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

By: EVA DREŠEROVÁ

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1. Introduction

The year 1989 was a significant year not only for the history of the world, but also more importantly for the history of the Czech Republic. This year marked the fall of communistic rule over the Czech Republic and sent the engine of reform into full force throughout the society. This arduous and needed reform that has taken place during the last 14 years has swept and permeated throughout the entire government and all of its associated institutions as well as the economy and market structures. The journey thus far has been turbulent and strenuous but has also been marked with many successes; none bigger than the expected accession into the EU (European Union) in 2004 and the EMU (European Monetary Unit) in 2007. The accession of the Czech Republic into the EU and subsequently EMU will undoubtedly challenge all of the privatization and liberalization work of the Czech markets and their major industries that has been accomplished thus far.

One industry that is certain to be affected with the accession to the EU is the Czech pharmaceutical industry due to its complex market and economic makeup and stringent government regulations. Specifically, my goal in this report is to provide detailed analysis and insight in regards to the following significant issues: (1) growth effect of the EU accession; (2) the effect of accession on foreign trade and evolution of net exports; (3) the effect of accession on FDI flows; (4) labor market effect of EU accession; (5) the effects of EU accession on the regulatory framework; (6) the effect of accession on the market structures; (7) and short-term policy measures related to the pharmaceutical sector. With this project and the seven areas I have outlined above I hope to give the reader a better understanding of the Czech pharmaceutical market as it scales the mountain peaks through the EU accession.

1.1. Development of the Czech Health System

Before we can explore and analyze the above stated significant issues that will be affecting the Czech pharmaceutical market as it moves to the EU accession, I believe, that one must have a solid understanding of the past and present before one can truly comprehend the future. Human health is a vital asset in every society that should be cherished and nurtured and the health status of the population is also one of the most significant indicators of the social as well as the economic development of a society.

This section of the report will attempt to describe briefly the history and the current state of the health care system of the Czech Republic, its advantages and disadvantages, system of financing, and list in detail some of the major issues of conflict within the Czech health system as it correlates with the pharmaceutical market. In addition, I will provide general information of the Czech Republic's largest public health insurance company VZP; which covers health expenditures of about 70% of the Czech population.

1.1.1. History and Current Situation

After the breakdown of the Eastern bloc in 1989, politicians in Central and Eastern Europe who wanted to lead their countries successfully towards the EU accession had to face a problem how to transfer health care system in their countries from the centralized state run system towards a system of public health. During the reform process, the EU didn't put any pressure on the candidate countries while pursuing their reforms nor did it offer them any united model on how to do so. There was no health 'chapter' to be negotiated, because the healthcare system itself remains largely off-limits to the EU under the subsidiary rule. Lack of experience and qualified

leadership through such a complicated transfer lead to many confusions and good will alone didn't help to establish the perfect system nor did it bring the desired results.

In the beginning of 1990, when the Czech economic system was going through the process of privatization, decentralization and the creation of a new legal framework, it was believed that market rules can also be enforced in the system of health care. Policy-makers, who did not have essential knowledge and experience with a market economy assumed, that the final version of health care should create as little regulation on the market as possible. Within the 90s, no compact concept of health care was created, centrally coordinated net of health care providers were destroyed without identifying a new one, and no basic basket of services guaranteed by state were defined.

An area of concern is the unfavorable record that the Czech Republic holds in the number of visits to doctor offices. Josef Suchopar, from Infopharm stated during a pharmaceutical conference in 2002, that the number reached 12.5 visits per year. This number is 2 to 3 times more than in any other European countries. Another negative fact is that 95% of all doctor visits resulted with a prescription of pharmaceuticals. Therefore, the main problem of health care funds is not the insufficient net of health services, but on the contrary it's the fact that the net is oversized and outdated. This results into useless and over needed health care services and in many cases worthless drug prescription.

Another example comes from the lack of interconnection between different health care providers and the insufficient sharing of information about the health status of patients. According to a TRANS 96 research, only 24% of general practitioners actively cooperate with specialists, and often this leads to many routine examinations are being duplicated as the GP is unaware of prior treatment on his or her patients by the specialist.

The Czech Republic introduced a SHI (Social Health Insurance) system in 1992/93 that is dependent on wage-based contributions. It is based on solidarity, justice and principles stated in the Charter on Human Rights.

There are four broad types of health care fund organizations within the EU:

1. Single fund for the entire population.
2. Single funds serving geographically distinct populations within a country.
3. Multiple funds serving the population in the same geographic area but which do not compete for clients.
4. Multiple competing funds.

The Czech Republic chose the fourth system and established twenty seven funds; of which 18 of them have already disappeared from the market. The funds collect the contributions from employed members of the society and all non-wage earners (retired, unemployed, housewives, children etc.) are individually insured and have their contributions transferred from the general tax-financed budget to the sickness funds.

Czech citizens also have an opportunity of private health insurance, which is currently offered by thirteen insurers. Health services provided in the framework of the private sector and paid from private sources must however be clearly separated from the public system.

The following table 1.1 shows the development of expenditures on health as % of GDP, ratio to EU average and expenditure on pharmaceuticals in % of total expenditure on health as it developed through the 90s. Especially significant is the sharp increase of expenditure in the first year (1993) after launching SHI by about 2 % points of GDP. One of the most significant reasons of such a drastic increase was the insufficient level of regulations, which resulted into wasteful purchases of pharmaceuticals (portion of expenditures on pharmaceuticals on total expenditure on health rose over 5 % points between 1993/1994 and the trend remained until now).

Table 1.1 - Macroeconomic Indicators in Health Sector:

Years	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Total expenditure on health as % of GDP	5.0	5.2	5.4	7.2	7.3	7.3	7.0	7.1	7.2	7.6
Ratio to EU Average	0.64	0.64	0.64	0.84	0.85	0.85	0.81	0.83	0.84	-
Expenditure on pharmaceuticals in % of total expenditure on health	21.0	18.4	21.1	19.4	24.7	25.6	25.5	25.3	25.5	25.1

Source: WHO Health for all database 6/2001

Although table 1.1 shows that the Czech Republic has not yet reached the average expenditures on health in the EU countries, it does not necessarily mean that there is a worse state of health in the population of CR in comparison to the population in the EU. As a matter of fact, the Czech Republic is the only candidate country where life expectancy improved over the course of the 1990s. In the year 2000, the average length of life for men reached 71.7 years and for women 78.4 years. These figures are quite comparable to the EU average. A favorable result in the relation between low-health expenditures and high-life expectancy is accomplished by extremely low wages in the public health sector; which is in strong contrast to the EU.

With the Ministry of Health fully aware with all of the above stated problems, they developed a midterm conception for the following years 2003 through 2006; which will be crucial for the EU accession. The main strategic goal of the Ministry of Health is improving the health state of population, and especially the following:

- Protection and support of health.
- Patient-oriented health care, teaching doctors an appropriate approach of patients, support of patients' responsibility for their health.
- Improving basic indicators of health state and reduction of the most frequent diseases and risk factors influencing their development.
- Improving life quality in old age.
- Equalizing prevention with health care.
- Launching system of control and evaluation of quality of provided health care.

- Developing communication and cooperation among particular health institution.
- Support of effective research and development in the field.

Table 1.2 - Health Sector SWOT Analysis:

Strengths	Weaknesses
High level of education	Insufficient system of quality and efficiency control
Relatively good equipment of health devices	High level of debts in health services
Improvement of environment	Low finance resources resulting from lower economic efficiency
Increase of life expectancy	Shortage of cash
High level of vaccination	
Opportunities	Threats
Good base for further development of high labour potential	Deepening of financial deficit of health utilities and insurance companies
Ongoing transformation process of health care system	Individual abuse of the health care system
Adoption of the WHO "Health 21" program	Low level of legal education of all subjects in the system
Control and affectivity of financial sources	Insufficient renovation and innovation of technical equipment
Increase of quality of provided care	
Support of research and development	

1.1.2. Health Insurance System (HIS)

As low financial resources are one of the weaknesses within the health system in the Czech Republic it is necessary to analyze and describe the system of health insurance. Public health insurance in the Czech Republic is a type of legal insurance on the base of which health care is provided to the insured person and it doesn't have the same characteristics of commercial insurance. Payers do not merely pay for "their" insurance; they contribute into a common health insurance fund, from which health care is being paid for those participants who need it. The system is based on solidarity and justice.

According to the law, participants on health insurance are all persons with permanent residence in the Czech Republic. The majority of persons who don't have a permanent residence in the Czech Republic contribute only for the period in which an employer employs them with a seat in the CR.

In 1992 all persons with permanent residence in the CR became insured by the VZP, and this helped to remain the biggest health insurance company covering almost 70% of Czech citizens. Nevertheless, VZP loses around 3 % of clients each year.

Currently, in addition to the VZP health insurance there is also health insurance being provided by eight other employee health insurance companies. Each insured person can be insured only with one health insurance company. The insured has the right to choose insurance company and is allowed to change it every 12 months. Right of choice is not being used for newborn babies who automatically become insured by their mother's insurance company.

Each VZP insured client has the right to be provided with care paid from public health insurance and according to the Chapter 31 of the Basic Rights and Freedoms List, each person has the right for health protection. On the basis of public health insurance, citizens have the right for free health care and health aids stated by the law, which is often understood in the way that all provided health care is free.

Insured clients also have the right to choose a doctor or health utility which has signed a contract with a health insurance company. In such a case it's illegal to require other cash payments from previously insured patients. There is also a possibility for insured persons to choose a health utility that doesn't have a contract with a health insurance company. However, in such case they lose the right for payments from public health insurance and have to cover all of their health costs with the exception of acute care.

Health insurance covers all health care, which is supposed to preserve or improve health state of the insured. It includes but it's not limited to the following:

- Treatment care, diagnostic care, rehabilitation and treatment of chronic diseases.
- Ambulatory and rescue services.
- Preventive care.
- Pharmaceuticals and healing aids, which are listed in the price list and spa care.
- Health care costs acquired abroad in an acute case in the amount equaling similar treatment in the Czech Republic.

Czech law recognizes three payers of health insurance:

1. Employer - covers 2/3 of insurance of employees. Another 1/3 the employer takes off employees' paychecks even without their agreement.
2. State - covers health insurance of about 56 % of citizens (children, unemployed citizens, women on maternity leave, pensioners, arrested people, military servicemen, employees on sick leave - average of 6 % of labor force is sick which causes big economic troubles, etc.).
3. Private entrepreneurs.

One of the permanent problems that health insurance companies in the Czech Republic have been facing is the amount of excessive debt. In the year 2001, the VZP showed unpaid receivables in the amount of exceeding 20 billion CZK, 13 billion of which is already past due. Therefore, the Czech Health Ministry took a significant step towards solving of the debt and transferred that part of debt that does not have any chance to be paid for (3.7 billion CZK) under management of the Consolidation Bank.

The Czech Health Ministry is about to submit a proposal about health insurance companies in March 2003. Its main goal is to motivate health insurance companies to improve their efficiency in providing services, increase their economic efficiency, create savings and take part on the integration process connected with the EU accession.

1.2. Features of the Czech Pharmacy

The Czech pharmaceutical industry belongs to the branch of qualified chemistry, and according to the Branch Classification of Economic Activities (OKEČ) and Standard production classification (SKP) respecting the international NACE qualification. The branch of pharmaceuticals and other products is signed NACE 24.4 and belongs to the branch of chemical and pharmaceutical industry (NACE 24). In 2001 the pharmaceutical branch controlled a 13% share in revenues on the total chemical production (in the EU countries the share is doubled, the reason for this is that the CR under communist regime developed heavy chemistry and backwarded in production of fine chemical product outputs). Table 1.3 shows revenues from the sale of products and services in current prices in the pharmaceutical sector and the total revenues in chemical industry in general between the years 1997 - 2001.

Table 1.3 - Revenues from the sale of products and services

CZK mil.	1997	1998	1999	2000	2001*
NACE 24.4	12 461.1	11 505.9	12 079.4	14 450.0	15 461.5
NACE 24	94 696.0	98 500.0	98 602.0	118 755.5	118 972.3

* preliminary value

Source: Czech Statistical Office, calculation by Ministry of Industry and Trade

Pharmaceutical industry can be described as a sector with the following characteristics:

- High level of basic raw material manufacturing
- High value-added
- Need for demanding technologies
- Need for highly qualified labor force
- High demand on investments and continuous renovation
- High profits

The Czech pharmaceutical industry was quite successful in the process of privatization. Before 1989 in the former Czechoslovakia there existed only one company, SPOFA (Spojené farmaceutické závody), and it included all the producers of pharmaceuticals. In privatization the company was divided into several companies usually taking the form of joint stock companies. Privatization was mostly followed by the influx of foreign capital; for example:

- In 1992 the first foreign investment occurred by the Swiss company Lonza which purchased part of the VÚBVL (Výzkumný ústav biofaktorů a veterinárních léčiv).
- Two joint ventures Interpharma a.s. and Ferring-Léčiva a.s. were established with the company Léčiva.
- In 1994 the company Galena was privatized by the US company IVAX Corporation (Galena was renamed as IVAX-CR a.s.).

All pharmaceutical producers in the Czech Republic are required to obtain permission from the State Institute for Drug Control (SÚKL), which is based on the company meeting requirements of the directive of GMP (Good Manufacturing Practice). These directives were issued by the former EC in 1989 and 1990 and entered into force in 1991 for producers in the EC. The Czech Republic's early acceptance of the GMP standard in 1995 required increased investments for meeting these requirements and continued reforms, but on the other hand it is sure to help Czech pharmaceutical companies with smoother adjustment to the EU market after the EU accession.

2. Growth Effects of the EU Accession

2.1. Supply of Pharmaceuticals

The pharmaceutical sector is directly dependent on the continuous introduction of new and continuous technological innovations that enable the advancement of new drug production and spur growth. Therefore it's crucial to invest sufficient financial resources for research and development. In average, the development of a new medicine (original product) and its introduction to the market takes between 10 - 20 years and 250 - 500 million of USD. Each original medicine is protected with a patent which should secure return on investments; patent protection in most of the countries in the world as well as in the Czech Republic last 20 years.

After the expiration of the patent, companies are able to start the development of so called (generic products); which are the imitations of original medicaments. The development of a generic product requires a small percentage of investment; which is in strong contrast to the development of an original product. Due to the limited amount of money that was and is invested into research and development in the Czech Republic the pharmaceutical production is mostly dependent on production of generics. The Czech government at this point has no plans to significantly increase their investment into the pharmaceutical market; thus little to no growth is expected in the area of production of original products as the Czech Republic moves to EU accession.

Production in the Czech pharmaceutical industry can be divided into two sectors; one of which is pharmaceutical *substances* (NACE 2441) and the other is the production of *final forms* (NACE 2442). To the date 31 January 2003, the State Institute for Drug Control (SÚKL) granted 50 authorizations to the producers of substances and 32 authorizations to the producers of final forms. Most pharmaceutical substances are being exported into developed industrial countries like the EU, USA, or Japan. On the other hand, the production of final forms is usually directed for the Czech domestic market and for export into central and eastern European countries.

In general, the production of pharmaceuticals has increased over the period of 1993 to 2001 as the main production indicators show in Table 2.1: The reason for this slow but continuous growth will be explained in the proceeding sections.

Table 2.1 - Main indicators of growth in the pharmaceutical sector:

CZK mil.	1993	1994	1995	1996	1997	1998	1999	2000	2001
Revenues (cp)	7 103	8 588	9 794	10 851	12 461	11 505	12 079	14 450	15 461
y/y index	x	120.9	114.0	110.8	114.8	92.3	105.0	119.6	107.3
Added value (c.p.)	2 693	2 932	2 962	3 534	4 667	4 288	4 476	5 741	6 554

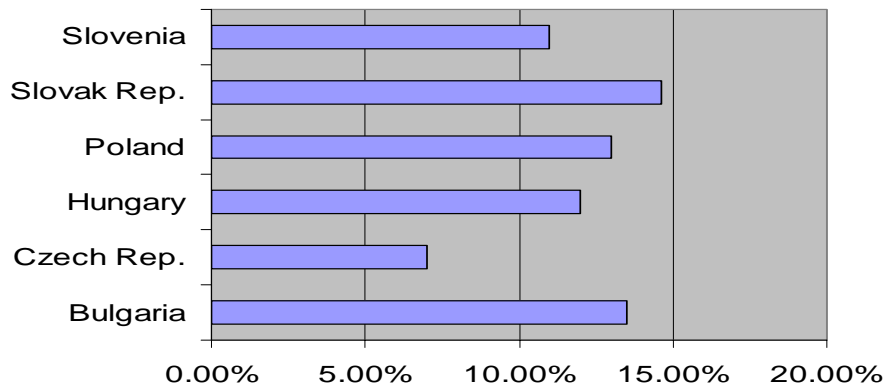
Source: EUROSTAT, c.p. - current prices

The pharmaceutical supply problems of the socialist system have largely disappeared after entry into and the direct investment of foreign companies to the Czech pharmaceutical market. At the present time and for the unforeseeable future, all of the major world producers of pharmaceuticals are present in the Czech market and

all mainstream products are available. Due to the above stated reasons, the supply of the Czech domestic market is stable and will continue to be stable even after the accession into the EU.

According to the IMS HEALTH Pharma Prognosis for Central and Eastern European countries, which was carried out in 2000, growth of pharmaceutical markets in these countries over the period of 1999 - 2004 is expected as the following figure 2.1 shows:

Figure 2.1 - Expected market growth, 1999 - 2004



Source: IMS Health's Pharma Prognosis Central and Eastern Europe

As it is obvious from the chart, the growth of pharmaceutical market in the Czech Republic is the slowest in comparison to the other listed central and eastern European markets and reaches only 7 %.

2.2. Demand on Pharmaceuticals

In general, foreign companies are attracted by the growing demand in pharmaceuticals, which is usually independent on the economic cycle and is normally influenced by the following factors:

- Aging of population (birth rate is decreasing and life expectancy increasing).
- The rise of population's purchasing power (wage increase).
- Technological development in pharmacy and medicine in general.
- Increased consumption of preventive pharmaceutical products connected with rising responsibility for own health.
- Rising pressure on individuals to contribute to pharmaceutical costs on self-inflicted ailments (e.g., obesity, lung cancer, etc.)
- Increased amount of anti-allergens resulting from the rising appearance of allergies.

A rapid increase in the consumption of pharmaceutical products occurred after the liberation of the market and above all after the launching of the SHI system. In spite of a fast cost escalation, the use of drugs rose from 678 defined daily doses (DDD – special volume measure of consumption) in 1991 to 1125 DDD in 2001 (Institute of

Health Information and Statistics, 2002) while the total expenditures on drugs rose from 6.96 billion CZK in 1990 to 44.24 billion in 2001. However, the actual number of packages consumed per year only rose from 271.2 million in 1991 to 342.9 million in 2001 (see Table 2.2). On the other hand in comparison with Slovakia where the DDD indicator for the year 2001 reached 1 493 the Czech number shows that the drug therapy in the Czech republic is more efficient.

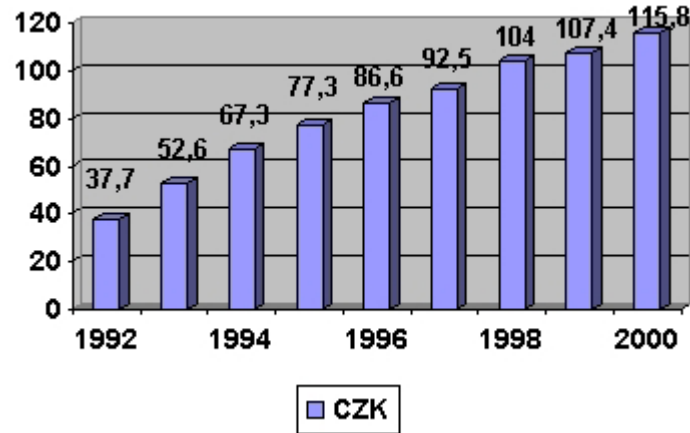
Table 2.2 - Development of amount of distributed pharmaceuticals

Years	DDD/1000/d	Expenditures on pharmaceuticals in billions CZK	Number of packages in millions
1991	678	6.96	271.2
1992	689	9.33	271.6
1993	756	13.96	277.9
1994	911	21.19	331.1
1995	945	25.64	332.2
1996	986	28.18	325.6
1997	1045	30.06	317.9
1998	1105	33.32	320.4
1999	1188	36.44	339.3
2000	1196	38.39	331.6
2001	1125	44.24	342.9

Source: State Institute for Drug Control

According to Lumir Krocek, director of the Czech Association of Drug Distributors (AVEL), the reason for this inadequacy in general is not only due to rise of prices, but is mainly created by the increased purchase of the more expensive foreign products. He also stated that the Czech pharmaceutical companies loose their market share because of insufficient promotion. On the other hand, according to Figure 2.2, the actual rise of prices of pharmaceuticals in the course of 90s is unquestionable:

Figure 2.2 - Development of an average price of pharmaceutical per package



Source: Pharmacological Institute, Charles University

The general population within the Czech Republic is taking more preventive measures and is being more cautious in regards to their individual health and because of this an increased demand on over the counter purchased anti-allergens is expected in the next several years as well as vaccinations (e.g., flu vaccination), and pharmaceuticals against cold and anti-smoking.

There are also differences in the structure of drug expenditures in financial terms between Europe and the Czech Republic. Figures 2.3 and 2.4 show that people in the Czech Republic spend significantly more money on pain-killers as well as on vitamins and minerals in comparison to the EU countries.

Figure 2.3 - Structure of drug expenditures in financial terms in Europe (with exception of the former USSR countries) in 2000

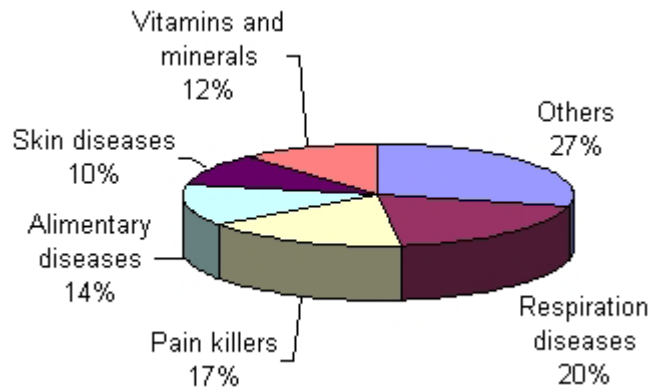
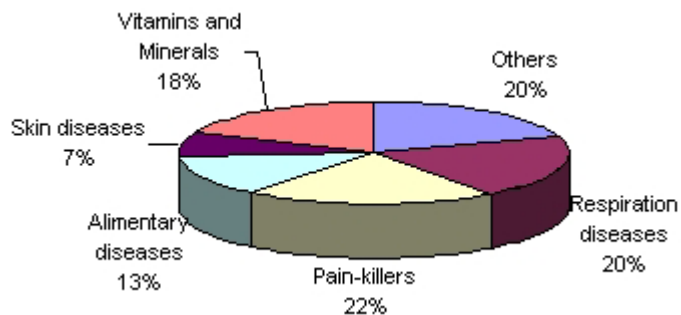


Figure 2.4 - Structure of drug expenditures in financial terms in the Czech Republic in 2000



2.2.1. Specific problems on the demand side

One of the major areas of concern, which is slowing down the development of growth in the pharmaceutical sector, is the debt of public hospitals resulting from general shortage of finance in the Czech health system as well as the lack of responsibility imposed on the directors of the hospitals. Specifically, most of the debts are being created by district hospitals which are directly administrated by the Czech Ministry of Health while the least amount of debts is created by private and church hospitals. This debt leaves the pharmaceutical companies with very little liquid cash and resources in order to invest into technological development.

According to the Health Ministry, the absolute amount of liabilities of the district hospitals past due is 2.9 billion CZK and the total amount of claims past due is 1 billion CZK. Therefore, the total debt creates close to 2 billion CZK.

In addition, starting 1 January 2003, all district hospitals were placed under regional administration without clear determination of who will become responsible for the debts. Analysis of the situation is being done and negotiations with regional mayors are being held. Proposal is being planned for submission by 30 June 2003. The proposal will not deal with the flat clearing of debts but will try to enforce an individual approach to particular hospitals and it is possible that many of them will be cancelled.

However, the suppliers of pharmaceuticals who are united in the Association of Drug Distributors (AVEL) do not believe that regional administration of hospitals will solve debt problems and do not want to wait any longer for governmental solutions. They have decided to stop supplying to the biggest debtors and they have filed a legal complaint against them.

2.3. Conclusion

It is possible to expect growth of the domestic pharmaceutical market especially connected with increased demand caused by the general problem of an aging population, stronger purchasing power and the increased effort in supporting prevention connected with increased consumption of supplementary preventive products. This growth is not directly connected with any elements of EU accession - and as past history tells us - nor will the EU accession act as a detriment to this growth.

3. The effect of Accession on Foreign Trade and Evolution of Net Exports

In general, the chemical industry itself suffers from an unfavorable increase of trade deficit. This trend was developing throughout 90s and the biggest contributor to the current state was the pharmaceutical sector. Table 3.1 shows the development of exports and imports in the pharmaceutical industry over the years 1995 - 2002.

Table 3.1 - Development of foreign trade in pharmaceuticals

CZK mil.	1995	1996	1997	1998	1999	2000	2001	2002
Exports (c.p.)	5 357	6 440	7 726	7 545	8 126	9 686	8 606	7 473
Imports (c.p.)	17 670	20 255	23 302	24 688	27 605	30 060	32 975	34 097
Trade deficit	-12 313	-13 815	-15 576	-17 143	-19 479	-20 374	-24 369	-26 624

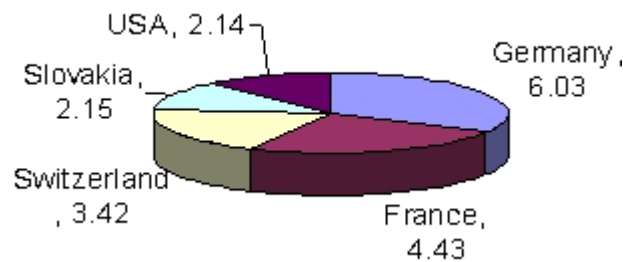
Source: Czech Statistical Office (CSU)

3.1. Imports of Pharmaceuticals

There is no custom duty applying for pharmaceuticals imported to the Czech Republic, there is only a 5 % VAT applying for all medicinal product.

The total value of pharmaceuticals imported to the Czech Republic during the year 2002 was 34.1 billion CZK. According to the statistics provided by the General Customs Directorate, the five biggest importers were Germany, France, Switzerland, Slovakia and USA, which all together cover over 50% of imports (exactly 18.17 billion). Figure 3.1 shows the distribution of import shares of the above stated countries. Slovakia, as one of the main importers of pharmaceuticals to the Czech Republic is especially significant due to the long and current common history of these two states, and the fact they are expected to join the EU around the same time frame.

Figure 3.1 - Biggest importers of pharmaceuticals, billions CZK



Source: General Customs Directorate

Another specific macro-economic category that directly influenced the increase of imports over the year 2002 was the sharp strengthening of CZK towards the euro and USD. From the fall 2001 to the fall 2002, the crown strengthened from 40 CZK/USD to 30 CZK/USD. This trend is comparable with the euro as well. The fact that with the Czech crown it was possible to buy more products from the EU and USA created a higher demand on imported goods and therefore attracted more distributors. In the case that the crown will get stronger in future - as financial analyst predicts it to - a steady increase of imports can be expected.

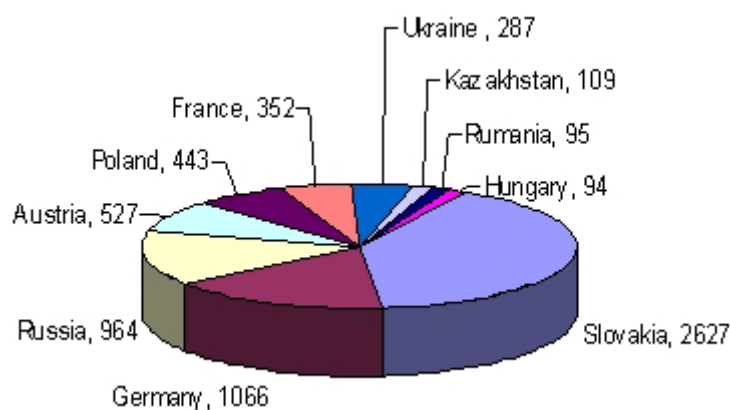
3.2. Exports of Pharmaceuticals

As was mentioned previously in this report, the exporting commodities in pharmaceutical industry are divided into two categories: (1) pharmaceutical substances (which are dominating the export into developed economies such as the EU countries, USA or Japan), and (2) final products (which are usually directed to the central and eastern European markets).

As a general trend in the Czech chemical industry indicates, after the decentralization the production was and is being transformed from 'heavy' chemical products to 'fine' outputs with higher value added and higher share of medium and high technologies.

In terms of pharmaceuticals, this trend means lowering the production of substances in favor of increased production of final forms. However, final forms of pharmaceuticals do not yet appear to be competitive enough to be able to enter western markets where a high level of competition and saturation already exists. Therefore, the Czech pharmaceutical companies are - and already started - marketing themselves in the eastern markets where they have a better market, cultural, and language understanding over their western counterparts and where the market is still rather open due to their own decentralization and privatization reforms. The growth rate of pharmaceutical markets in Central and Eastern Europe helps to prove that this strategy appears to be correct (see figure 2.1). In addition, the targeting of eastern markets is obvious from the following Figure 3.2.

Figure 3.2 - Major Exporting Destinations



Source: General Customs Directorate

Among the 10 biggest exporting destinations - besides the traditional markets of Slovakia, Germany, Russia, Austria and France - the other Central and Eastern European markets are already playing a big role and new markets are now opening in the Caucasus states. The three biggest Czech exporters (Léčiva a.s., Pliva-Lachema a.s. and IVAX-CR a.s.) are developing the lead in this respect.

3.3. Conclusion

It is necessary for the Czech pharmaceutical market to deal with the sharp increase of the trade deficit. One of the several possible ways of improving it is entering the markets of present EU members. It is certainly true that after accession of the Czech Republic into the EU, the Czech pharmaceutical products will be recognized as competitive ones meeting all necessary requirements of the EU. However, the effort of entering the EU markets would be connected with significant increases of investments into innovative technologies, research and

development and promotion. In addition, to the fact that with these markets are already well developed and saturated with established MNEs, this way of increasing imports is highly unlikely and will only concern a minimum amount of products after EU accession.

The second way is to increase the focus on imports on the central and eastern European markets. EU candidates are obliged to unite their legislation with the EU standards and this unification will become valid after their accession. At that time, access to these markets will be easier for all producers from the EU and it's expected that some will attempt to enter. Therefore, it is crucial for the Czech pharmaceutical companies to continue to develop a good distribution base and invest into promotion and advertising, so they can establish a solid brand awareness and image and keep and grow their market share after the EU accession.

A third market on which the Czech pharmaceutical producers should focus on after the EU accession is the market in the former U.S.S.R. countries. The big advantage of this market is that it is not yet saturated and the market entry costs are limited in comparison to the above stated markets. Also, consumers in these countries will certainly welcome lower prices offered by Czech companies than possible EU importers would be willing to offer them for a comparable quality required in the EU countries. The biggest Czech pharmaceutical exporters already realized this big opportunity in the past several years and the increase of imports is likely to rise after the EU accession.

Table 3.2 - Foreign Trade SWOT Analysis

Strengths	Weaknesses
good relations with the central and eastern European countries and former USSR countries	rising trade deficit
after the EU entry the quality of Czech products will be recognized as comparable with the EU products	low chance to enter western European markets due to average quality of products
	low protection of domestic market share (low level of promotion)
Opportunities	Threats
increase incentives for exporters	continual increase of trade deficit
gain market share in central and eastern Europe and former USSR countries	due to low promotion of Czech products, Czech customers might turn their interest towards imports
develop high quality product capable to enter western European markets	

4. The Effect of Accession on FDI Flows

Economic theories suggest several different approaches for governmental incentives in order to attract foreign investments into specific industries. Incentives and subsequent investments should support the following:

- Sectors with a high added value of labor.
- Sectors with high wages.
- Sectors with a large share of HT (high technologies).

The Czech government decided to primarily support the sectors with a significant share of HT, which could be at the same time sectors with a high added value of labor and elevated wages. One of the most important *representatives* in this regard is the pharmaceutical industry, which fulfills all of the above stated characteristics.

Although, there are still insufficient sources invested into research and development of pharmaceuticals in comparison to the current EU countries, the present foreign investments has lead to obvious favorable trends:

- Increase of complexity; due to the access of biotechnologies.
- Pressure on minimizing the production cycle.
- Pressure on lowering fixed costs of big pharmaceutical companies.
- Gradual erasing of borders defining pharmaceuticals.
- Global cooperation.
- Co-marketing and co-development.

To retain these favorable trends and to increase research and development, it is necessary for the government to keep developing the investment base and continue to foster a positive economical, political, and legal environment in order to attract foreign capital.

4.1. Advantages for Investment

In order to attract foreign direct investments, it's necessary to offer possible investors favorable conditions in comparison to the other surrounding and competing countries such as Poland and Hungary. Over the period of 1990 to 2002, a total of over 32 billion USD flew to the Czech economy out of which, according to CzechInvest (Czech Agency for Foreign Investment), approximately 3% of it was aimed at the chemical and pharmaceutical industry. The major reasons, why foreign companies entered the Czech market are the following:

- Central position in Europe and improving transport links.
- Stabilized political and economical system.
- Over a 100 year tradition of chemical production with a large scale of products.

- Comparable quality of products.
- Progress in legislation towards harmonization with the EU standards, liberalization of international business relations with the CEFTA and EU countries.
- State participation on removing ecological burdens of the past.
- High level of technically educated people coupled with low labor costs.
- Well-developed domestic supply base.
- Renewing economic growth and restructuring of industry.
- Investment incentives and other business support measures which emerged in a large scale after 1998.

4.2. Disadvantages for Possible Investors

The following is a list of possible disadvantages of foreign direct investment into the CZ:

- Very few products reaching top quality.
- Small consumer market (only 10 million inhabitants).
- Very limited sources of raw materials.
- Low productivity of labor, aversion to move for labor, low language skills.
- High tax burden.
- High ecological burden requiring enormous costs.

The above stated unfavorable conditions for foreign investors cause a shift of investor's interest away from the Czech market towards promising markets in other central and eastern European countries such as former U.S.S.R. countries and Asia. Currently, one of the biggest competitors and attractors of FDI is India, due to its abundance of new technologies, less legislative restrictions, lower tax burden, and most importantly its high level language skills (especially English, with all written documentation in English as well).

4.3. Present Foreign Share in Czech Companies

One of the most significant characteristics of the Czech pharmaceutical industry is the fact that foreign capital is already present in the majority of the companies. The first significant entry of foreign capital occurred in 1992, when the Swiss company Lonza bought a part of the Research Institute for Bio-factors and Veterinary Medicaments (VÚBVL); which orientate at research in the field of biotechnologies. In the same year, two joint ventures - Interpharma a.s. and Ferring-Léčiva a.s. - were created with Léčiva a.s. The biggest investment in pharmaceutical industry happened in 1994, when the US company IVAX Corporation bought 94.6% share of the Galena a.s. for 64 million USD and Galena was renamed to IVAX-ČR. The company Léčiva CZ; which was established by the company's management with the capital support of the American investor Warburg Pincus as financial partner, purchased the company Léčiva a.s. in 1997. In 1998, the Research Institute of Anti-biotic and Biotransformation (VÚAB) was purchased by another American company ICN Pharmaceuticals. In 1999, two

thirds share of Lachema a.s. were sold to the Croatian company Pliva, that in 2002 also bought another share from the company Aliachem. At present, Pliva owns over 95% shares in the company, which was renamed Pliva-Lachema.

Out of the six most important Czech pharmaceutical companies (Léčiva a.s., IVAX-ČR a.s., PLIVA-Lachema a.s., FARMAK a.s., SPOFA-DENTAL a.s., INFUSIA a.s.), only FARMAK a.s. remained so far without participation of foreign capital. All of this activity in regards to buyouts, mergers, acquisitions, partnerships, and capital investments demonstrates that the Czech pharmaceutical industry is solidifying its base and repositioning itself as it gears up and prepares for EU accession.

4.4. Expected Developments of FDI after the EU Entry

Due to the fact that the Czech pharmaceutical market is already stabilized, no giant changes in the influx of foreign direct investment are expected. After the EU entry, the Czech pharmaceutical market will be exposed to the same problems with which the other pharmaceutical companies in the EU and generally all over the world are and will be facing in the future:

- General slow-down in pharmaceutical industry depending on productivity of research and development.
- Expected patent expirations in 2000 – 2005 and increase of generic competition (which will be favorable for the Czech Republic in case that Czech companies will aim at producing of generics).
- Diminishing merger opportunities for pharmaceutical giants.
- Global slow-down in pharmaceutical industry plus reduction of European market share in favor of American companies.

One of the most significant factors influencing the FDI flows is the relatively low level of wages in the Czech Republic. However, the trend of the strengthening the CZK as well as the growing economy will cause fast wage increases. Therefore, this advantage of low wages is expected to slowly fade away in the future and the possibility of larger scales of foreign direct investments with them.

5. Labour Market Effect of the EU Accession

The Czech pharmaceutical industry has been one of the model industries for the Czech government and economy during its reform and privatization process due to its ability to maintain or reduce its overall number of employees while at the same time experience a 100% growth in revenue (refer to figure 2.1). This was and is mainly due to its early acceptance of EU regulation (1995), investments in advanced technologies, streamlining of operations, increased and better training of employees, and the capital and management know how which came with FDI. Despite this trend, labor productivity in the Czech Republic still does not compare to the EU and there are still needed reforms and room for improvements. Table 5.1 shows the number of employees as it developed through the course of 1997 - 2001 in the pharmaceutical sector (NACE 24.4) and in the chemical industry in general (NACE 24).

Table 5.1 - Number of employed persons, 1997 - 2001

Employees	1995	1996	1997	1998	1999	2000	2001*
NACE 24.4	6 019	6 705	6 948	6 887	6 487	6 525	6 554
NACE 24	-	-	49 067	48 562	47 502	43 535	41 401

Source: Czech Statistical Office, Ministry of Industry and Trade

* preliminary value

In general, as table 5.1 demonstrates, there is a strong trend of the reduction of labor in the chemical industry while the pharmaceutical sector has remained somewhat consistent. A believed leading contributor this trend - as it was described in the 3rd section of this report (effect of accession on foreign trade) - is the fact that the attention is being shifted from the production of 'heavy' chemical products to 'fine' ones with a higher added value. This shift in production to 'fine' chemical products has naturally led to increased job cuts in the chemical industry and job transferring to the pharmaceutical sector.

It is expected that the Czech pharmaceutical companies will continue to develop and explore new ways of increasing labor productivity before and also after the EU accession. In the pharmaceutical sector this exploration is usually geared towards production technologies which in of itself will lead to a reduction of labor after the accession to the EU as the Czech pharmaceutical company's strive to cut costs and improve efficiency in order to compete with their western counterparts. Table 5.2 shows the development of labor productivity in the pharmaceutical sector and in the chemical industry in general.

Table 5.2 - Labor productivity expressed as a value added (thousands of CZK per employee)

	1997	1998	1999	2000	2001*
NACE 24.4	671.7	622.7	734.9	879.9	928.1
NACE 24	498.8	537.5	525.8	698.7	726.2

Source: Czech Statistical Office, Ministry of Industry and Trade

* preliminary value

The numbers in table 5.2 show that the productivity of labor in the pharmaceutical sector (NACE 24.4) raised faster than general productivity of labor in chemical industry (NACE 24) and in comparison to other chemical sectors, labor productivity in pharmacy raised on the whole the fastest. The labor productivity is expected to rise even faster after the EU accession because of the ever-increasing competitiveness of the Czech pharmaceutical sector.

Below, table 5.3 indicates the share of personnel costs on the value added. It's important to note that the pharmaceutical sector is at a lower level in comparison to the general chemical industry. This is caused by the higher costs of labor in the pharmaceutical sector as well as the high value added by capital (mainly advanced technologies). Expectations are that with further increases of labor costs and share of capital this figure will be decreasing in the future.

Table 5.3 - Share of personnel costs on the value added

	1997	1998	1999	2000	2001*
NACE 24.4	0.324	0.375	0.377	0.350	0.365
NACE 24	0.390	0.403	0.432	0.368	0.384

Source: Czech Statistical Office, Ministry of Industry and Trade

* preliminary value

The following table 5.4 shows the personnel costs in the pharmaceutical sector in billions of CZK and the total personnel costs in the chemical industry. In section 1.2 (Features of the Czech Pharmaceutical Industry) it was stated that the pharmaceutical sector in the Czech Republic controlled in the year 2001, a 13% share of revenues of the total chemical production. In the same year, personnel costs in the pharmaceutical sector controlled over 18% of total personnel costs in the chemical industry (2.24 billion CZK out of 12.25 billion). These two correlated factors are results of the higher wages on average in the pharmaceutical sector.

Table 5.4 - Personnel costs in current prices, billions of CZK

	1997	1998	1999	2000	2001*
NACE 24.4	1.55	1.65	1.87	2.09	2.24
NACE 24	10.19	10.78	11.423	11.71	12.25

Source: Czech Statistical Office, Ministry of Industry and Trade

* preliminary value

5.1. Education and Skills

Before the fall of communism, the Czech Republic was regarded as a country with a highly educated and skilled labor market, but after the fall of communism the Czech Republic has seen its highly educated and skilled labor market decrease in comparison with the other countries of the former communist bloc. This is primarily due to the fact that after the fall of communism and with the subsequent privatization and deregulation the Czech government's interests were focused on industry banking, etc., and not education.

One of the initial attractions of Czech Republic for foreign investors was the high skilled labor force, but as stated above this advantage seems to have diminished over the course of the 90s and the pharmaceutical

companies have had to invest more time and money into training of personnel. Undoubtedly, the Czech Republic possesses a high number of technically educated people, but that education mostly applies to vocational schools where the level of technical training is not directed nor is it sufficient enough to match the needs of the Czech pharmaceutical sector. The Czech industrial sector - especially in the field of research and development - desperately misses university-educated people with high levels of language skills. Those people who do have both of the above mentioned skills, have left or are leaving the Czech republic to be adequately financially compensated and for a chance at greater career advancement abroad.

Unless the Czech pharmaceutical companies start to increase financial benefits for scientist, chemist, and doctors a new wave of 'brain drains' could be expected after the EU entry.

On the other hand, the current EU countries do not have to fear a vast invasion of the lower skilled Czech labor force because of the low level of language skills and the fact that among Czech population there exists a huge social aversion against moving for work even within the Czech Republic itself. The Czech Labor Office recently substantiated this fact by stating that a crucial factor for the high unemployment (exceeding 10%) is the reluctance of people to move for work. In summary, a large movement of population after the EU entry to the current EU countries appears to be inaccurate due to the societal and educational factors described above.

5.2. Conclusion

All indicators show that the long and generally accepted successful process of preparation toward EU accession within the pharmaceutical sector will mean a stable labor market. In order to be more competitive the labor productivity was steadily forced to increase and is expected to increase after EU accession. With regards to this fact, approximately the same amount of workers will be required and needed for covering the anticipated increased demand on pharmaceuticals after EU accession. Therefore, no major layoffs or hiring's are expected in the Czech pharmaceutical sector after accession.

Movement of labor from the Czech Republic after the accession is unlikely; with the exception of the few skilled workers with high education coupled with good language skills. Only, increased financial compensation will keep those workers in the Czech Republic. Therefore, increase in compensation for areas of scientific work after the EU entry is highly probable. Movement of labor into the Czech pharmaceutical labor market is doubtful because of the market saturation that already exists. Lastly, the increase of competition within the pharmaceutical domestic labor market is likely to occur after the EU entry, due to the layoff trends in the chemical industry and subsequent retraining for work in the pharmaceutical sector.

Table 5.5 - Labor Market SWOT Analysis

Strengths	Weaknesses
Skilled workforce	Aversion of workforce to move for work
Still a high level of university education	Labour productivity not yet reaching the EU average
Opportunities	Threats
Further increase of labour productivity	'Brain drain' from scientific sector and state paid universities and research institutes
Create advantageous environment for scientists	
Investment into education	

6. Effects on the Regulatory Framework

Before I begin this section of the report I feel that it is important to first emphasize that since 1995 the Czech pharmaceutical sector has been in harmonization with the majority of EU legislation in regards to medicaments, pharmaceuticals, and intellectual property rights (standard 20 years + 5 years with the Supplementary Patent Certificate in certain cases). Therefore, this section of the report will not focus on description of harmonized legislation but rather it will describe legislation that is and will cause some specific problems with the accession to the EU. In addition, I will give a brief and general overview of legislation that is affecting not only the Czech Republic, but also the entire EU.

6.1. Pharmaceutical Act

The most important legal document about medicaments is the Pharmaceutical Act (no.79 from the year 1997 which helped to solidify previous legislation) that is now being amended and awaiting further negotiations in Parliament. The main goal of the amendment is to ensure that all future legislation that is put into law by the EU is readily accepted without the need for further laws or amendments. They amendments are being established in coordination with the EU member states, European Agency for the Evaluation of Medicinal Products (EMA) and European Committee. The centralized procedure will provide scientific credibility and transparency for all member states.

The Pharmaceuticals Act currently includes 11 governmental notices; the most important of which is the notice defining the Good Manufacturing Practice (GMP). GMP tests are focused on technological proceedings in production, on the quality of a medicine, and on clinical studies and tests. GMP was accepted for the first time in 1995, and since then all Czech companies producing pharmaceuticals are required to meet GMP standards. Acceptation of the GMP standards highly increased production costs of pharmaceuticals in the Czech Republic and required high investments into production technologies. However, this step was very important for bringing the Czech products in harmonization to the EU markets.

6.2. Role of the State Institute for Drug Control

The State Institute for Drug Control (SUKL) is responsible for the complete registration procedure of new drugs. For this purpose, SUKL issues its own sets of legislation, which again are already fully harmonized with the EU standards. The registration process lasts 8 months (compared with Poland - 10 months, Slovakia - 7 months, Hungary 24 months).

The Czech republic's registration procedure meets both types of registration applying in the EU: 1) the *centralized procedure*, entered into force in April 2001 (effective especially for biotechnology and innovative medicinal products, applications submitted directly to the EMA- European Medicines Evaluation Agency). 2) *Mutual Recognition Procedure*, entered into force in June 2002 – decentralized procedure, used for majority of medicinal products, includes only a limited number of Member States in the procedure.

On the day of the accession of the Czech Republic to the EU all Czech products registered in the EU will become valid in the European pharmaceutical market and they will be ready to be traded without further requirements on registration. At the same time, foreign products registered in the EU will become valid in the Czech Republic.

6.2.1. Mutual Recognition Procedure (MRP)

MRP is one of the most significant measures accepted by SUKL, which will provide Czech products with easier access to western markets and secure the quality for consumers of pharmaceuticals. In addition, it means that most of the pharmaceutical products (both original and generic) registered in more than one EU state (including the EU candidates) will have to go through this procedure to enter simultaneously into all EU markets.

For the Czech Republic, the acceptance of the MRP means that the number of required registrations will be reduced and the process of registration will be accelerated (there are strictly defined time limits for the procedure). This is due to the fact that other EU countries will no longer have to register their product in the Czech Republic thus reducing the number of overall registrations and the amount of needed regulatory oversight. Therefore, the State Institute for Drug Control, which is now responsible for registrations of all new products, will be able to focus on rare cases of small Czech companies producing pharmaceuticals exclusively for the Czech market.

6.2.2. Problems caused by early acceptance of MRP

However, one significant problem that has emerged for some of the Czech pharmaceutical producers in connection with the MRP is that the registration requirement became mandatory for all new products since 1997, which means that all products that had entered the market prior to 1997 are not registered with MRP.

In the 1997, the government of the Czech Republic accepted without objection all regulatory requirements (while Hungary and Poland asked for delays). One of the outcomes of this categorical acceptance is that starting 30 June 2003, *all* of the pharmaceutical products on the market will be forced to acquire necessary documentation, even those, which have been on the market already for a long period and with which the positive effects on health has been undoubtedly proven. Pharmaceutical companies which produce some of these affected products are now facing complicated decisions whether to invest vast amounts of money to acquire necessary MRP tests even for the cheap medicaments purchased on the Czech market and increase their price significantly, or to leave the market all together.

The problem seems to be even more extreme than the EU anticipated and in a recent attempt to mend the situation they have accepted the possibility of automatic re-registration for the candidate countries. The principle of the 'well established use' will be applied for pharmaceuticals that are already on the market longer than 10 years.

The problem also concerns foreign distributors (e.g., there are products on the Czech market which are manufactured in India and do not have relevant documentation), who will probably also disappear from the Czech pharmaceutical market. On the other hand, strict requirements of relevant documentation will bring security to consumers of pharmaceuticals and will help to break down the trade barriers.

6.2.3. Parallel import

In the framework of the most important purpose of existence of the EU, which is the allowing of the free trade, there exists a principle within the EU called 'parallel import.' Specifically, parallel import in the pharmaceutical sector means that the purchase of medicines at low prices in one country and their subsequent resale at higher

prices in another country after repacking and re-labeling (the costs of repacking are still lower than the profit created by selling a medicine in a different country for higher price).

Allowing of parallel import is being sharply criticized especially by the European Federation of Pharmaceutical Industries and Associations (EFPIA) stating that, “prices in the pharmaceutical sector are largely determined by national governments based on public policy considerations. They do not reflect the normal interaction of supply and demand. The desire to create a single market for nationally price-controlled pharmaceuticals in Europe through the encouragement of parallel trade is unrealistic and damaging as it creates a significant loss to the research-driven pharmaceutical industry”.

Nevertheless, the European Commission did not accept stated complaints and the parallel imports are still in force. In the Czech Republic this measure was not yet used and will enter into force after the EU accession. Since the prices of pharmaceuticals are still lower than in the EU countries, parallel trade may become an important issue, which can lead to the shift of a certain amount of supplies anticipated for the Czech market to another country in the EU. Furthermore, it may cause a disturbance of drug supply to Czech patients and the potential for confusion as a result of re-labeling.

According to Jean-Francois Dehecq of the EFPIA, the other relevant legislative factors that affect not only the Czech Republic but also the entire EU are the following:

- In contrast with the US, the pharmaceutical industry in Europe remains confronted with a patchwork of pricing and reimbursement regulations.
- Outdated European legislation regulating information to patients. (Directive 92/28/EEC).
- Continuing attempts to erode intellectual property rights protection.
- The absent of an efficient and sustained industrial policy to foster and reward innovation.

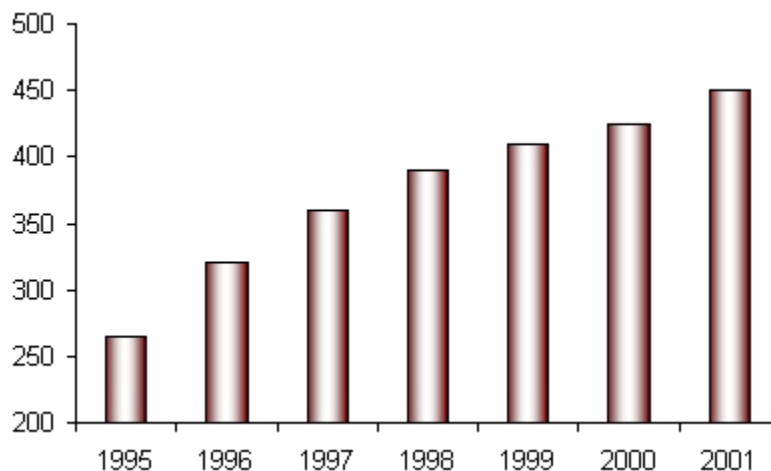
6.2.4. Regulation of drug advertising

The definition of advertising is of a crucial importance in regulation of drug advertising. For example, mere providing of informational data, answering questions of patients or doctors is not considered as an advertisement and the regulation does not apply for such action.

Absolute ban on advertising applies for medicinal products not registered or approved in the Czech Republic and on prescription drugs. Distributors may only advertise prescription drugs to medical workers; the advertisement must not be aimed directly at patients. It is prohibited to offer, promise or provide medical workers with presents or other benefits in order to increase the number of prescribed pharmaceuticals.

Advertisement on preparations fully or partially covered by health insurance is not prohibited. However, the advertising effort is mostly aimed at the over-the-counter medicines. Figure 6.1 shows development of expenditures on advertising of OTC medicines.

Figure 6.1: Development of expenditures on advertising of OTC medicines in the Czech Republic



Source: Advertisement Council, 2002

6.2.5 Regulation of price

Maximum price regulation applies almost for all pharmaceuticals purchased in the Czech Republic. Domestic products are being regulated by the “cost method”; maximum price for imported products derives from the market situation and calculates by the “supply method”. Fully covered drugs prevail on the Czech pharmaceutical market; the share of uncovered drugs is being minimized. Patients’ participation is minimal and rises very slowly.

6.2.6 Reimbursement of pharmaceuticals in the Czech Republic

The Public Health Insurance Act from the year 1997 does not distinguish between OTCs and prescription drugs. There is total of 521 groups of “active ingredients” and in each of them there must be at least one, which is fully reimbursed from the health insurance. This results into a situation, when many of OTCs are fully reimbursed.

Regulation of reimbursements is in the competence of the Health Ministry and it is based on proposals of a Categorization Committee. In the year 2001 there were approximately 7000 medicaments on the Czech market out of which 3250 were reimbursed fully and 2100 partly.

7. Effect of Accession on the Market Structures

The Czech pharmaceutical market has been a very dynamic and expanding market since the fall of communism and the subsequent, privatization, deregulation, and heavy influence of FDI. In addition, this time frame in the market has been characterized with changes, mergers, buyouts, partnerships, and acquisitions and it's expected to continue as the market matures and strengthens itself. The Czech pharmaceutical market consist of 10.2 million potential consumers with an expected growth rate of 7% (refer to figure 2.1) and sales revenue experiencing a 100% growth (refer to table 1.3) in the last 10 years. These figures demonstrate a very successful market but caution should be taken as the market is still developing and will be facing another daunting hurdle as it nears EU accession.

7.1. Present Market Structure

The Czech pharmaceutical market consists of one big market player controlling approximately 12% (Léčiva a.s) of the market, while five others each have a market share higher than 3%. The remainder of the market is filled and shared with many smaller players (see table 7.1).

Each of the market players usually offer a minimum of 4-5 products treating a similar scope of diseases (e.g., the company Schering-Plough, which controls 2% of the market, specializes in sales of pharmaceuticals treating allergic and dermatologic diseases and it's top selling products are Leucomax, Remicade and Avonex). Due to the small size of the Czech market (only 10 million consumers) there are usually no regional differences between the distributions of certain drugs and pharmaceutical companies seek to cover the entire Czech market.

Table 7.1 - Overview of Leading Pharmaceutical Companies

Company name	Ownership	Market share	Best sellers
Leciva a.s.	US owned Czech company	11.7%	Insulin, Ibalgin, Paralen, Celaskon
Slovakofarma	Slovak	5.7%	Acylpyrin, Bronchosan
Aventis	French/German	4.5%	
Novartis	Swiss	3.8%	
GlaxoSmithKline	U.K.	3.3%	
Bristol-Myers Squibb	U.S.	3.1%	Taxol, Lipostat
Sanofi Synthelabo	French	2.9%	
Merck Sharp & Dohme Idea	U.S.	2.7%	Zocor/Mevacor Fosamax, Singulair
Abbot Laboratories/Knoll	U.S.	2.5%	Klacid, Reductil/Meridia
Pfizer	U.S.	2.1%	Lipitor, Viagra
Schering Plough	U.S.	2%	Claritine, Avonex
Ivax	U.S. owned Czech company	1.9%	Cyclosporin, Silymarin
Aliachem	Czech	unavailable	Carciferol, Benzocain
Infusia	Czech	unavailable	Insuline, Aprotinine
Biopharm	Czech	unavailable	Livacox

Source: CEEBIC (Central and Eastern Europe Business Information Center), September 2001

The share of Czech producers on the domestic market fell from the original 45% in 1989 down to 20% in 2000 of all the financial volume spent on medicaments in 2000. However, according to the number of packages, the Czech producers still controlled a share of approximately 40 % in comparison to 55% in 1989. It is obvious, that the domestic pharmaceutical industry is capable of securing a significant part of the basic medicine consumption.

7.1.1. Anticipated market change

Through out the year 2002 the largest acquisition on the Czech pharmaceutical market was being prepared. According to a contract signed on 20 January 2003, the U.S. company Warburg Pincus LCC, which owns the biggest Czech pharmaceutical company Leciva a.s since 1998, will gain a major share in the Slovak company Slovakofarma. The acquisition will create the biggest pharmaceutical subject in the Czech and Slovak market, but the group will also became one of the top 5 pharmaceutical companies in central and Eastern Europe.

For the Czech Republic the acquisition would mean that a subject controlling approximately 17% of the Czech pharmaceutical market would emerge. It is questionable though, whether both the Czech and Slovak Anti-monopoly offices will allow such major market change.

7.2. Market size

According to AESGP national association, the size of the Czech Republic's pharmaceutical market in the year 2001 reached the value of 30.3 billion CZK which equals 889.5 million euro, and the market is expected to grow of 7% each year (see Figure 2.1) within the years 1999 - 2004.

The source of further growth of the market will come from the aging population, increasing wages of the Czech population, and a mounting societal change to a healthier from of lifestyle. These changes will be reflected in an increased demand on preventive pharmaceuticals, and OTC medicines (over the counter medicine). Specifically, the demand for OTC medicines is expected to increase after the EU entry as the total investment of health care per Czech family (1.79% in 2000) rises and becomes more comparable with that of the EU average. This investment will also be affected by the Health Ministry's campaign to increase the share that each family spends on health care thus reducing the total amount of government expenditures.

7.3. Conclusion

After the fall of communism, the Czech pharmaceutical market went successfully through the process of privatization and liberalization. In the course of 90s, many foreign companies entered the Czech pharmaceutical market, gained a solid position there and at the present time, the shares of different companies on the market seem to be stabilized.

Therefore, the structure of the Czech pharmaceutical market is not expected to be particularly influenced by the EU entry. All possible future changes (pre- and after the EU accession) in the distribution of the market shares are expected to happen already in accordance with the general trends within the European and world pharmaceutical industry.

8. Short Term Policy Measures

EU accession can represent a very significant challenge for policy makers and corporations alike. There are several measures that can be taken by both the government and by corporations within the pharmaceutical sector that can ease the accession process and help to ensure that the Czech pharmaceutical sector maintains its growth and market share. The government is capable of the following actions in order to enhance the adjustment capacity of the pharmaceutical sector:

- Health Ministry should attempt to free up the debt in the hospitals that is owed to pharmaceutical companies so they can use the money in order to maintain and increase their competitiveness.
- The government could increase tax cuts and incentives in order to increase exports and reduce the trade deficit.
- The government sponsorship of research and development grants within the pharmaceutical sector would help to ensure continuous and innovate drugs by Czech producers.
- The government can increase tax cuts for companies providing training and as well they can make available additional funding for training and educational programs in regards to the pharmaceutical sector in order to increase labor productivity.
- Continued reform of the Czech health care system is needed in order to reduce waste and redundant costs.
- Continue current FDI incentives in order to maintain the positive trend of FDI on the Czech pharmaceutical market.
- Freeing of the domestic housing market would help to encourage people to move in order to find employment.
- The increase of minimum wage would help to raise the overall wages in the pharmaceutical sector; thus helping to prevent an anticipated 'brain drain.'
- Sponsorship or funding of the costly MRP registration would help to ensure all products currently on the Czech market would be maintained.

Corporations within the pharmaceutical sector can take the following measures in order to ease the accession process and to ensure that their companies maintain their growth, market share, and competitiveness:

- Seeks ways to expand their foreign markets in order to reduce the trade deficit and to increase their capital inputs.
- Companies can streamline operations and update their technologies so they will be more attractive for increased FDI.
- Increase wages and benefits to prevent the 'brain drain.'
- Boost training and education in order to increase overall labor productivity.

- Companies can start to invest and register for the MRP immediately so to eliminate future problems and costs.
- Protect domestic market share by increasing brand image and awareness.

9. Conclusion

As this report attempted to demonstrate, there are very little changes expected in the Czech pharmaceutical industry in connection to the expected EU entry. Growth of the pharmaceutical sector is expected to remain at the same level (approximately 7%) with very little influence coming from EU entry. Possible effect of the growing trade deficit expressed by increased entry of foreign products on the Czech pharmaceutical market could lead to rising prices. The Czech companies have a big opportunity to retain their present market share and lessen the trade deficit by broadening their promotion activities, increasing their investments into research and development, and human resources.

Since the foreign capital is already present in most of the Czech pharmaceutical companies, very little influx of FDI directly connected with the EU entry is expected after the accession. In the short-term, movement of the production of pharmaceuticals might occur after the EU entry, but only for a short time as wages remain lower in the Czech Republic than the rest of the EU.

Labour market after the EU accession will continue to increase labor productivity that will cover the growth of demand; while at the same time wages are expected to grow. In the long-term, the pharmaceutical market will experience reduction of labor force after the demand stops to grow and technology increases.

Since the legislation for the pharmaceutical industry is already fully harmonized with the EU standards no effects of accession are expected which would concern the regulatory framework. The measures included in the legislation have previously caused increased costs in the past (acceptance of GMP in 1995). A few legislative measures are going to cause difficulties before the EU accession (costly MRP for all medicaments required from June 2003, some of which might leave the market). Certain measures will enter into force by the day of the EU entry (parallel import). However, all of the named measures are already incorporated in the legislation and are firmly defined. Only changes expected in the regulatory framework in the future are those newly accepted by the EU and therefore valid for the Czech Republic as well.

The structure of the Czech pharmaceutical market is already stabilized and possible changes will happen in accordance with the world changes. With increased investment into promotional activities the Czech pharmaceutical companies are likely to retain their market share, because their production cost will still be less expensive than most foreign manufactures. Some of the products, Czech as well as foreign, might leave the market due to their need to register, but the number of such products and their market share is not predictable.

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