced more by public expenditures (regulated and re-distributed by the state) and measures imposed by the state on prescribing doctors—i.e. regulatory elements—than the OTC market. Market factors, of which purchasing power, advertising, or consumers preferences are amongst the most important, do not play a crucial role in the prescription segment. On the contrary the OTC market is strongly shaped by market forces in a similar way as the standard consumer goods are. As mentioned earlier in this paper, today’s Slovak OTC market, however, is heavily distorted by reimbursement of drugs from health insurance companies. After EU enlargement (May 2004) and enforcement of the principles of healthcare reform by the current government, the OTC market will be further liberalized. The prescription drugs market is going to move towards market principles only gradually, especially from the viewpoint of getting patients more involved in pharmacological treatment by higher out-of-pocket payments.

Diagram 1

Position of OTC and prescription drugs market in 2001/2002



Position of OTC and prescription drugs market in 2004/2005



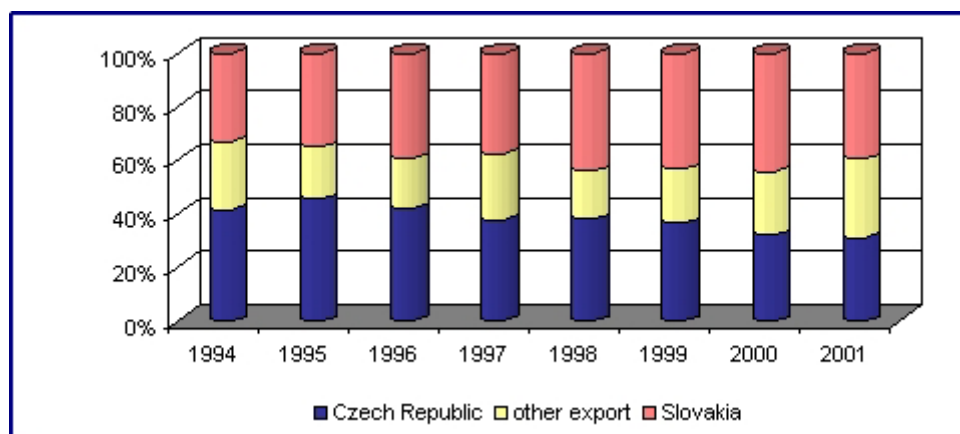
Source: Symsite Research

The pharmaceutical industry in Slovakia is very much influenced by the pricing and reimbursement policies on export territories and in Slovakia. The restrictive measures applied in the field of drug policy by the new and resolute health minister, Rudolf Zajac, did not automatically lead to a greater reduction in the growth of drug sales in 2002, but the results of such will be more evident in 2003 and 2004. The most serious competitors of domestic producers—Western pharmaceutical companies selling mainly original drugs—will profit from the strong Slovak crown in 2003 – 06. On the contrary, their profits will be diluted by lower reimbursements by health insurance companies as the consequence of pressure on cutting drug expenditures. Slovak crown appreciation may hamper greater export expansion of the local producers. The gains due to gradual increase of productivity and lower labor costs (compared to Western Europe) will compensate for losses caused by strong SKK, however. Visegrad countries together with other Central and Eastern European countries will be crucial export targets for Slovakoforma after the enlargement. The sector's dependence on the Czech and Slovak market will likely diminish in the long run in favor of other Eastern and Western countries. However the massive expansion to former Soviet Union states may be hindered by import restrictions, pressures of which are increasingly growing (e.g. Russia).

Graph 10

The sales structure of Slovak pharmaceutical companies

%



Source: AFV SR—Association of pharmaceutical producers SR

Positive outlook for Slovakofarma

The above trends will, according to Symsite Research, lead to a slight increase in the market share of local producers on the domestic market in the medium term. A natural consequence will be an increased share of generics on the domestic drug consumption. The wave of patent expirations will bring in new producers of generics, causing further fragmentation of the local market. The mentioned health reforms will increase the importance of the OTC market. All this will benefit the major local pharmaceutical producer, Slovakofarma. Similar trends are expected also on neighboring markets.

Table 15

Key features of the Slovak pharmaceutical market (%)

	1999	2002	2004
domestic production (%)	15	10	11
key therapeutic drivers*	genito-urinary cardiovascular nervous system antiinfectives	nervous system blood, blood forming organs cardiovascular oncology	nervous system alimentarytract/metabolism respiratory cardiovascular
generics (% estimate)	60%**	35%	35-40%
TOP 10 vendors (% of the market)	49%	45%	40%
OTC market growth	-4%	+4%	+12%
SKK/USD exchange rate	41.4	45.2	38.0

* therapeutic groups valued over Sk 500m with the largest y/y change

**1996

note - data for 2002 are preliminary, data for 2004 are projection by Symsite Research

Source: SUKL, Symsite Research

OTC market will grow in importance

The economic slowdown in the late 1990s resulted in the stagnation of the OTC drug market in Slovakia. As the OTC drug market is even more sensitive to economic development than the prescription drug market,

awaited acceleration of economy will bring a revival of OTC consumption. After EU enlargement Slovakia is anticipated to experience a double-digit growth in OTC market, driven almost entirely by consumption in the Bratislava region. The Health Ministry aims to motivate patients for switching from prescription drugs to OTC drug category, with two goals in mind. The first one is to ease the pressure on the limited budgets of health insurance companies. The second reason is to improve information awareness on self-medication treatment. Patients should use self-medication where possible, which is in line with trends in EU countries. This will further ease pressures on health insurance funds - less patients visiting doctors or staying in hospitals. Such "switching climate" will surely contribute to the growth of OTC drug sales after EU enlargement. The current supply of around 2,500 OTC drugs (including all drug forms) on the Slovak market will be broadened in two ways. First, the number of drugs available will be increased, much as the indication base of OTC preparations (e.g. the discussions to release some hypolipidemics are being held). There are still many therapeutic areas in Slovakia with high potential to go OTC, including nervous and respiratory systems, alimentary tract or musculo-skeletal system. Improved purchasing power and awareness of the population regarding opportunities for self-treatment, together with ongoing efforts of the state to reduce the level of coverage of OTC drugs from public funds, will bring a slight 7% to 9% growth in sales in 2003, with double digit outlook for mid-term period after the enlargement of the EU. All of those features provide great opportunities for OTC expansion of Slovakofarma/Leciva in Slovakia, and in the Central and Eastern European markets as well.

In the long term the adoption of the Euro will eliminate the impacts of exchange rate fluctuations on Slovak exporters. The export towards West will be stimulated from this point of view. With regard to the export to former Soviet Union territories the currency moves will remain one the key influencing factors. The benefits of adopted EU marketing authorization standards will fully transform into simplified and easier access to the EU market. Slovak generics designed for treatment of cardiovascular diseases, alimentary tract and metabolism and anti-infectives may become competitive products on the Western market. Moreover, if we look towards the future in the context of capital acquisition resulting in the planned merger of Slovakia/Leciva, Biotika with its key production currently focused on substances faces a higher risk of price oscillations than finalized production of human drugs. Its future will depend strongly on the form and intensity of cooperation with its partner – Aventis.

The effect of accession on foreign trade

The outcome of the swift liberalization of foreign trade in early 1990s is a rapid growth in imports, resulting in a long-term deficit in trade with pharmaceuticals. In line with WTO rules, imports of pharmaceuticals are subject to no barriers. Local drug producers are exposed to a strong competition mainly from west European producers of original molecules. The trade deficit in pharmaceutical products is gradually increasing to nearly Sk 16bn in 2002, but with the outlook of slowing down a bit. The prospects of selling generics made by Slovakofarma—the largest domestic producer—in the single EU market will improve after joining the EU. The already mentioned shift towards greater use of generic drugs in the EU will benefit Slovakofarma. One of the impacts of accession of Slovakia to the EU may be the so-called parallel trade—lower prices of drugs sold in Slovakia may cause their re-export to countries with higher price levels. However, Slovak authorities see the threat of re-exports to be well treated.

The export of pharmaceuticals is represented to three quarters by final products—generic drugs and products of licensed production (in Hoechst-Biotika). The key export market of Slovak producers is the Czech Republic accounting for two thirds of overall pharmaceutical export in 2002. The rest was exported to the countries of Central and East Europe, such as Russia (5%), Poland (3%), Bulgaria (3%) and Ukraine (2%). The pharmaceutical export to Netherlands (9% share on overall export in 2002) is on the rise thanks to the increased production and export of cotton wool and gauzes. Pharmaceutical exports are stagnating, which when taking into account the double-figure growth in exports seen by the country as a whole, represents a drop in the share of this sector in overall exports from 1.5% in 1997 to 0.9% in 2000-2002.

The share of pharmaceutical exports in overall exports of Slovakia will continue to fall also thanks to the continuing high level of dynamics of export growth in sectors with foreign investors (automotive, electro-technical and paper industries). Exports of drugs from Slovakia to the main export territories (CEE, EU) are not subject to any customs duty or quotas, even though certain countries of the former Soviet Union are putting continued pressure on the introduction of customs duties.

Table 16

Structure of exports of pharmaceutical products

Sk m

	1999	2000	2001	2002
Drugs for sale in small amounts	3.459,8	3.313,7	3.921,7	3.934,3
Human and animal blood, anti-serum, vaccines, toxins and other blood components and modified immunological products	51,4	22,8	40,7	34,9
Drugs not in measured dosages or in packaging for sale in small quantities	55,6	47,2	56,1	84,1
Cotton wool, gauze, bandages and similar goods	15,7	31,4	226,7	438,6
Glands and other organs for organo-therapeutic purposes	1	0	4,5	9,9
Other pharmaceutical products *	19,4	31	18,6	25,9

Source: Ministry for the Economy SR

* sterile surgical materials, dental cements and fillings, diagnostic reagents, hormonal and spermicidal anti-conception, first aid kits

Slovakofarma exports its products to more than 30 countries, whereby the value of exports accounted for as much as 76% of sales in 2001. Export is focused on the markets of Central and East Europe and the former states of the USSR. Slovakofarma placed 57% of all sales in the Czech Republic in 2001. A key market (excluding the Slovak and Czech republics) continues to be Russia with Sk 284m in exports going to this large market in 2001. Slovakofarma went forward with massive expansion in the Polish market, when sales in this territory increased by an amazing 120% to Sk 184m in 2001. The Central and Eastern Europe is crucial export territory also for Hoechst-Biotika (mainly the Czech Republic, Hungary, Bulgaria, Lithuania). The export of this firm—the only operation in V4 countries—represented 46% of all the production in 2001. The third pillar of domestic pharmaceutical industry Biotika exported over 80% of its production in 2001. Two thirds of human medicines went to the Czech Republic. EU enlargement, namely the harmonized regulatory framework, will facilitate the access of drugs to Western and Eastern Europe as well. Nonetheless, better legislation and institutional environment is not the key to success in internal market. Quality of products and corporate strategy to expand count more.

Imports of pharmacy is rising sharply—

The outcome of sharp liberalization of foreign trade with pharmaceutical products at the beginning of the 1990's is a long-term trade deficit, similar to neighboring transition economies. The foreign trade deficit of the Slovak Republic in pharmaceutical products is gradually increasing, to Sk 16bn in 2002. The main reason is the double digit increase in imports of final products during 1999-2002, mostly original products. Stagnating exports, mainly concerning generic drugs also contributes to the deficit. Drugs are the fifth most significant import item in terms of financial volume.

Table 17

Development of foreign trade of Slovakia with pharmaceutical products

Sk m., %

	1997	1998	1999	2000	2001	2002
Import of finished products	10,915	11,152	14,021	15,890	18,706	21,158
Import of raw materials	1,080	983	893	851	1,024	1,089
Total imports	11,995	12,135	14,914	16,741	19,730	22,247
<i>Year-on-year growth (%)</i>	<i>N</i>	+1.2	22.9	+12.3	+17.9	+12.8
<i>Y/Y growth in total imports of SR (%)</i>	+4.3	+17.4	+1.8	+26.0	+21.0	+4.7
% of all imports to SR	3.0	2.6	3.2	2.8	2.8	3.0
Export of finished products	3,557	3,203	3,599	3,445	4,262	4,516
Export of raw materials	1,450	1,184	1,161	1,265	1,485	1,511
Total exports	4,873	4,441	4,760	4,709	5,747	6,027
<i>Year-on-year growth (%)</i>	<i>n</i>	-8.9	+7.2	-1.1	+22.0	+4.9
<i>Y/y growth in total exports of SR (%)</i>	+2.5	+16.4	+12.1	+29.4	+11.4	+6.5
% of all exports of SR	1.5	1.2	1.1	0.9	0.9	0.9
Balance	-7,122	-7,694	-10,154	-12,032	-13,983	-16,220
% of overall balance of SR	12.1	9.3	22.4	28.4	13.6	16.8

Source: SU SR, Symsite Research

—mainly due to the import of original drugs from the EU

The import of pharmaceutical preparations is made up by 95% of finished products. These are mostly original drugs from Western Europe and generics from the neighboring countries of Central and Eastern Europe. The dynamic of growth is influenced to a great degree by categorization of drugs—i.e. the level of reimbursement of drugs by health insurance companies, and corresponding demand. Overall, in the past three years imports of pharmaceutical products have constituted around 3% of all imports to Slovakia, with the share seen as stable in the long-term with a growth in real wages of Slovaks. On the other hand, we can expect short-term fluctuations in connection with the reform of the financing of the health service and costs for drugs over the next 2-3 years. If the cost-containment measures prepared by the Health Ministry are imposed, a significant drop in imports is quite possible.

Table 18

Structure of imports of pharmaceutical products

Sk mill.

	1999	2000	2001	2002
Drugs for sale in small amounts	12,065.7	14,003.9	16,500.9	18,825.6
Human and animal blood, anti-serum, vaccines, toxins and other blood components and modified immunological products	801.0	751.3	1,005.3	1,188.2
Drugs not in measured dosages or in packaging for sale in small quantities	413.1	326.1	322.3	247.9
Cotton wool, gauze, bandages and similar goods	301.8	293.8	313.4	314.8
Glands and other organs for organotherapeutic purposes	9.7	17.1	13.9	9.5
Other pharmaceutical products *	579.7	650.2	737.7	785.1

Source: Ministry for the Economy SR

* sterile surgical materials, dental cements and fillings, diagnostic reagents, hormonal and spermicidal anti-conception, first aid kits

Customs duty on drugs is mostly zero

Slovakia's trade policy is shaped by its membership in World Trade Organization and related obligations as well as by harmonization with trade policy applied in the EU. The latter regards mostly the chapter on free movements of goods, one of the cornerstones of the EU single market. In general, there are no import restrictions concerning drugs and importers are not required to possess an import license. The tariff protection of the market with pharmaceutical products and appliances is minimal in Slovakia. Drugs are subject to general customs duty of 10% of the value of the import, although the tariff for absolute majority of imports is zero. This is the contractual tariff for WTO member countries. Preferential tariffs are applicable to so-called developing countries, among which Slovakia has included most of the countries of the former USSR, Latin America, Asia and Africa. For less developed countries, as they are referred, including the poorest countries of Africa, the Caribbean and Asia, customs duty is automatically waived. The main imports of medicines to Slovakia in financial terms come from Western Europe (Germany, France, Switzerland, Belgium, Great Britain), however number of them are headquartered in USA.

Table 19

Volume of imports of drugs to Slovakia by country

Sk mill.

Country	1997	1998	1999	2000	2001	2002
Germany	1.860	2.326	1.948	2.231	2.814	3.536
France	809	928	1.068	1.486	1,875	2.378
Switzerland	1.368	1.377	1.186	1.392	1.842	2.171
Czech Republic	1.958	1.689	1.917	1.944	2.100	2.153
Belgium	729	884	973	1.255	1.576	1.822
Great Britain	729	777	837	995	1.292	1.768
Italy	277	409	449	661	801	948
Netherlands	265	372	438	556	755	852
Slovenia	612	699	730	657	775	755
Hungary	532	517	572	606	654	678
Denmark	345	347	439	391	440	534

Source: SUKL

The Customs tariff code, which is set by government resolution once per year, specifies hundreds of drugs and their components in detail, including determined customs tariffs. A brief overview of the main groups of drugs with their pertinent customs tariffs in the Slovak Republic is given in Table 20. In line with obligations of the Slovak Republic to the WTO the tariffs on agreed range of pharmaceutical products are continually decreasing since 2000 up to zero until 2004. Similarly to drugs, medical devices and appliances are also stated in the Customs tariff code with specific divisions. General duty is in the range of 5-12%, however the majority of imports are subject to lower contractual tariffs.

Table 20

Level of customs duty on selected pharmaceutical products and groups of products as of 1 January 2003

%

Product	General duty	Contractual duty	Preferential duty
Glands and other organs	10	No duty	-50
Antiserums	10	No duty	--
Vaccine substances	No duty	No duty	--
Human and animal blood	7	No duty	-100
Medicinal mixtures for wholesale	10	No duty	-50*
Drugs for retail, in units or dosages	10	No duty	-50**
Cotton wool, gauzes and so on	10	No duty	--
Plasters	17	No duty	-50
Sterile material for surgery	7	No duty	-100
Diagnostic reagents	10	No duty	-100
Dental cements and fillings	15	No duty	-50
Hormonal and spermicidal contraceptives	13	No duty	-50

Source: Customs tariff code, Digest of laws (part 728/2002)

* only for selected drugs, containing alkaloids or their derivatives

** only for selected drugs containing hormones and alkaloids

The arguments to support the thesis about the stronger competitiveness of the Slovak pharmaceutical producers after EU enlargement prevail over those in the favor of loosing in the EU single market. The significant ownership changes (Slovakofarma and Biotika as well) occurring in the pharmaceutical industry in 2002-2003 should bring in the capital for investment and expansion. The alliance between Leciva and Slovakofarma leading to their merger will form one of the TOP 5 pharmaceutical companies in Central and Eastern Europe. Company representatives believe that by joining the forces Slovakofarma / Leciva will succeed on the single market after the EU enlargement. There is a high probability that the merger will be successful with favorable synergic effects also thanks to the cultural and geographical proximity. According to the Standard and Poor's rating agency the mergers of pharmaceutical firms from the same country perform better compared with mergers of partners from different countries (however some exceptions exist, for example a successful merger of AstraZeneca). The strong and diverse drug portfolio of top quality generics will be one of the key benefits of a merger.

Aventis decided to sell the joint venture business with Biotika (Hoechst-Biotika) in line with its global strategy to reduce too many manufacturing operations in the world. Aventis however assumes to keep close relations with Hoechst-Biotika. This would benefit the partner interested in acquiring the stake—Biotika. Moreover, the current management of Biotika was able to stabilize financial situation during the past two years. The future of Imuna—sole producer of blood serums and derivates in Slovakia—remains unclear even after acquisition by new Slovak investor. The company's fate depends on whether it is able to arrange the operation fully in line with good manufacturing practice until the EU enlargement. The following scheme provides the brief outlook of factors influencing the pharmaceutical industry within the short-term period.

Harmonized regulatory framework with common principles and standards will make export easier. The registration dossiers applied in compliance with EU standards are more strict than those required by authorities in non-candidate Eastern countries. Once a dossier is elaborated under the tough EU rules the exporter's entry to countries applying less strict criteria is much facilitated. Some Eastern countries require specific information when handling with dossiers (e.g. Ukraine). Those however are just minor (e.g. the structure of leaflet information) and according to Mr. Martinec are not related to the very essence of the dossier. A need to fulfill some minor national requirements in Eastern countries do not negate the benefits of EU standards adherence in those market.

From this point of view EU enlargement will lead to the facilitation of trade as claimed by several representatives of pharmaceutical companies. Generic producers are increasingly benefiting from the support of cheaper drugs by governments both in Eastern and Western Europe due to growing public healthcare expenditures. This may be a plus for domestic generic industry. On the other hand competition from foreign generic producers may have negative impact on sector's competitiveness—Scheme 1.

Scheme 1

Key factors to influence the competitiveness of the Slovak pharmaceutical industry

Positive impacts-opportunities	Negative impacts-threats
<ul style="list-style-type: none"> - easier access to EU market - facilitation of trade - promotion of generic prescribing due to cost-containment measures in healthcare - huge patent expiry wave in 2000-2005 	<ul style="list-style-type: none"> - generic competition from CEE and Western Europe - uncertain future of Imuna - aggressive marketing by producers of patented drugs

Source: Symsite Research

Parallel trade with medicines—

Price control within the individual countries remains one the barriers of free movement of medicines. The market imperfections resulting from miscellaneous systems of price controls and drugs reimbursement together with different price levels throughout Europe (EU members and candidates) are widely considered to cause parallel trade. Wholesalers buy medicines in the EU parts with lower prices while selling them in the higher priced parts of the European Union. Fears of re-exports is widely spread amongst pharmaceutical industry as the representatives worry about the dilution of profits. Mr. Ludevít Martinec, director of SUKL, says Slovakia is not involved in re-exports. With the establishment of a single market however the re-exports may arise according to him. He adds the re-export issue is going to be treated by legislation to a certain level in 2003 by proposed complex amendment to the Act 140/1998 on drugs and medical appliances. The proposed amendment should determine the space where wholesalers can operate, but rather in general (e.g. to secure safety and quality of medicines when handling with medicinal products). It is impossible to entirely deter re-export activities (that are driven by economic interests of vendors) by legislation.

—strongly prevented by legislation

Mr. Jozef Slany of the Health Ministry thinks that already adopted regulatory conditions in Slovakia (as an importing country) strongly discourage possible re-exports. He believes one of the key obstacles is the drugs labeling and the leaflets which must be translated to Slovak when entering domestic market. Otherwise the drugs cannot be released onto the market. Subsequent re-labeling and customs control would make re-exporting too complicated and even tricky according to Mr. Slany. The representatives of pharmaceutical companies selling drugs in Slovakia do not exclude an increased parallel trade. This is conditioned by a number of factors, pricing and reimbursement policy or economic factors (e.g. transportation costs, adequate

profit from such operation). Parallel trade, if relevant, is not going to hamper the competitiveness of key Slovak pharmaceutical companies—Slovakofarma, Hoechst-Biotika and Biotika.

The effect of accession on FDI inflow

The drug market is closely linked with the general good state of the healthcare system in Slovakia and so is foreign direct investment. The only foreign strategic investor in the local pharmaceutical production, Aventis, plans to sell the operation in Slovakia. The sole foreign financial investor in the Slovak pharmaceutical industry, Warburg Pincus, will focus on consolidating Slovakofarma (and Leciva) to get it ready for a single market challenge in enlarged EU, and subsequent sale. While the current debt-producing and un-reformed health care system in Slovakia does not provide sufficient stimuli for any strategic investor, the future looks considerably brighter. Potential strategic investors in this sector will enjoy the rather small, but reformed healthcare system as well as the advantage of low wages—the lowest around the V4 region. On the other hand, until now R & D demanding industries (like pharmaceuticals) are still rather reluctant to move capacities to the wage-favorable countries in the East.

Within the Slovak economy there are a number of manufacturing sectors providing more favorable opportunities to invest than pharmaceuticals. The key sectors from the point of view of FDI are metallurgy (U.S. Steel) and automotive. The automotive industry is shaped by Volkswagen (French PSA is on the way) with strong multiplication effects on other industries that supply car makers (metals, plastics, rubber, electronics, textile, etc.). Global pharmaceutical corporations do not move production eastward as swiftly as seen in sectors facing declining margins, e.g. automotive, electronics, textile or food. FDI in chemical production (incl. pharmaceuticals) amounted to Sk 6.8bn by end of September 2002, which is less than 7% of overall FDI volume in the Slovak manufacturing. Wage favorable Eastern countries are thus more attractive for investments into labor-intense than R&D demanding industries.

Table 21

TOP six manufacturing sectors based on FDI volume

SKK m, as of September 30, 2002

sector	FDI	key investors
metallurgy	34.790	US Steel, Norsk Hydro, AFE Metal, Punch, Glacier
food products	13.190	Coca Cola, Heineken, Kraft Foods, Eastern Sugar
coke and refined petroleum products	7.481	MOL
chemicals and chemical products	6.798	Henkel, Degussa, Rhodia, Gruppo Bonazzi (Aquafil)
metal constructions and metal products	6.243	INA, Tower Automotive, Harsco, Rautenbach, Bekaert
motor vehicles	5.945	Volkswagen, Sachs, Teleflex, Kuster
Slovak manufacturing total	101.011	-

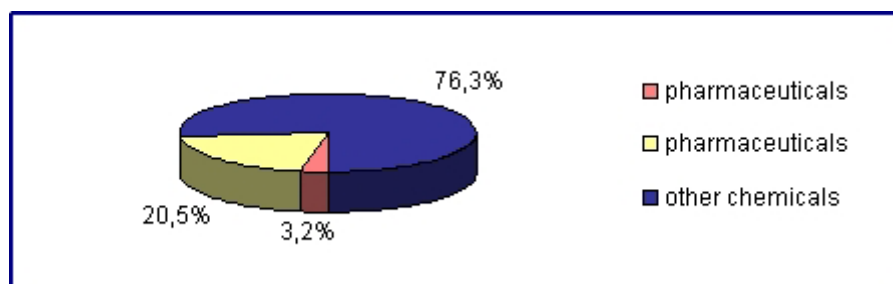
Source: National Bank of Slovakia, Symsite Research

Up to the end of 2002 FDI in pharmaceuticals accounted for one fifth of all FDI in the chemical production in Slovakia (graph 11). The share of FDI in pharmaceuticals on overall chemical production was actually just 3%, as the Austrian S.L Pharma Holding—majority owner of Slovakofarma—is owned by managers of Slovakofarma (see further).

Graph 11

FDI in pharmaceuticals within the production of chemicals and chemical products

%, as of September 30, 2002



Source: National Bank of Slovakia, Symsite Research

Unlike Hungary and the Czech Republic the interest of foreign investors in entering the pharmaceutical sector in Slovakia is weak, as only one of the four key Slovak pharmaceutical companies was in foreign hands as of the end of 2002—the joint venture Hoechst-Biotika belongs to the German-French concern Aventis. All privatization sales of former state enterprises therefore went to Slovak hands with foreign investors only acquiring small share in Slovakofarma and Biotika by the subscription of global depository receipts GDR and secondary purchase on the stock exchange. Slovakofarma and Biotika were partially privatized via coupon privatization in 1993. One year later the privatization of Slovakofarma culminated in the direct sale of shares to the management and political supporters of the ruling government party of the time HZDS. The privatization of Biotika was completed in 1996 by non-transparent direct sale of the FNM's (National Property Fund; privatization agency) stake under the unfavorable conditions.

Table 22

Overview of privatization of pharmaceutical companies

	year	method of privatization/ establishment	package of shares	acquirer	note
Slovakofarma	1994	direct sale	78.08%	S.L. Pharma Holding, Vienna	Managers sold their majority stake in Slovakofarma to Warburg Pincus in January 2003
Biotika	1996	direct sale	53.82%	G.V. Pharma, Presov	company managers are majority owners
Hoechst-Biotika	1992	joint venture	53.39%	Hoechst	part of the concern Aventis, which announced its plan to withdraw from venture
Imuna	2002	sell off of bankrupt estate to selected prospects	SKK 120 million	Imuna Pharm Holding	after bankruptcy imposed on Imuna in June 2002, acquired by Slovak investor in November 2002

Source: Symsite Research, National property fund (FNM SR)

The only strategic investor in pharmaceuticals production—

The only strategic foreign investment to be made in Slovak pharmacy to date comes in the shape of the joint venture Hoechst-Biotika. Hoechst Biotika is also the only company with any substantial production of original preparations in Slovakia. The joint venture of Hoechst-Biotika based in Martin (HBM) was created in 1992 with the entry of the German concern Hoechst (52.23%) to the Biotika plant in Martin (Biotika owns 47.77%). Hoechst subscribed technological equipment to the joint company for the production of solid and semi-solid medicinal forms, as well as know-how concerning the technology of producing tablets, ointments and creams. Biotika contributed a new pharmaceutical pavilion, equipped with technological equipment for the production of injection preparations, as well as qualified personnel. At the time there were three main reasons for the entry of the German concern to Slovakia (in fact, it concerned Czechoslovakia; Hoechst would probably not have come if it had forecast the division of the federation). The first reason comprised the comparatively low costs in Slovakia (labor costs, new market). The second reason was the existence of a fairly modern plant at the time, and the third was the high level of technical knowledge and qualified level of the personnel. The project was intended to produce for the Czech and Slovak market. Due to its own financial problems, Biotika decided to sell its stake in HBM to Aventis in 2000. The German-French concern has not expressed interest in buying the remaining stake in HBM. Quite the reverse, in the autumn 2001 the management of Aventis decided to get rid of its majority share in the operation in Martin.

—intends to leave the country

Aventis has not yet managed to fulfill its aim of selling off its share in Hoechst-Biotika, accounting for the "difficult times" in world pharmacy. The concern has expressed several times that it is not determined to sell at any price. The turnover of HBM is negligible within the scope of the Aventis concern—roughly 0.2%. According to Aventis representatives, thanks to the fusion of Hoechst Marion Roussel and Rhône-Poulenc in 1999 the concern has too many operations in the world when compared with other pharmaceutical companies. The scope of production possible at the Martin plant is limited and will always only constitute a small share of the whole range of Aventis products. Aventis, however, will keep close relations with Hoechst-Biotika after the sale. We expect Aventis to hold the sale back until such times as the price of the share is acceptable for the market, which will certainly include the Sk 1bn plus investment injected into Hoechst-Biotika during its presence in Slovakia.

Slovakofarma to American hands

For more than a year Slovakofarma has been holding sales talks with American investment trust Warburg Pincus. Even though the plan was to conclude the contract in 1H 2002, the contract was postponed considerably due to differing ideas about the price. On January 20th, 2003 representatives of S.L. Pharma Holding (majority owner of Slovakofarma; managers plus Vladimir Poor, formerly HZDS supporter) and Warburg Pincus signed a contract on selling a majority stake in Slovakofarma to the American trust. The financial terms of acquisition were not disclosed however. The transaction still needs to be judged and approved by antimonopoly authorities in Slovakia and the Czech Republic. The effect of the deal on Slovak and Czech pharmaceutical market will depend on the verdicts of the antimonopoly offices.

Since 1998 Warburg Pincus has been the majority shareholder of the largest seller of drugs in Slovakia and the Czech Republic, Leciva. After the entry of the Americans to Slovakofarma, the company would gradually be merged with Leciva, thereby creating a strong Central and East European pharmaceutical player according to representatives of both companies. Jiri Michal, Managing Director of Leciva, considers the accumulation of sources to speed up the drug innovation as the chief effect of the merger.

The position of Slovakofarma, which has a quality portfolio of top generics, is strengthened following a successful year in 2001. Still, Slovakofarma is only a relatively small player among generic producers in Central Europe (Table 23). The interest of joining forces with Leciva would enable it to reinforce its

competitiveness, which is required in an integrated Europe. The intended merger with the working name "Alliance for Europe" would, according to Mr. Lowcock, Managing Director of Warburg Pincus, create one of the TOP 5 largest pharmaceutical companies in Central and Eastern Europe.

Table 23

Largest pharmaceutical producers in post-socialist countries of Central and East Europe

USD m, %

company	country	sales 2001	R&D*
Pliva	Croatia	634	8.0
Lek	Slovenia	323	10.4
Gedeon Richter	Hungary	310	7.3
Krka	Slovenia	294	n
Slovakofarma	Slovakia	160	2.7
Leciva	Czech Rep.	156	2.3

** as a percentage of turnover*

Source: company reports, exchange-rate calculations by Symsite Research

Biotika's privatization politicized—

In the first wave of coupon privatization in 1993, 17,000 shareholders acquired 56% of the shares in Biotika, with the FNM acquiring 41% and 3% going to restitution by law. In 1996 the FNM sold its stake to the then unknown company G.V. Pharma, personally linked to the management of Slovakofarma, despite much lower bids compared with the bids of the actual employees and management of Biotika. G.V. Pharma acquired 41% in Biotika for just Sk 486.5 million spread out into a first installment of Sk 100 million and the rest payable until 2002. The Anti-trust Authority of the Slovak Republic objected to the personal links between Biotika with Slovakofarma via G.V. Pharma. In 1997 the top managers and owners of Slovakofarma were recalled from the Supervisory Board of Biotika and replaced.

—the company wants a majority stake in HBM

In the past two years the management managed to stabilize the situation in Biotika, reduce retained losses and end 2001 in the black. At the beginning of 2003 Biotika announced an interest to acquire the stake of Aventis in joint venture Hoechst-Biotika (in 2000 Biotika intended to sell its stake in joint venture). According to Mr. Jozef Kristofcak, CEO of Biotika, via the purchase of Aventis share the company wants to strengthen its position as a producer of generic drugs and keep the cooperation with Aventis in the future. Both partners are in the process of negotiations of a deal.

Sharp decline at Imuna—

During the period of office of Meciar's government from 1994 to 1998, Imuna was excluded from privatization by law as a strategic company as it processed human blood and its derivatives. Without the assistance of private investors, this step put Imuna at the fate of regular state subsidies. With the arrival of the new government of Mikulas Dzurinda and the abolition of the Act on Strategic Companies, a 61% stake in Imuna was supposed to be sold to a strategic investor at the proposal of the Privatization Ministry. The FNM (National Property Fund) was supposed to retain 34% in the company with 5% going to employees. As these conditions were not of interest to investors, the government subsequently decided to sell off the entire

assets of Imuna to an investor by way of direct sale on the basis of a tender. After three unsuccessful rounds of privatization tenders the government eventually decided to impose bankruptcy on Imuna at the beginning of November 2001. The aim of the state to attract an investor to the company failed. In June 2002 the County Court appointed a provisional bankruptcy trustee to Imuna.

—seems to be over for a while

In the space of five months, the bankruptcy trustee had sold the estate of the bankrupt to Kosice company Imuna Pharm Holding, closely linked to the well-known entrepreneurs Ladislav Krajnak and Juraj Kamaras, for Sk 120m. The new investor wants to revive the company via extensive investment, renew original production and regain lost market share. At the beginning of 2003 the production in the company seems to get starting up gradually in all the key divisions. However, it is not clear yet, how the production of blood serum and derivatives will develop in the near future. Imuna, however still do not comply the Good Manufacturing Practice (GMP) norms, which is a prerequisite for survival on the EU single market. It is questionable whether the new investor can arrange Imuna to be competitive from this point of view until the entry to EU.

The neglected privatization, miserable and un-reformed healthcare system together with a specific R&D feature of pharmaceuticals (resulting into disinclination to transfer operations to low-cost Eastern countries when compared with other margin-pressurized industries) caused a weak interest of foreign investors to invest here. The Aventis case proves that low-costs business environment does not play as important role in pharmaceuticals as in labor demanding industries. The only strategic investment in the Slovak pharmaceutical production is going to leave. On the other hand the sector is surely pleased to lure American investor to Slovakofarma. One of the benefits is also the division of managerial and ownership functions in the corporation. However, it is quite reasonable to expect from the investment fund that it will sell its stake with profit at a suitable moment. If so, it would happen after EU enlargement when the company would be well established on a single market. Moreover the healthcare system, currently cash-strapped, is supposed to be reformed and closer to EU standards. Global pharmaceutical players may find the Slovak pharmaceuticals sector an attractive place to invest. As the original molecule producers are increasingly interested in buying the generic producers (to optimize drug range, but to control generic competition as well), the entry of pharmaceutical giant to Slovakofarma/Leciva is quite possible. Recent acquisition of Slovenian LEK by Novartis may support such a claim.

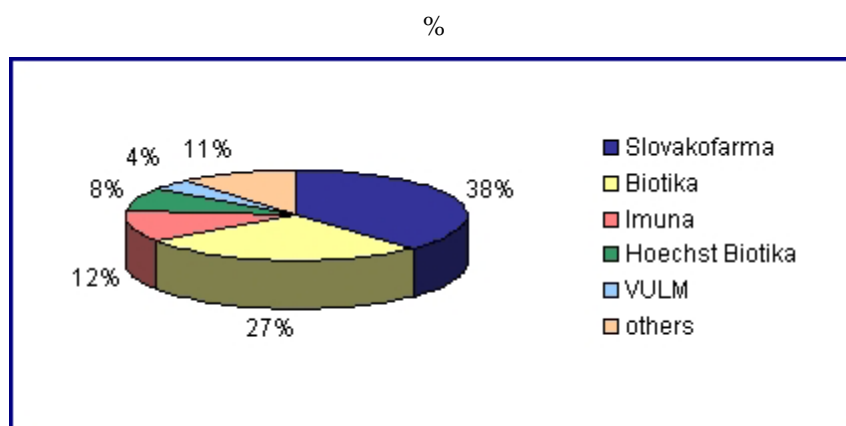
Labor market effect of EU accession

Labor market in pharmaceuticals will not see any major changes right after joining the EU. One of the most important causes for this is the 7-year transition period for labor movement. No massive brain-drain is expected. Local pharmaceuticals companies are currently downsizing, still coping with over employment. Therefore even increased production, stemming from increased demand for generic drugs, is unlikely to spur job creation. Greenfield investment into pharmaceuticals would create jobs, however we do not consider this to happen in the short run.

The status of pharmaceutical industry within the Slovak manufacturing corresponds also with the number of employees representing a mere 1% of overall labor in manufacturing. The share of pharmaceutical employees on overall employment in the chemical industry remains at level of 20-21%. A reduction in surplus employment in the sector is ongoing, with pharmaceutical operations in Slovakia employing an average of 3,838 employees in the 1H/2002. Compared with 1996 this is a 28% fall. Two thirds of employees in the sector come from Slovakofarma and Biotika. The sector employment is strongly dependent on performance of those companies together with Imuna and Hoechst-Biotika (covering another one fifth of employees in pharmaceuticals).

Graph 12

The structure of employment in Slovak pharmaceutical industry in 2001



Source: SU SR, companies, Symsite Research

The average wage in the sector rose y/y by 12% to SKK 17,515 in 2001. The progress and restructuring seen in the pharmaceutical industry is attested to by the 26% growth in productivity, i.e. double that of the growth in wages. The pace of growth in productivity and in wages in the pharmaceutical industry balanced out in the first half of 2002 (see graph 13). Each employee in pharmaceutical production produced SKK 2.5 million in sales in 2001, which is two fifths more than the overall productivity in industrial production in Slovakia.

Graph 13

Dynamic of growth in wages and productivity per employee

%



Source: Statistics Office SR, Symsite Research

The major regulatory component dealing with labor migration is the *acquis communautaire* chapter 2 - Freedom of movement for persons. The chapter covers four areas with free movement of workers as crucial. Slovakia closed the chapter in December 2002. Austria and Germany fearing a massive labor force migration from the East won a transitional arrangement. The arrangement protects the labor market of these countries from migration of employees from candidate countries for the seven years after the EU enlargement. On the other hand, some countries (Sweden, Denmark, Ireland, Netherlands, Great Britain) will open their labor market just after enlargement. With regard to its role in the economy, the pharmaceutical sector is not going to be hit by this measure sharply. The intense emigration of a highly-skilled pharmaceutical labor that would endanger the labor supply in Slovak pharmaceutical sector is not likely. We do not exclude a brain-drain occurring sporadically however. The domestic labor supply in pharmaceutical industry will not be endangered by immigration from the East. The employment in the sector will be influenced more by the restructuring of companies (mainly Imuna, Biotika) rather than the migration of labor in the short run.

The effect of EU accession on the regulatory framework

In the run-up to the EU accession, Slovakia has already adopted legislation and adjusted its regulatory framework towards the EU standards. Nowadays the most demanding task lies in update of drug registrations to ensure they meet all EU requirements. Harmonization of legislation with EU norms will significantly speed up the drug registration process and make drug supply more flexible. The weak law enforcement together with deficiencies in building-up the institutions still remain a problem.

Healthcare sector is generally a matter of a country rather than of any common European Union's legislation. A quite broad space is left to deal with on the national level of candidate countries, including pricing and mechanism of drug reimbursement, drug policy and the very organization of the healthcare system. While the process of drug authorization in Slovakia is profoundly linked with EU regulatory norms, the system of price control and reimbursement remains a national issue.

SUKL as the main regulatory body—

All new drugs and medical appliances being launched on the Slovak market require official registration, or certification, a maximum price measure, with many also applying for full or part reimbursement from health insurance companies. The entire procedure of drug registration is managed by the State Institute for Drug Control—SUKL (Statny Ustav pre Kontrolu Lieciv). SUKL must assess the registration application by 210 days. SUKL enables an applicant for registration of a drug, which has already been registered in the EU by a centralized procedure or by mutual recognition procedure, to request a modified procedure when registering in the Slovak Republic. The applicant must include the evaluation of the EU drug agency, the EMEA, with the application for drug registration. This process is in line with the harmonized process of the EU and is shorter (five months on average). The capacity of SUKL is insufficient resulting into inappropriate delays in delivering the decisions in many areas.

—with Ministry of Finance—

The other key intervention by the state in the drugs market comes in the shape of price regulation together with drug categorization. The major directive dealing with price and reimbursement mechanism (89/105/EEC) is according to Mr. Jozef Slany—representative of the State Drug Policy Department at the Ministry of Health (MH SR)—rather general and vague. It requires the transparency of regulatory measures taken on prices and reimbursement as well as their accordance with the principles of national health insurance system. Ministry of Finance determines the maximum prices of drugs on the basis of price comparisons with nine European countries. In the case of domestic producers, the maximum prices are set as the sum of economically justifiable costs plus a 30% margin. Foreign pharmaceutical companies do not have such obligation. Therefore Slovak producers are at a disadvantage, moreover EU does not require such measure for domestic producers. The process of EU enlargement induces the equalization of the conditions and pressurize authorities to change this measure. There is pressure arising from pharmaceutical companies and Health Ministry as well to equalize such pricing treatment for domestic and foreign firms. According to Mr. Slany by legislation amendment in 2003, however much depends on Ministry of Finance's approach. Upon a change in the exchange rate of at least 5% between the Slovak crown and the currency of the importing country, the producer is entitled to request a change in the maximum price from the Ministry of Finance. In practice however, this provides the possibility of applying for the issue of a decision on maximum prices only once a year. The Ministry of Finance largely ignores the applications for a price increase, however. This exchange-rate issue caused serious problems to pharmaceutical companies especially during the 2000-2001 period when the Slovak crown lost ground substantially (SKK stood at 47.5 - 48.5 USD, while the prices of most of the drugs were set in the first half of 1990s with exchange rate of 28-33 SKK/USD). MH SR is struggling vehemently for a long time to acquire the power of setting the price of drugs from MF. This should happen in 2003 according to Mr. Slany. Most of the representatives from

pharmaceutical firms consider the maximum price as useless and idle. The real price regulation tool is reimbursement within the categorization of drugs.

—and Ministry of Health in assistance

Ministry of Health (namely the Categorization Commission) determines the level of reimbursement from insurance companies and issues the categorization list, within 90 days by law from submission of an application. The 90 days period is not obviously met. The categorization list should be issued four times per year on the contrary of just one or maximum two categorization in practice. Categorization of drugs (i.e. determination of the level of reimbursement by health insurance) as performed in Slovakia provides only minor support for the objectives pursued by the Ministry of Health—to stabilize drug expenditure. One of the reasons for this is the fact that partial coverage by patients is still low. Maximum drug reimbursement by insurance companies are firmly fixed, providing the opportunity for pharmaceutical companies to lower the amount of out-of-pocket payments of patients to bearable levels via their pricing policies. Firmly established reimbursements from insurance companies, together with the possibility of reducing payments from patients (and thus maintain a high demand for drugs) is the main driving force behind the high consumption of drugs.

The proposed change by MH will lead to a turnover—firmly fixed will be out-of-pocket coverage by patients and the opportunity of reducing prices will be transferred to the level pharmaceutical company versus health insurer. The aim of the proposed change in reimbursement is to fix the amount of patient participation in payments for drugs and, also conversely to free up partial reimbursements provided by insurance companies. Thus for pharmaceutical companies it will be more complicated to boost the drug sales through modifying the price and co-payments after the categorization comes into force. There is a sharp disagreement throughout the pharmaceutical companies both domestic and foreign, claiming such a system of reimbursement is not usual in developed Europe. According to the representatives of several pharmaceutical companies if such measure is implemented it could lead to a lowering the level of transparency in the process of categorization. Professional organizations AFV (Association of Pharmaceutical Producers in Slovakia) and SAFS (Slovak Association of Research Based Pharmaceutical Companies) are afraid that co-payments may be socially unbearable for patients. They also doubt the conformity of this measure with EU directive. Mr. Jozef Slany from MH considers such draft to be in full compliance with 89/105/EEC directive.

One of the highlights of the healthcare reform introduced by the new health minister Zajac is the strengthening of the status, jurisdiction, and inspection activities of health insurance companies. From the aspect of drug policy a number of representatives of health insurance companies in the Categorization Commission will increase in the future. In this way the MH is trying to boost the economic aspect in determining the level of drug coverage, which is the major interest of insurance companies. If the austerity measures are introduced they are likely to lead to the slowdown of drug consumption in 2003 and 2004.

Slovakia has made a great progress in legislation—

In recent years Slovakia, similarly to other Central and Eastern European (CEE) countries, has introduced pharmaceutical legislation implementing important changes in line with EU laws. Dr. Jozef Slany claims that in general the legislation concerning Slovakia's accession to the EU is already passed. At present the registration process of drugs is carried out in accordance with EU standards as Mr. Ludevit Martinec, director of Regulatory body SUKL adds. Slovakia has approximated the process of drug registration to both types of authorization applying in the EU – centralized and decentralized procedures:

- The centralized procedure – is compulsory for medicinal products derived from biotechnology, and available at request of companies for other innovative new products. Applications are submitted directly to the European Medicines Evaluation Agency (EMA).

- The decentralized procedure (or mutual recognition procedure) – applies to majority of conventional medicinal products. It is based on the principle of mutual recognition of national marketing authorizations. This is the only way for generic companies to receive an authorization for selling their drugs in more than one national market at one time.

As Mr. Martinec stresses Slovakia together with the Czech Republic have made the greatest advancement amongst candidate countries in the legislation convergence and medicines authorization process. In the spring 2000 both countries launched the pilot project of approving medicinal products under the EU's mutual recognition procedure (MRP). Slovakia's experience with shortened and simplified drug approvals under the MRP scheme has strongly equipped our country for an EU single market. However, there are still some assignments that need to be done.

—lots of work still to be done however

One of the crucial tasks of SUKL, and regulatory bodies in other CEE countries as well, is a requisite to update the dossiers on a number of pharmaceuticals. There are numerous drugs already sold in Slovakia that were not registered fully in compliance with EU requirements. Pharmaceuticals must receive marketing authorization every five years. This is a huge problem for older drugs, which got their approval under the national schemes not in line with current EU requirements. EU insists that all registrations of such drugs must be re-vetted up to the date of EU enlargement in accordance to the EU norms. Otherwise the drugs must be withdrawn from the market. Slovakia has proposed a five-year transition period (2002-2007) to fulfill EU requirements on marketing authorization of medicinal products. The proposal was transformed into an Act 457/2002, stating that SUKL is obliged to review the dossiers to July 1st, 2007 at the latest. But the EU was strongly opposed. With the closure of the chapter on free movement of goods the European Union did not accept the transition period. Slovakia is thus obliged to amend the legislation during 2003. According to Mr. Martinec such an EU approach is the result of its fears from Eastern pharmaceutical competitors on the EU single market. On the other hand, Hungary and Poland won transition agreements. This came as no surprise, taking into account the strategic status of Poland as a candidate as well as the fact that virtually all production of drugs in Hungary is in the hands of Western European pharmaceutical companies. Mr. Martinec underlines that even EU member countries do not have all the registrations of older drugs in conformity with required rules. Thus, he considers such a pressure from the EU on CEE countries as inadequate with intention to hamper the competitiveness of Eastern pharmaceutical industry. Mr. Martinec is however optimistic and presumes all the registrations will be renewed and harmonized up to date of Slovakia's entry to EU.

After EU enlargement the powers of domestic regulatory authority SUKL will concentrate at national registrations, while the centralized procedure will be in charge of EMEA. SUKL will become a reporting partner of EMEA and hold other competences—monitor drugs safety, advertising on drugs, or post-marketing studies just to mention. Observers to the EMEA agency are to be appointed. According to Mr. Martinec when considering the central registrations, SUKL will work under the EMEA after enlargement. Slovakia may even become a reference country for authorization of some drugs in the future.

Patent protection and data exclusivity periods are standard—

Intellectual property rights protection is one of the most important part of legislation concerning medicinal products. Already in 1990 the former Czechoslovakia launched (as the first country amongst post-communist states) a general 20-year protection period for patents, including pharmaceutical products. In 2001, the so-called Supplementary Protection Certificate (SPC) was introduced—further step in line with EU norms. SPC allows pharmaceutical producers of original molecules to extend their patents for another five years. The registration data exclusivity during six years from the registration in one EU state or in Slovak Republic was firstly launched in 2000 by amendment to the Act on Drugs and Medical Appliances. In 2001, another amendment to the said act was approved, which for the purposes of harmonizing Slovak legislation

with that of the EU, introduced the opportunity of extending the 6-year patent protection period to 10 years for drugs manufactured using high-tech technologies. The data exclusivity period commences on the date of the first registration in the respective EU country, or in Slovakia. The government has approved this alternative despite pressures from American original producers, who insisted on an exclusive 10-year period from registration in Slovakia. This period relates only to drugs registered after this amendment assumed validity with no possibility of retroactive modification of the deadline for already registered drugs. Mr. Martinec considers patent and data exclusivity protection as perfectly standard in full compliance with the practice in the EU. To support generic manufacturers so called "Bolar provision" applies in Slovakia since 2001. Bolar provision enables generic producers to develop and test their drugs before the patent on the original molecule has expired. It is a common practice in developed countries. Although EU legislation does not deal with Bolar provision, several EU member countries apply that within their national regulatory frameworks (but the Review 2001 has dealt with such provision as Mr. Martinec points out).

—as well as the advertising of drugs

Marketing and advertising in the health sector is subject to a greater degree of regulation than the majority of consumer products due to the fact that information about drugs or medical appliances are regarded as specialized, which a common citizen cannot adequately evaluate. Drugs are also dealt with separately in the Act on Advertising. General requirements concerning advertising are governed by Act 147/2001 Coll. on advertising and Act 140/1998 on drugs. All drugs offered via advertising must be registered in the Slovak Republic. Only the holder of the registration decision for a drug may order an advertisement, i.e. not distributors or pharmacies. Advertising of prescription drugs and preparations that are at least partially covered by health insurance companies are completely prohibited. However, preparations that do not come under the strict definition of a drug (a drug as a medicament or mixture of medicaments and auxiliary substances modified by technological process into a drug form) are not affected by such restrictions. These mainly concern medicaments such as vitamins or vaccine substances, as well as nutritional supplements. Prescription drugs as well as those with partial payment may therefore be promoted by the producer only to the professional community, physicians and specialists, but not patients (patients can be made aware about specific diseases that their drugs are linked to, but specific drugs may not be mentioned). Furthermore, advertising may not be deceptive, i.e. invoke the impression that visiting the doctor is pointless.

The same practice is exercised in the European Union for example, while the USA permits advertising of prescription drugs. All elements of an advertisement must be in compliance with information contained in the brief description of the drug properties. The advertisement must unambiguously demonstrate that it concerns an advertisement for a drug and must inform about the risks of use and contain the recommendation to consult the use of the drug with a person authorized to prescribe or issue the drug. As part of the recommendations of EU directive (92/28/EEC), the Act expressly prohibits advertisements referring to the action of a drug for treatment of tuberculosis, sexually transmitted diseases, grave infectious diseases, tumorous diseases, chronic insomnia, metabolic disorders and mental diseases. According to Dr. Pavol Gibala from the inspection section of SUKL, while Slovak legislation anchors the requirements of pertinent European directives, in practice certain problems arise with respect to their diverse interpretation.

Pharma-firms generally satisfied with the legislation advancement—

Pharmaceutical companies appreciate the legislative progress being made in the field of pharmacy. At the same time however, they are continually sending warning signals about certain negative phenomena they have to deal with while performing their daily activities (for example, problems related to delays by the state). The drug registration process in Slovakia is comparable to similar processes in other countries. Most criticized is the system for establishing maximum drug prices used by the Ministry of Finance. A frequent target of criticism from pharmaceutical companies is also the non-transparent application of certain elements of the drug policy (in particular categorization and pricing of drugs). However, drug producers also acknowledge that the categorization process for drugs and medical appliances has been greatly improved

over the past two-three years—both from the professional and technical perspective, but also with regard to the provision of information and transparency.

—despite the problems of enforceability in practice

Problems still persist regarding the application of the law in practice however, as representatives of SAFS (Slovak Association of Research Based Pharmaceutical Companies) claim. The technical, personal and organizational capacities of SUKL are under an optimal dimension. According to Jozef Slany, the European Union is accusing Slovakia of weak enforceability of the law and deficiencies in building up the necessary institutions (here it requests strengthening the position of SUKL). The weak enforceability of the law - confirmed by several pharmaceutical companies - is seen throughout the Slovak economy in general not only in pharmaceuticals.

Table 24

Development of regulatory framework in Slovakia

	1998	2002	2004
Transparency	*	****	*****
delays	*	**	***
intellectual property rights	***	*****	*****
registrations	**	***	****
advertising	***	****	****
enforceability of law	**	**	***

*assessment scale - *significantly non-standard status, incompatible with EU practice
 - ***** EU standard, full compliance with EU norms*

Source: Symsite Research

Other regulatory issues include prescription limits—

In addition to categorization, there are several other regulatory mechanisms used by the state as major weapons to affect public drug expenditures. Their application by the MH and the level of their efficiency differs. The arsenal of instruments regulating the drug expenditures is both on the supply side (e.g. regulation of business margins) and on the demand side (e.g. control over drug prescription). According to advisor to the Minister of Health on Drug Policy, Mr. Jan Sipeky, one of the most important tasks of the drug policy, albeit not yet introduced, is the introduction of financial prescription limits for doctors. However, obstacles in legislation prevent any real implementation of such limits. Mr. Slany thinks that financial limits must be enforced by insurance companies (at the level of the triangle: insurance company—doctor—or producer) and not by the state. Through the adoption of a legislative measure the MH planned to achieve a status of affairs where health insurers would be authorized to conclude contracts with healthcare providers concerning drug expenditure budgets. Although at the present time there are some prescription limitations (drug must be prescribed by specific specialists) and indicative limitations in place (drugs may be prescribed only for strictly defined diseases), doctors are not financially motivated to prescribe more prudently. According to Dr. Slany, in the countries of Western Europe the application of financial limits for prescribing doctors is fairly common. However, these limits are not determined by the state, but by insurance companies.

—or regulation of business margins

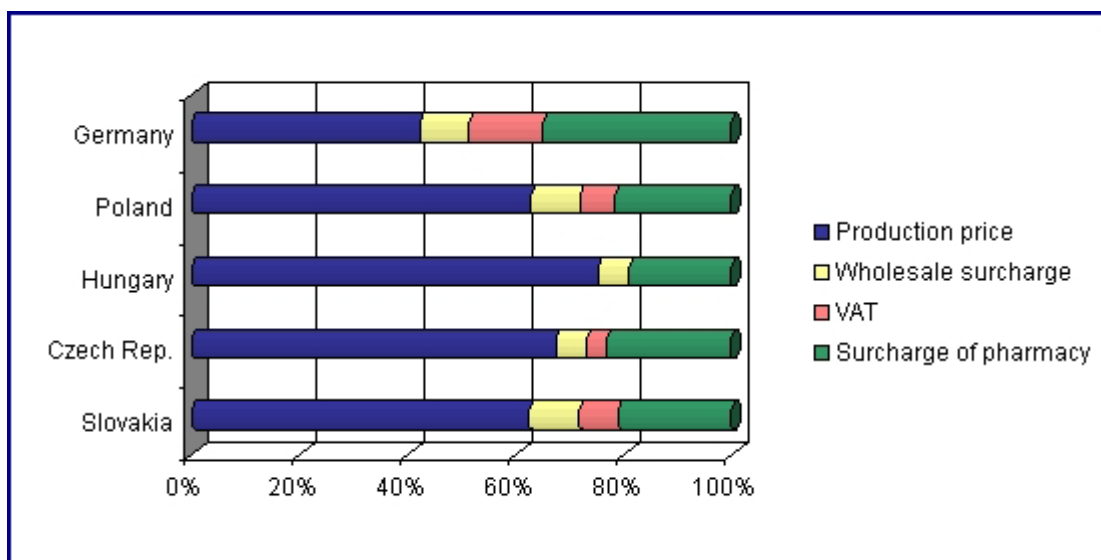
The common feature of regulatory mechanisms applied in the EU and Slovakia is the regulation of margins for distributors and pharmacies. The levels of margins and the method of their application is left to be

decided by individual states. In Slovakia, this margin is fixed by the Ministry of Finance to the amount of 13% of the manufacturer's price for distribution companies and 21% of the manufacturer's price for pharmacies. In many EU countries the regressive margins are being applied (the higher the drug price, the lower the margin). There were several attempts to enforce the regressive trade margin system in Slovakia, but lobbying by distributors prevented any such attempts to materialize. At the same time, the ministry admitted that the introduction of the regressive margin would require the preparation of new principles for determining prices of drugs and medical appliances and also the clearance of debt throughout the entire drug chain. Drug distributors are among the largest critics of regressive margins. Their argument is in the indebtedness of the drug chain, the funding of which lies with them. Besides margins, VAT applies to sales of drugs in the majority of countries, most frequently calculated from the wholesale price. EU members are allowed to apply a standard VAT rate or one or two reduced rates. Medicines are often on the list of reduced VAT rate with many exceptions applying for specific situations. In Slovakia VAT rate on drugs rose from 10 to 14% (standard rate dropped from 23 to 20%) as of January 2003.

Graph 14

Structure of end consumer prices of drugs in selected countries in 2001

%



Source: AESGP, graph by Symsite Research

**Margins depend on production price of drugs – the higher the price, the lower the trade margin. Margins for less expensive drugs were used in this instance*

The effect of accession on the market structures

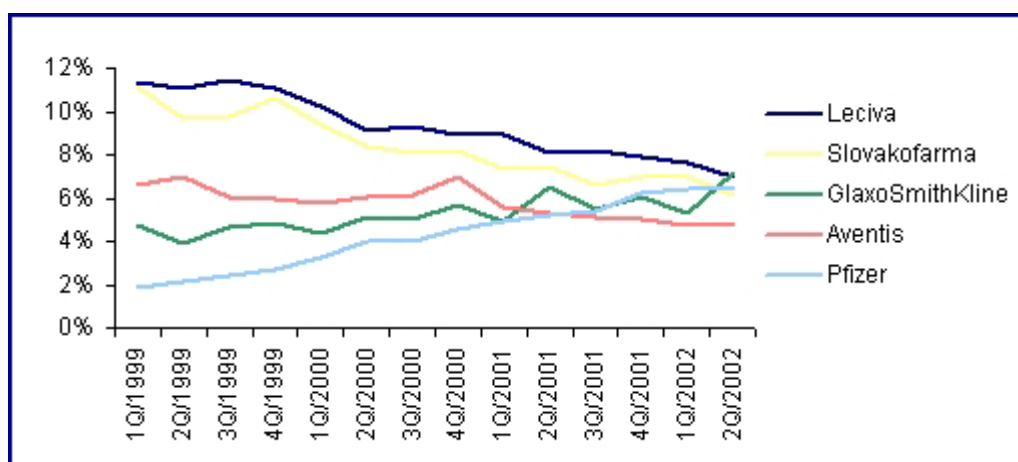
The forthcoming EU enlargement brings a considerably larger pharmaceutical market for companies in member as well as in candidate countries. However, the market structures of pharmaceutical sector are strongly shaped by forces other than EU accession. European single market can facilitate global trends in pharmaceutical industry, but their source lies in the specific nature of this sector concerning demand, R&D or high regulation. The wave of consolidation in pharmaceutical sector occurs in EU members and EU candidates as well, crossing frontiers regardless of the level of integration. While the market of pharmaceuticals will benefit from EU convergence in the form of faster drug authorization, the domestic pharmaceutical industry will remain strongly influenced by global forces regardless of the integration process.

The largest pharmaceutical vendors are Leciva and Slovakofarma—

All major international pharmaceutical companies operate in Slovakia. Only the French-German concern Aventis operates also its own production facility in Slovakia, in the town of Martin. First place in 2001 was held by Czech generic producer Leciva, followed by Slovak generic producer Slovakofarma. However, since 1999 the market shares of these two companies have dropped significantly. This was probably one of the reasons why these companies initiated talks on closer cooperation in the second half of 2001. On the other hand, three producers of original drugs, which comprise the TOP 5 largest companies - GlaxoSmithKline, Pfizer and Aventis - increased their sales of drugs in Slovakia. In contrast to the global TOP 10 list of the largest pharmaceutical companies, the Slovak TOP 10 list (based on financial volume of sold drugs) also includes two generic companies - pharmaceutical manufacturing monopolies of former Czechoslovakia. The preliminary data for 2002 indicates that Leciva maintains its leadership, while Pfizer and GlaxoSmithKline got closer to Slovakofarma in the TOP 5 list

Graph 15

Market shares of TOP 5 pharmaceutical companies (%)



Source: SUKL; Symsite Research

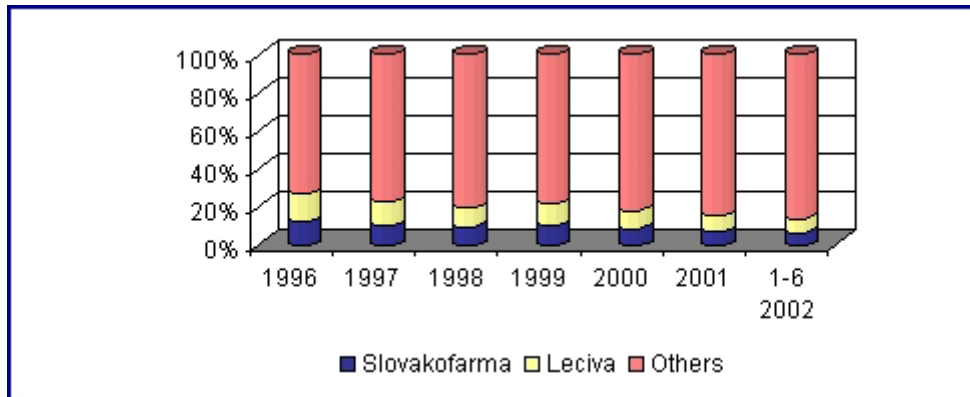
—their significance is steadily weakening however

After the partial halting of the dramatic decline of market shares of the two dominant companies on the Slovak market—Leciva and Slovakofarma—in 1999, their combined share in financial terms once again declined to under the 20% level a year later. In 2001, their combined market share represented just 15%. Results for 2002 once again indicate a further downward trend.

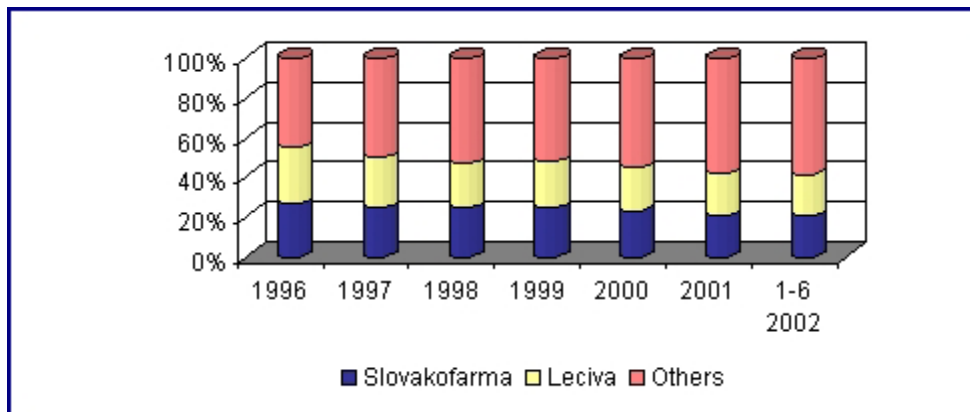
Graph 16

Share of drug sales in Slovakia: Slovakofarma and Leciva compared with other companies (%)

A. financial volume



B. units



Source: SUKL, calculations by Symsite Research

When comparing producers from both parts of the former Czechoslovak Federation, “domestic” (i.e. Slovak and Czech) producers still occupy approximately 25% of the Slovak and Czech markets. However, Czech and Slovak pharmaceutical companies are experiencing a decline in their market shares in both markets with regard to both the financial value and the number of sold units. While in 1995 Slovak producers enjoyed a 15% share of the total financial value of consumed drugs in Slovakia, in 2001 this number represented less than 11%. An even more radical decline was recorded in the Slovak market with Czech producers (Table 25). The same applies for Slovak producers in the Czech market, with their former 12% market share in 1995 declining in 2001 to a mere 5.8%. Czech producers recorded a less dramatic decline in the Czech market than Slovak producers.

Table 25

Comparison of the Slovak and Czech pharmaceutical markets

% of total market value

	Slovak market		Czech market	
	1995	2001	1995	2001
share on sales				
foreign* producers	58.5	77.6	63.5	76.3
Slovak producers	15.1	10.9	12.4	5.8
Czech producers	26.4	11.5	24.1	17.9
share on sold units				
foreign* producers	27.2	45.8	28.8	45.9
Slovak producers	31.0	25.7	28.3	15.2
Czech producers	41.8	28.5	42.9	38.9

Source: SUKL in Slovakia and Czech Republic

**except for Slovak and Czech producers*

The acquisition of key pharmaceutical producers in the Czech Republic and Slovakia (Leciva, Slovakofarma) by American investment fund Warburg Pincus may result in the cessation of falling market shares. As the generic industry is going to expand due to the huge patent expiry wave and heavy pressures on public expenditures on drugs, the outlook for those TOP generic makers is good. The possibility of re-gaining the lost market share of Leciva/Slovakofarma and strengthening the position is quite realistic. However, generic competitors from Western (Germany) and Eastern (Slovenia, Hungary) Europe may be a risk. Five traditional Eastern European companies hold their positions (Table 26) in the TOP 20 pharmaceutical companies in Slovakia (Leciva, Slovakofarma, Krka, Lek and Richter Gedeon), mainly thanks to their generic products. The rest of the list is comprised of Western European and American producers, mainly developers and producers of original molecules. The TOP 20 largest companies represented 65.9% of the total value of sold drugs in Slovakia in 2001. Compared with the previous year (TOP 20 companies represented 69.7% of total drug sales), this represents a mild de-concentration of the Slovak market.

Table 26

TOP 20 pharmaceutical companies in 2001 by sales

SKK million, %, thsnd units, %

Producer	Value	Share on total consumption	y/y change*	No. of sold units	key assortment
1. Leciva	1,506	8.2%	5.1%	33,981	digestive tract / metabolism
2. Slovakofarma	1,294	7.1%	-0.4%	32,651	cardiovascular
3. GlaxoSmithKline	1,051	5.7%	35.7%	2,870	anti-infectives
4. Pfizer	992	5.4%	63.1%	2,236	cardiovascular
5. Aventis	946	5.2%	13.1%	6,355	cardiovascular
6. Janssen Cilag	685	3.7%	29.4%	1,371	blood and haemopoietic organs
7. Novartis	670	3.7%	24.0%	2,239	cardiovascular
8. Abbott Labs	584	3.2%	18.7%	2,314	cardiovascular
9. Astrazeneca	456	2.5%	39.5%	988	cardiovascular
10. Servier	424	2.3%	59.8%	1,833	cardiovascular
11. Merck & Co.	408	2.2%	83.4%	631	cardiovascular
12. Krka	402	2.2%	3.5%	5,386	cardiovascular
13. Lek	373	2.0%	30.0%	3,895	anti-infective
14. Eli Lilly	368	2.0%	23.8%	398	nervous system
15. Bristol-Myers Squibb	351	1.9%	-2.3%	2,286	cardiovascular
16. Roche	343	1.9%	44.7%	607	oncology drugs
17. Ratiopharm	326	1.8%	34.9%	3,965	nervous system
18. Sanofi-Synthelabo	302	1.6%	19.2%	1,011	cardiovascular
19. Schering-Plough	292	1.6%	11.5%	1,335	respiratory system
20. Richter Gedeon	285	1.56%	13.9%	2,924	nervous system
Total for TOP 20	12,060	65.9%	-	109,277	-

* of the market share compared to 2000

note - data based on maximum prices set by Ministry of Finance

Source: SUKL, calculations by Symsite Research

Producers of original drugs have experienced a boom in recent years in the Slovak market, however planned restrictions by the Health Ministry will dampen their expansion together with patent expirations. In 2001 the two American companies enjoyed more than a 40% y/y growth in sales - Pfizer, Merck & Co (in 2000 Eli Lilly was with them). From the TOP 20, fourteen companies were producers of original drugs, half of which are from the USA (all seven companies from the USA are original producers). The remaining six companies are producers of generics, one from Western Europe - German company Ratiopharm (Table 27). From West

Europe there were Servier, which has increased its turnover in Slovakia by 60% two years in a row, and the Swiss company Roche.

Table 27

TOP 20 companies on the Slovak market by region and growth in sales in 2001

number

country of origin	drop in sales	0-20%	20-40%	40% +	total
		sales growth	sales growth	sales growth	
East Europe	1	3	1	0	5
West Europe	0	2	4	2	8
USA	1	2	2	2	7
total	2	7	7	4	20

Source: Symsite Research, SUKL

Table 28

TOP 20 companies on Slovak market in terms of nature of production and sales growth in 2001

number

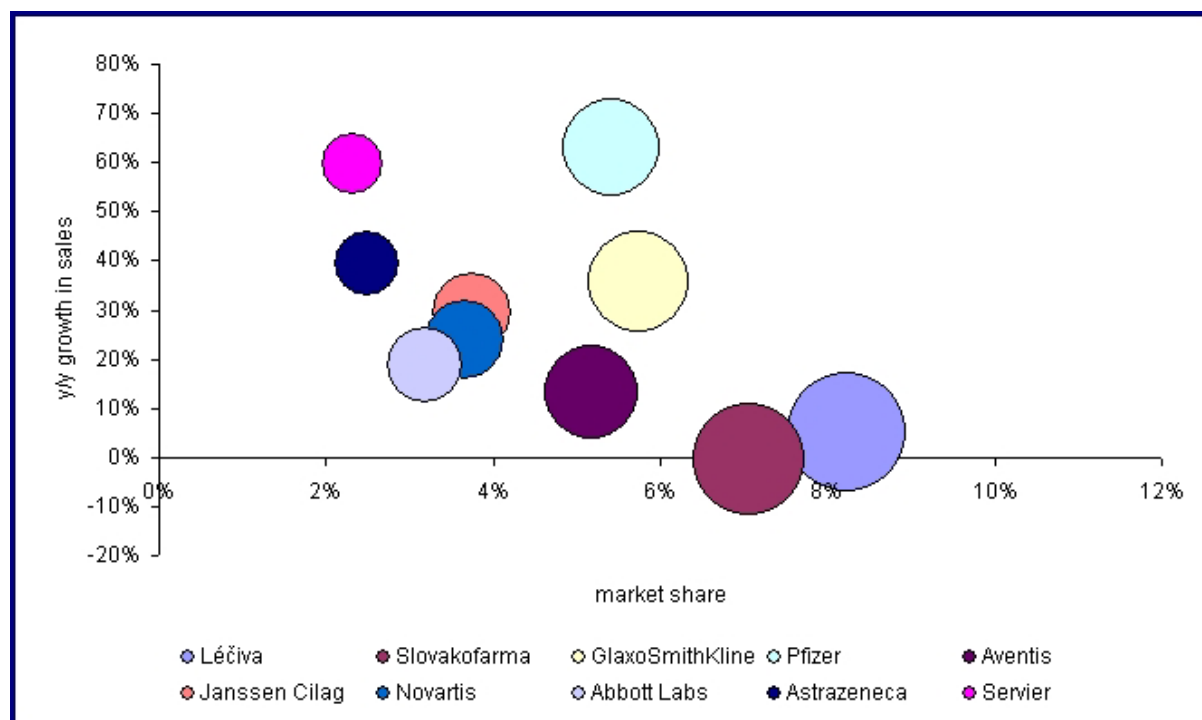
nature of production	drop in sales	0-20%	20-40%	40% +	total
		sales growth	sales growth	sales growth	
producers of original drugs	1	4	5	4	14
- of which, USA	1	2	2	2	7
producers of generics	1	3	2	0	6
- of which, Central and East Europe	1	3	1	0	5
Total	2	7	7	4	20

Source: Symsite Research, ŠÚKL

The entry of foreign producers on the market has had a predominantly positive impact. In the majority of basic ATC groups the concentration of sales has fallen. In 2001 the leading company had more than a 20% share of sales in three basic ATC groups (H, P and B), compared with six in 1997. The substantial differences in market shares in individual groups have gradually diminished, with a few exceptions. The sales shares of the top five producers are in the range of more than 50% in the majority of groups.

Graph 17

Market positions of TOP 10 companies in 2001 (%)



Source: SUKL, SymSITE Research

Companies mostly specialized on 1-2 ATC groups

Of the TOP 20 producers on the Slovak market for 2001, six had at least half of their sales concentrated in one ATC group (mostly concerning the cardiovascular system), while in 1999 this situation applied to 12 companies. The largest sellers in Slovakia also have the most diversified portfolio (Leciva, Slovakofarma, Aventis, Novartis, GlaxoSmithKline). The global trend of specialization in a small number of therapeutic groups hit Slovak market and regards also large companies with diverse ATC assortment. Five of the most sold drugs (excluding variances and units) normally cover a minimum of half of total sales, although there are exceptions (the three leaders- Leciva, Slovakofarma, GlaxoSmithKline). In particular American producers of original molecules (Merck&Co, Pfizer, Schering-Plough) are dependent on the sale almost of a single drug, or on several types of drug, i.e. sales are more sensitive to changes in prices and in reimbursement levels.

Original preparations replacing generic ones—

Due to the decline in the market shares of both dominant generic companies, the share of generic drugs also declined. While back in 1995 the share of original molecules in overall consumption was one quarter lower than generic drugs, the situation reversed four years later with sales of original drugs being 1.5 times higher than of generic drugs. The situation in Slovakia is therefore on a par with the situation in more developed nations, where the average share of generic drugs represents 15 to 30% in financial terms. On the other hand, due to persisting pressure from governments for lower drug expenditures, the share of generic drugs in Western Europe and North America is rising slightly.

—especially with oncology and cardiology preparations

According to the estimate by SymSITE Research, generic drugs (based on sales of TOP 20 vendors of pharmaceuticals in 1996) represented some 60% of total drug sales in Slovakia in 1996. Six years later this share was nearly half. In contrast, sales of original drugs increased in financial terms to 65% of the overall

market in 2002. The structure of the drug market was only estimated because of the impossibility of determining the exact specification in many cases of a drug as a generic or an original. According to SUKL estimates, original molecules dominate in particular in the groups of oncology and cardiovascular drugs and nervous system drugs (70% of the financial value). Generic drugs are relatively more present in the groups of drugs for the digestive system drugs and metabolism (80%), hormonal drugs – excluding sexual hormones (75%), with the presence of generic drugs in the group of musculoskeletal system drugs and dermatological drugs being roughly identical (60%). Symsite Research estimates the share of generics on overall drug sales will raise mildly in the medium term oscillating around 35-40%.

Table 29

TOP 5 ATC groups with the highest presence of original drugs (%)

ATC group	Original drugs	Generic drugs	Not specified
cardiovascular system	70	30	-
antineoplastic and immunomodulation preparations	70	10-15	15-20
nervous system	70	30	-
respiratory system	60-65	35-40	-
sensory organs	60	35	5

Source: SUKL estimates

The shape of the Slovak pharmaceutical market is determined more by global forces in pharmaceuticals rather than the level of EU integration. Pharmaceutical industry has seen a process of forming mergers and alliances as a result of searching for more diverse drug portfolio, more extensive geographical coverage, more effective marketing policy and benefits of combined R&D capacities. The only strategic investor in the Slovak pharmaceutical production, Aventis, decided to get rid of its majority stake in its production plant - joint venture Hoechst-Biotika in Martin. This is the global strategy of the concern to reduce too many operations throughout the central and Eastern Europe rather than the outcome of EU integration. As Mr. Nick Lowcock, Managing Director of Warburg Pincus (new acquirer of Slovakofarma) underlines, the interest of this private equity firm to invest in Czech and Slovak pharmaceuticals is not driven by EU enlargement per se, though it does create opportunities for future growth for accession countries.

Market structures of pharmaceutical sector are strongly shaped by forces other than EU accession. On the other hand, global trends are accelerated by a formation of the EU single market. The most tangible consequences include a flexible launch of drugs or greater facilitation of the trade. The wave of consolidation in pharmaceuticals occurs in EU members and EU candidates as well, crossing the frontiers quite independently of the level of integration.

Two crucial pharmaceutical producers in Slovakia—Slovakofarma and Biotika—see fundamental changes awaiting in the medium term. The acquisition of Slovakofarma by financial investor Warburg Pincus accompanied by a gradual merger with Leciva will help the company to compete on the EU internal market. Aventis is currently holding talks on the sell-off its stake in joint venture (Hoechst Biotika in Martin) with Biotika. The concern expressed its interest to keep close ties with the new owner. Given an adopted drug portfolio together with Aventis’s patronage, Biotika (if successful in acquiring remaining stake from Aventis) would become the second pillar of the Slovak pharmaceutical industry. Struggling Imuna needs huge investments to modernize its production in line with standards. It will be a hard task for new local owner of the former state-owned company without foreign investments and skills to compete in an enlarged EU. The

other companies—Pharmagal, Pharmagal BIO and Mevak—play a minor role, suffering from weak local demand and strong competition from abroad.

Table 30
Structure of pharmaceutical industry in Slovakia in 2001

SKK m, %

company	ownership/ investor	key assortment	turnover	Export (%)	outlook
Slovakofarma	foreign/financial	human drugs	7.743	76%	merger with Leciva
Hoechst-Biotika	foreign/strategic	human drugs	1.749	46%	merger, close cooperation of Biotika with Aventis
Biotika	local	substances	1.594	84%	
Imuna	local	blood serum and derivatives	95.2	12%	former monopoly need huge investments
Mevak	local	veterinary products	73.7*	15%*	-
Pharmagal	local	veterinary products	72.8	18%	-
Unimed	local	ophthalmologic preparations	37.9	24%	-
Pharmagal BIO	local	veterinary products	30.2	9%	-
Salviapharm	local	food supplements	25.6*	27%*	-
Biomin	local	calcium and derivatives	15.9	60%	-

*2000

Source: AFV SR, companies, Symsite Research

Distribution of drugs

Distributors of drugs in Slovakia are still in the hands of domestic owners. This is quite unusual, as in the surrounding countries the markets have been dominated by foreign wholesale distribution concerns for several years. The reasons for the lack of willingness of foreign capital to enter the Slovak distribution market are many. Apart from the relatively small market, Slovakia also “offers” a miserable health service status, which has still not seen any major changes or reforms that would improve the outlook for accelerated financial flows. The turnover periods of receivables in Slovakia are more than twice as long as the surrounding V4 countries. The designation of Rudolf Zajac to the post of health minister (with radical pro-reform bias) could very well increase the interest of investors to enter the wholesale market with medicaments.

In the course of the past 2-3 years, domestic owners of Slovak distribution companies have greatly consolidated the wholesale pharmaceutical market by increasing their market shares and by acquiring smaller entities. The leading company on the market, Fides ZZ, boosted by entering three smaller distribution companies during 2002 (Biamo, Drug Impex and Villa Pharm), controls almost 40% of the wholesale market with drugs. The top three distributors therefore controlled more than 70% of the market in 2002. Pressure to consolidate comes as the result of the inability of smaller distributors to deal sunk financial

flows in the health service. What's more, the sales policy of pharmaceutical companies is becoming more and more restrictive.

There are eleven distribution companies with a market share of over 3% operating on the Slovak market, even though around 180 entities have permits to distribute drugs and operate healthcare facilities. Seven distributors already generate an annual turnover in excess of Sk 1bn. Key players on the distribution market are in the hands of domestic owners, with the exception of the company West Export Import, which is owned by a Belgian citizen. Sanitas SR, one of the TOP 10 distribution companies in SR, was established by the subsidiary of American biochemical concern Searle Monsanto. Following the merger with American Pharmacia & Upjohn, the new company got rid of non-core business activities including drugs distribution in Eastern Europe. In December 2000, 100% of Sanitas was bought by local financial group Penta Group. Slovakia still waits in anticipation for the entry of important strategic investors to the distribution of drugs.

Table 31

Market shares of the largest drug distributors in Slovakia

market share for past 12 months to end of December 2002, %

	Company	Majority owner	Market share
1	Fides ZZ a.s.	Management	21.77%
2	Unipharma a.s.	Pharmacists	20.37%
3	Med-Art s.r.o.	Natural entities, management	12.79%
4	Biama a.s.*	Management	8.18%
5	Inforama s.r.o.	Natural entity	5.42%
6	Drug Impex s.r.o.*	Natural entity	4.47%
7	Sanitas SR a.s.	Penta Group	4.42%
8	Farmakol s.r.o.	Natural entity	4.41%
9	Villa Pharm s.r.o.*	Slovakofarma via SL Plus, entry of Fides in 2H 2002	4.38%
10	West Export Import a.s.	Natural entity (Belgium)	3.84%
11	Unimed s.r.o.	Natural entity	3.82%

Source: SUKL, Symsite Research

** ownership links of companies to leader Fides ZZ*

The market is gradually consolidating. While in 1997 the five largest distributors controlled just 38% of the value of sales, just two years later this figure was 56%. In 2002 the top five distributors already controlled over 68% of the market. The TOP 10 largest distribution companies accounted for 90% of all drug distribution sales. In the last three years two groups of the largest distributors have emerged. The first three (Fides, Unipharma, Med-Art) currently enjoy 55% of the market. The differences in the market shares of the other three companies—Villa Pharm, Biama and Inforama (all of which hold less than 10% of the market), are much narrower. The market leader continues to be the company Fides with a 21.8% share in 2002.

The chief aim of the largest distributors is generally to acquire a larger market share, often at the price of reduced profits or long turnover periods for liabilities of pharmacies. In 2000 the burden of debt in the drug

chain started to shift from the producers to the distributors. Producers and importers of drugs that complain about the unwillingness of the Ministry of Finance to increase the maximum prices of drugs, are forced to tighten sales conditions for their customer-distribution companies. The pressure translates as a shortening of receivable days with respect to distributors. The average turnover during the period from 1999 to 2001 was shortened by roughly 50 days; to 139 days for receivables in 2001 and liabilities to 132 days. Distribution partially finances receivables for the sale of drugs also to the detriment of profits from the legally established maximum 13% margin or from loans. Almost all Slovak distributors are deep in debt, to about 75 to 90% of their assets. Profitability is still low, even though a significant improvement was seen in 2001.

In 2000 sales of wholesalers with pharmaceutical goods grew sharply by 58%, with the dynamic of growth slowing one year later to a 12% y/y sales growth to Sk 26.7bn. Nevertheless, profit and the return on sales in the sector is still low. To the end of 2001 liabilities of distribution companies monitored by the Statistics Office grew by 3% to Sk 9.7bn (Table 32). Receivables rose y/y by 14% to Sk 10.1bn as of 31 December 2001. A sharper growth in receivables of distributors (against pharmacies) as well as growing liabilities (against producers) proves that producers intensified pressure on wholesalers with medicaments.

Table 32

Selected financial indicators of wholesale with pharmaceutical companies

SKK m, number of days, companies with 20 and more employees

	1997	1998	1999	2000	2001
Number of companies	19	29	31	37	29
Sales	11,516	12,938	15,016	23,781	26,660
Pre-tax income	202	-53	52	168	946
Sales return (%)	1,75%	-0,41%	0,35%	0,71%	3,5%
Receivables	4,333	5,777	7,570	8,857	10,127
- average turnover (days)	137	163	184	136	139
Payables	4,187	6,312	8,002	9,408	9,673
- average turnover (days)	132	178	194	144	132

Source: Statistics Office SR, SymSite Research

Table 33

Selected indicators of the most important distribution companies in Slovakia in 2001

SKK m

	sales 2001	sales 2000	change 01/00	net profit	indebtednes s	employees
Fides	5,016	4,045	+24.0%	57.6	88.5%	205
Unipharma	3,612	3,219	+12.2%	123.1	68.8%	194
Med-Art	2,560**	2,530**	n	n	n	220
Biama	1,451	1,285	+12.9%	56.9	72.3%	134
Villa Pharm	1,300	1,271	+2%	n	n	150
Inforama	1,299	1,176	+10.4%	21.8	88.6%	175
Sanitas SR	1,127	887	+24.9%	11.0	93.0%	135
Drug Impex	840**	782	n	34.7	86.4%***	91
West Export-Import	839**	630**	n	n	n	

Source: Trend Top, companies, Symsite Research

* *indebtedness – debt/assets*

** *estimate of Symsite Research (sales only for drugs registered and statistically processed by SUKL)*

*** *year 2000*

n – not available

With the rising pressure of pharmaceutical companies on distributors the concentration of the distribution sector will intensify. Concentrated distribution together with the encroaching reform of the health service by way of new health minister Rudolf Zajac, could make investments to the sector more attractive for large foreign wholesale concerns. 2003 or 2004 at the latest will therefore probably witness the entry of foreign investors to this sector. Capital links between four important distribution companies could very well be motivated by the endeavor of distributors to offer a strong company (group of companies) to potential foreign strategic investors, although Sina Niku—director of the largest distributor Fides ZZ—believes that the company will not rely on the entry of a foreign investor and regards the concentration more as a natural development of the distribution market. We assume the market of drugs distribution to be pretty concentrated with foreign investors operating after EU enlargement. Thus the Slovak distribution market will be similar to those in the Czech Republic, Hungary or Poland, where foreign investors already operate (e.g. Phoenix, Gehe, OPG, Alliance Unichem). No doubt the decision of foreign investors to enter the Slovak market is influenced by EU enlargement. Nevertheless, there are other driving forces to get investors attracted—concentration and consolidation of the market, healthcare system status, market size or drug policy principles (business margins, possibility of ownership in pharmacies) just to mention a few.

Short-term policy measures in pharmaceutical sector

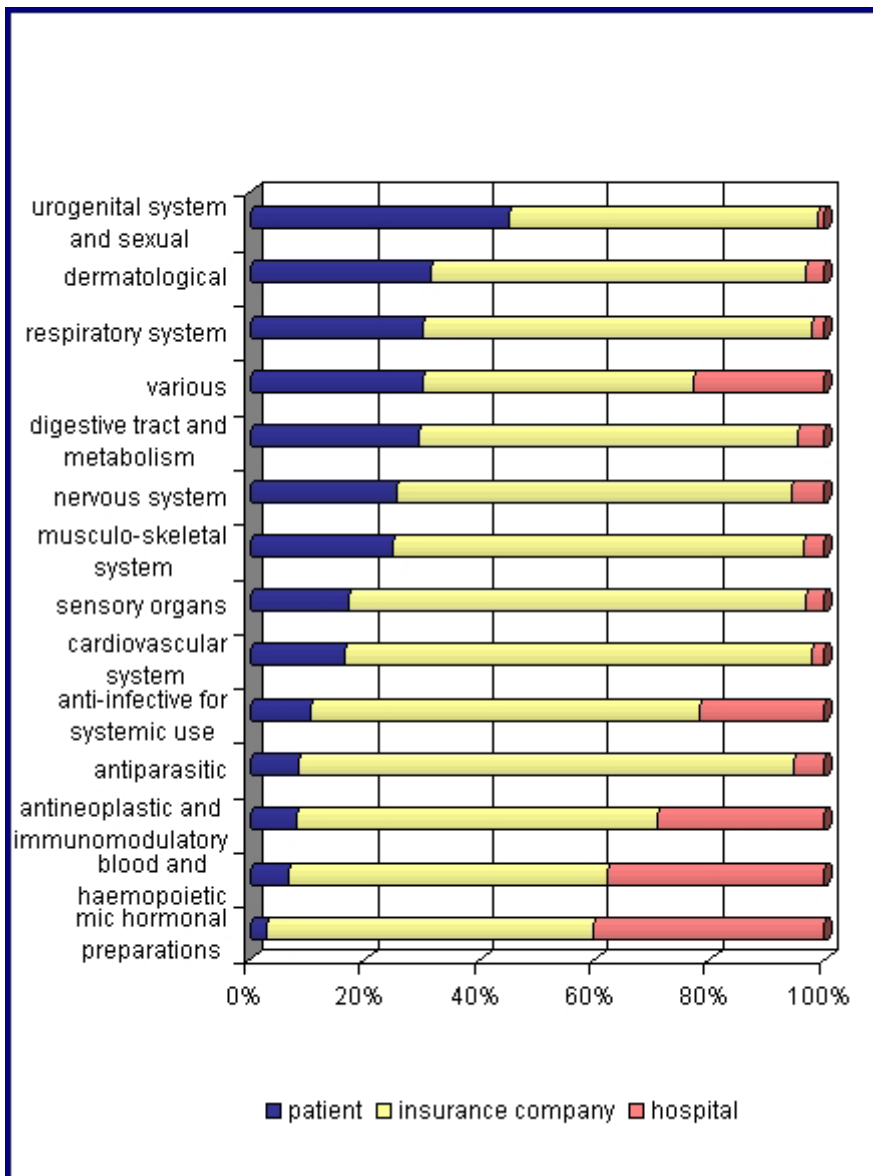
The performance of the domestic pharmaceutical industry is closely linked with health-care system not only in Slovakia, but to a large extent with those abroad, as the industry is strongly export oriented. Therefore pharmaceutical companies pay a close attention to the policy measures taken by the government. After the parliamentary election in the fall of 2002 the new ruling coalition expressed the intention to launch radical reform of the healthcare system. One of the features of the proposed reform with serious impact on the pharmaceutical industry is the intention to put brake on a rapidly growing drug consumption. This is going to happen on the background of fundamental change of the health insurance system. The key and most closely watched economic mechanisms used to control drug expenditures is drug categorization—the system of drug reimbursement.

Sharply growing expenses for prescription drugs are forcing the Health Ministry and individual health insurance companies to apply more pro-active measures to regulation of prescribing. The importance of these regulatory measures is highlighted by the fact that prescription drugs represent approximately 80% of all consumed drugs.

The out-of-pocket payments of citizens for drugs remain low (in absolute terms and also when compared with the Czech Republic), leading to over-prescription. According to SUKL's estimates, patient participation in settlements for drugs rose from 17.8% in 2000 to 21.5% in 2001. In relative terms, partial payments by patients are highest in the case of urogenital drugs, dermatological preparations, respiratory system drugs, drugs for the digestive system and metabolism (ranging from 29% to 45% in 2001). On the other hand, systemic hormonal preparations (excluding sexual hormones), together with blood preparations and haemopoietic organs, anti-neoplastics and immunomodulators and anti-parasitic agents, represented the drug groups with relatively the lowest partial participation of patients (from 2.9% to 8.3%). The real level of co-payments by patients is much lower (see note under the graph 18)—only 10% according to Mr. Jan Sipeky, the advisor of minister Zajac for Drug policy.

Graph 18

Partial coverage by patients for drugs in 2001 (%)



Source: SUKL, graph by Symsite Research

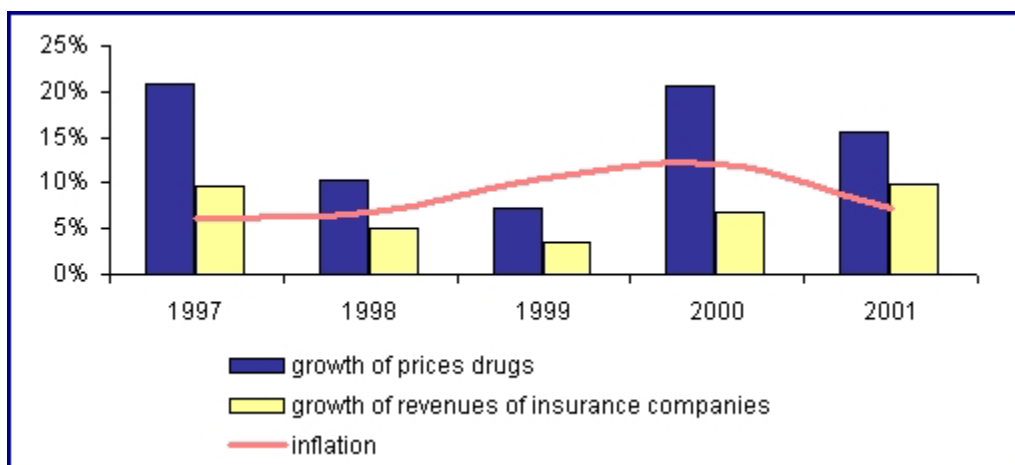
Note by Symsite Research – Estimates of partial coverage by patients were calculated by MCR based on SUKL data using maximum prices of drugs and amounts reimbursed by insurance companies according to categorization from 15 October 2001. Due to the fact that after this categorization came into force many pharmaceutical companies adapted the prices of their drugs in a way that it was possible to classify them as fully reimbursed drugs (or lowered the amount of patient participation in order to retain these patients), the real volume of partial participation by patients in prices is lower than SUKL estimates.

Health insurance companies are unable to cope with reimbursements of ever increasing drug costs, also because of the steep increase in drug prices, which outpaces the increase in their revenues y/y (Graph 19). Dominik Tomek, director of the Review Section at health insurance company CHZP Apollo and renowned expert in pharmaco-economics, thinks that the rise in drug prices is caused mainly by the entry of new and expensive drugs to the market. In 2000, the average drug price rose sharply by 21% (to Sk 100.80 per unit), while a year later this growth slowed a little to 16% (Sk 116.40). After a 5-year period of decline, in 2001 health insurance companies recorded a real increase in their revenues. In the first nine months of 2002 the real revenues rose by even 10%. Despite this, resources allocated to drugs constitute an ever greater share of

the expense structure of health insurers. At the end of 2002 the share of drug costs on overall health insurers budgets was close to 40%.

Graph 19

Comparison of y/y change in revenues of health insurance companies and drug prices in 1997 – 2001 (%)



Source: SUKL, SU SR, Symsite Research

Health insurers face the problem by motivational mechanism of bonuses when doctors keep the level of prescriptions low. Inspections performed by insurance companies also highlight the problem of financially demanding preparations being prescribed as first-option drugs without sufficient consideration of the possibility of prescribing less expensive drugs (generics). The new health minister, Rudolf Zajac, advocates economical treatment and the use of generic preparations. One of the first decisions of Rudolf Zajac as minister was to introduce a Sk 20 prescription fee.

The crucial regulatory tool for pharmaceutical companies to watch is categorization—rather complicated process of determination the reimbursements by health insurers. The most recent categorization (valid from 1 October 2002) includes 3,351 drugs (Table 34) in the category of partially reimbursed drugs, of which 39% are drugs with partial coverage from patients not exceeding Sk 50. However, the market determines the real amount of patient coverage (by pricing policy of pharmaceutical companies) in the end, as the state regulates only maximum prices and margins of distributors and pharmacies.

Table 34

Structure of drugs co-financed by patient according to last three categorizations

SKK, units

Patient participation	January 2001	October 2001	October 2002
SKK 0*	1,368	1,036	957
not exceeding SKK 50	1,445	1,363	1,296
not exceeding SKK 100	515	602	624
exceeding SKK 100	1,064	1,203	1,458
Total for partially covered drugs	3,024	3,168	3,351

* fully reimbursed drugs

Pharmaceutical companies in many cases adapt—i.e. reduce—the prices of their drugs to ensure patients do not pay for the drug. Voluntary cuts of drug prices are usually applied by their producers only in the case of selected preparations, as any major across-the-board price reductions could eat into profit too deeply. In this respect, the key aspect for pharmaceutical companies is the price of the drug that is being introduced to the market. In this regards Mr. Martinec from SUKL considers a lot of drugs as been overpriced when launched on the Slovak market. Companies offering their drugs in Slovakia using world prices usually have more scope to “cut” prices in order to eliminate patients’ payments. Price cuts are therefore usually performed by original producers while generic producers tend to attempt to force the Ministry of Finance to approve increases of maximum prices. Ondrej Gattnar, CEO of Slovakofarma, complains that the state pricing policy lacks any strategy and the institute of maximum price results into the situation that some 40% of company’s products is at the edge of profitability. He even threatens to withdraw some drugs from the market, limiting consumer choice. Pro-reform government tends to repair the pricing policy by enforcing more liberal principles.

Different prices across Europe—

The prices of medicines widely differ across the Europe not only as a consequence of unique pricing and reimbursement systems in individual countries. The price level of a country reflects a number of other issues, i.e. inflation, exchange rate fluctuations or purchasing power. The final level of drug consumption will strongly depend on the level of margins and VAT, for example. No matter of the pace of ex-factory price convergence of pharmaceuticals toward EU level. The estimates for yearly increase in drug consumption range from Sk 0.5-0.7bn thanks to VAT change since January 2003 (from 10% to 14%). The Ministry of Finance intends to introduce the uniform VAT rate (between 15-20%) in the near future. Thus the drug consumption is supposed to rise further thanks to the increased prices in this regard.

— are not likely to equalize quickly

Representatives of AFV SR considers the prices of original drugs in Slovakia to be closer to the level in the EU. Generic price level in Slovak market is much more away from the average of EU. While the price level of innovative drugs in Slovakia represent some 80% of the average EU level, average price level of generics accounted for just 35% of that in EU as they claim. An efficient single EU market would tend to equalize the prices. Thus the lower price level in Slovakia should come closer to the pricier EU market. Mainly the prices of some generics will grow, while some original drugs may even fall with price. Much will depend on reimbursement policy by the state, however. We do not expect that the process of price harmonization will be speedy after the enlargement. Integration experience of many countries reveals that wide differences in prices of medicines (but of most consumer goods as well) linger throughout European Union. Quite paradoxically the arbitrage parallel trade may contribute to the convergence of price levels within enlarged Europe.

The EU enlargement in terms of the economy development as well as the state drug policy will drive the adoption of corporation policy. One part of the drug policy in member states is crucially affected by the EU enlargement—harmonization of registration procedures. The need for dossier renewals of drugs (regarding mainly domestic generic companies) is of the highest importance from this aspect. The other part—pricing and reimbursement—is an individual issue. With regard to domestic sales corporations will have to adapt their short-term business plan to the proposed change in reimbursement system. Both factors increase the need for deeper cooperation between companies, state authorities and health insurers companies.