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THE EXPECTED EFFECTS OF EU ACCESSION ON THE PHARMACEUTICAL INDUSTRIES IN THE VISEGRÁD COUNTRIES

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1. Introduction

One industry that is certain to be affected by the accession to the EU is the pharmaceutical industry due to its complex market and economic makeup and stringent government regulations. This paper1 summarizes the main findings of the four country (Czech Republic, Hungary, Poland, Slovakia) studies, concentrating on the common trends that characterize the four accession countries.

2. Health systems

After the beginning of economic transition one problem faced by policy makers was how to transform healthcare system from centralized, state-run ones to mixed, private-public partnership public health sector. The main problem of healthcare systems is not the insufficient net of health services, but on the contrary that it is oversized and outdated. This results in useless and unneeded healthcare services and in many cases worthless drug prescription.

It is observable that the healthcare systems, health insurance systems and associative legislation have gone through necessary changes. Nevertheless, in each country there are similar problems that need to be solved urgently.

3. Drug consumption

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

- Aging of population (birth rate is decreasing and life expectancy is 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.

[1] Summary of the Studies of the Pharmaceuticals Industry Section, AMCHAM-ICEG Conference on the Expected Effects of the EU Accession on the Visegrád Countries, March 20-21, 2003, Budapest

Total (public and private) healthcare expenditure in Hungary is still low, not just compared to the average per capita figure of the EU, but compared to a few CEE countries, such as the Czech Republic or Slovenia. Hungary spends around 6.8% of its GDP on healthcare (calculated on Purchasing Price Parity), vs. 7.2% of the Czech Republic, 8.5% of the EU and 13.0% of the US. However, more than 26% of the healthcare expenditures is spent on drugs, which is significantly higher than the average 15.5% of the EU.

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). 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).

However, the fact that CEE countries have not yet reached the average expenditures on health in the EU countries, does not necessarily mean that there is a worse state of health in the population of CR in comparison with the population in the EU.

4. Pharmaceutical industry

Pharmaceutical industry in the four candidate countries can be described as a sector with high level of basic raw material manufacturing, high value-added, need for demanding technologies and highly qualified labour force, high demand on investments and continuous renovation and high profits.

According to the IMS HEALTH Pharma Prognosis for Central and Eastern European countries, the growth of pharmaceutical market in the Czech Republic is the slowest with an expected growth rate of 7%, in comparison to the other listed Central and Eastern European markets. Slovakia has the largest opportunities in this occasion due to its special market character. Hungary and Poland stay in the middle of the list with approximately 12% and 13%.

5. Market structures

The CEE pharmaceutical markets have been very dynamic and expanding markets since the fall of communism and the subsequent privatization, deregulation and FDI. In addition, this time frame in the market has been characterized with changes, mergers, buyouts, partnerships and acquisitions and it is expected to continue as the market matures and strengthens itself.

The Czech pharmaceutical market consists of one big market player controlling approximately 12% (Léčiva - US) of the market, while five others (Slovakofarma -

Slovakia, Aventis – French/German, Novartis – Swiss, GlacoSmithKline – UK, BristolMyers - US) have a market share higher than 3% each. The remainder of the market is filled with and shared among many smaller players.

In Hungary we can observe that the Richter Gedeon statehold company leads the sector with his 9% market share. Close beside Richter exist subsidiary companies with foreign involvement, like Egis, Novartis, Sanofi-Synthelabo, Teva. Hungary is proved to be the most liberalized and opened economy in this case. In addition, the Hungarian government means to convert into cash the state's majority share in Richter.

Therefore the structure of the pharmaceutical markets in these countries 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.

In the medicaments production sector in Poland (the most important market for EU) there are 66 enterprises employing above 49 persons. The leading producers are 15 plants of the former POLFA Holding. Smaller manufacturers operating in the sector are specialized, primarily in production of OTC medicaments.

Over the last couple of years the competition among domestic manufacturers of pharmaceuticals have intensified sharply. Substantial changes on the Polish pharmaceutical market are to be expected in the nearest future. First, consolidation of pharmaceutical wholesale warehouses will continue, as their number is currently too high compared to European standards. Second, Poland's EU accession will speed up that process: Poland's entry into the structures of the Single European Market will contribute to growing interest of major European distributors in the Polish pharmaceutical market. The presence of foreign investors in the medicaments distribution sector has been only marginal so far.

On the market of pharmacies no radical change can be expected in the nearest future. Recently, the number of pharmacies in Poland has increased sharply as a result of controversial regulations provided by the new Pharmaceutical Law. Under its provisions, only pharmacists are now authorised to open pharmacies. This resulted in an avalanche of applications for permits to run pharmacies, filed by persons wanting to start up a business before the new provisions enter into force.

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

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

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

6. OTC

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 in healthcare per family rises and becomes more comparable with that of the EU average.

There exist countries like Hungary, where prices of OTC products are freely set up, therefore OTCs are not reimbursed unless they are included in the special list of drugs, which are available free of charge for low-income groups. OTC products are allowed to be sold by licensed pharmacies only.

The main products in this category are vitamins, food supplementary products, baby-care and nutrition and medical nutrition etc.

In Slovakia these products are partially or fully reimbursed by health insurance companies. In addition OTC preparations are subject to the regime of maximum prices, also in the majority of EU countries their prices are liberalized.

EU accession is to bring a remarkable growth of OTC market share in total pharmaceutical market due to further liberalization of this market segment and the accelerating consumption of preventive and health retentive products.

7. Employment, labour market

Experts believe the EU accession would have marginal impact on the employment in the CEE pharmaceutical sector. The transitional layoffs in the production and the administration have been done. Continuous strengthening of nominal exchange rates (especially in Hungary and Czech Republic) set back the competitiveness of pharmaceutical companies, which forced further cost rationalization through new layoffs. The coming EU accession will certainly put pressure on the companies to rise

wages. This could lead to new wave of layoffs in the pharmaceutical sector, as well. However, we expect only a moderate decrease in the employment, as the labour-capital switch is rather limited.

Job losses can be expected in the coming years in the distribution sector, especially as regards wholesale distribution. Integration will speed up consolidation processes in that segment of the sector, which will surely contribute to restructuring of employment. The entry of foreign investors into the wholesale market pharmaceuticals should also improve the efficiency of operation of domestic firms, this way allowing to cut employment.

The continuously growing number of pharmaceutical companies, the growing number of products and overall, the growing size of CEE pharmaceutical market could partly compensate for the fall in the number of the administrative staff. The lower wages and the supply of well-qualified chemical, medical, biological and clinical professionals could allure MNCs to establish research affiliates in V4 countries.

One of the initial attractions of CEE countries for foreign investors was the high-skilled labour force, but this advantage seems to have diminished. The pharmaceutical companies have had to invest more time and money into training of personnel.

In the field of research and development the main problem is the absence of university educated people with high level of language skills. Those people who do have both of the above mentioned skills have left or are leaving the domestic market to be adequately compensated financially and for a chance of a greater career advancement abroad.

Unless pharmaceutical companies in the region 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 labour force because of the low level of language skills and the 7-year transition period for labour movement. Austria and Germany fearing a massive labour force migration from the East won a transitional arrangement. The arrangement protects the labour 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 labour market just after enlargement.

Overall, we expect the fall in the employment to slow down gradually in the next two years, and start growing thereafter.

8. Foreign Direct Investment

Foreign direct investment was significant in mid 90s when most pharmaceutical companies were privatized in the region. The inflow of foreign investment to the pharmaceutical sector is involved in the process of ownership transformations taking place there. A major part of large privatisation schemes has been completed with involvement of foreign investors.

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

Although there are still insufficient sources invested into research and development of pharmaceuticals in comparison with the current EU countries, the present foreign investments has lead to obvious favorable trends. They include 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.
The major reasons why foreign companies entered these markets 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.
- Progress in legislation towards harmonization with the EU standards, liberalization of international business relations with the CEFTA and EU countries.
- Well developing domestic supply base.
- Investment incentives and other business support measures which emerged in a large scale.

EU accession may contribute to a rise in foreign investors' interest in the pharmaceutical sectors of the region. First, this is indicted by good development prospects of CEE market. Such a big and fast-growing market guarantees interest on the part of foreign investors. Second, accession to the European Union will diminish investment risk associated with capital repatriation from these countries. Third, EU accession may contribute to an intensified interest of foreign investors in the pharmaceuticals distributions market.

9. Trade balance

The trade deficit of the region's pharmaceutical sector continuously widened during the 90s. CEE states are net importers of medicaments as well as pharmaceutical and medicinal products. The main reasons were the booming import driven by the spread of the relatively new innovative drugs on these markets and the strengthening currencies of CEE countries with weak USD.

In the future the deficits will stagnate or decrease in 2004 and 2005 because of the following reasons:

- Further strengthening of the currencies seems to be limited. This could stop further decrease of the competitiveness of the export.
- Growth of main export markets (Russia, CEE countries, Baltic countries)

We see the current trend of the CEE pharmaceutical markets (viz the change in the consumption structure in favour of the new original drugs) to continue in the next couple of years. EU accession could strengthen this trend with the acceleration of the mutual recognition and the more transparent regulation of the reimbursement system. These could lead to a further increase in the share of the import drugs on these pharmaceutical markets.

The commodity composition of CEE trade in pharmaceuticals is different for exports and imports. CEE imports medicaments and pharmaceutical products mostly from advanced economies. France, Germany,. Switzerland, the United Kingdom, the Netherlands, USA and Italy.

At the same time, Russia, CEE countries and EU are importers of medicaments, substances (which are dominating the export into developed economies such as the EU countries, USA or Japan), and final products (which are usually directed to the Central and Eastern European markets).

EU accession will speed up further modernisation of the pharmaceutical industry in CEE. That process will be partly enforced by intensification of competition in the sector.

Development of an own research base is one of the strategic goals of investment processes in V4's pharmaceutical sectors following the accession to the European Union. Producers of medicaments will be able to get involved in innovative processes in pharmaceutics on a larger scale than before.

This does not mean that accession to the European Union will transform the pharmaceutical sector from one dominated by generic firms into one dominated by innovative firms. On the other hand, in the future it can be expected that, as is the case in the world with such firms, producers of generic medicaments will be engaged

more actively than before in such areas as new technologies of synthesis of known medicinal substances and new technologies of classical and improved forms of medicaments.

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

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

Higher competitiveness will give rise to new trends in international trade. A gradual improvement of the balance of trade in pharmaceuticals can be expected, mostly as a consequence of a rise in exports. Better quality of the domestic offer should also render the replacement of a part of currently imported medicaments with inland produced ones.

Accession to the European Union means not only a gradual increase in exporting capacities of the pharmaceutical industry, but also changes in the geographical composition of international trade. Although the countries of Central and Eastern Europe still remain the largest importers for each other, their share clearly declined in the second half of the 1990s. At the same time, the share of the European Union in exports of these products has been growing.

EU accession is to intensify the above phenomenon, and in several years' time the European Union is likely to become the largest importer of CEE medicaments. This is a positive development for exporters of medicaments, as Western European markets provide opportunities to obtain high profits, and consolidation of position on those markets may ensure stable revenues for producers.

The competitiveness of producers of pharmaceuticals is largely determined by prices of their products. At present the prices for CEE medicaments are approximately four times lower than those of imported medicaments. Although that difference has diminished in recent years it still remains relevant.

Lower prices for domestic-produced medicaments result primarily from the fact that most of them are generic medicaments, which are usually much cheaper than a major proportion of innovative imported medicaments.

We can observe a gradual modification of production structure from 'heavy' chemical products to 'fine' outputs with higher value added and higher share of medium and high technologies. This trend means lowering the production of substances in favour of increased production of final forms. But 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 CEE pharmaceutical companies are - and have 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 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 is 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 that they could establish a solid brand awareness and image and keep and grow their market share after the EU accession.

A third market on which CEE 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 with the above stated markets.

10. Legislation

HUNGARY

Act 25 of 1998, which came into force on 1 January 1999, concerns medicines for human use and specifies the basic measures governing medicines, their supply and the rights of medicine consumers. The Act takes into consideration international legal regulations including EU legislation. With the Act and other regulations, Hungary practically accepted the EU legislation and regulation practice. For instance, all the GLP (Good Laboratory Practice), GMP (Good Manufacturing Practice) and GCP (Good Clinical Practice) standards have already been inserted to the Hungarian law.

Intellectual property standards and enforcement are similar to the ones existing in the EU and compatible with the provisions of GATT/TRIP (Trade Related Intellectual Property). This includes a twenty-year term for product patents plus up to five years Supplementary Protection Certificate (SPC), as well as effective data protection and adequate means of enforcement.

The reimbursement policy in Hungary came into force in February 1995. This reimbursement system applies to all Hungarian citizens. The price of pharmaceutical products is set freely by companies in the Hungarian market. (87/1990 Act on setting prices) The wholesale and retail margin on pharmaceutical products is maximized by the Ministry of Health, which means that in practice the ex-manufacturer price can be set freely.

However, the ex-manufacturer price of products at which they are reimbursed by the social security system (social health insurance) is subject to negotiation between the pricing and reimbursement committee, formed by experts of National Health Fund, Ministry of Finance and manufacturers prior to the marketing of the reimbursed product. Changes in reimbursed prices, initiated by manufacturers, must be approved by the committee. For non-reimbursed medicines, the Ministry of Health is informed of price changes by either the manufacturer or the importer, and the price is published on a quarterly basis in the Official Gazette.

POLAND

The basic legal acts adjusting the Polish legislation relating to the pharmaceutical sector to EU regulations were adopted in 2001. The adoption of these solutions provides opportunities for more effective operation of Polish pharmaceutical firms under conditions of a single European market.

The Pharmaceutical Law of September 6, 2001 introduces radical changes into pharmaceutical legislation and provides a number of new solutions. The scope of the new law covers such areas as bringing new medicaments into circulation,

manufacture of medicinal products and their advertising, as well as operation of pharmaceutical wholesale warehouses and pharmacies.

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

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

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

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

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

Summing up, it should be stated that Polish law has been fully aligned with EU regulations relating to the pharmaceutical sector.

CZECH REPUBLIC

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.

The most important legal document on medicaments is the Pharmaceutical Act (no.79 from the year 1997) that is now being amended and awaiting further negotiations in the Parliament. The amendments are being established in coordination with the EU member states, European Agency for the Evaluation of Medicinal Products (EMEA) and European Committee.

The Pharmaceuticals Act currently includes 11 governmental notices, the most important of which is the notice defining the Good Manufacturing Practice (GMP). The State Institute for Drug Control (SUKL) is responsible for registration of new drugs. SUKL issues its own sets of legislation, which again is already fully harmonized with the EU standards through a system of centralized registration procedure.

On the day of the accession of the Czech Republic to the EU, in accordance with the MRP (mutual recognition procedure) all Czech products registered in the EU through the centralized procedure will become valid on the EU 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.

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. It means that most pharmaceutical products (both original and generic) will be registered in more than one EU states (including the EU candidates) will have to go through this procedure to enter simultaneously all EU markets.

SLOVAKIA

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 organization of the healthcare system itself. 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.

All new drugs and medical appliances being launched on the Slovak market require official registration, a maximum price measure, with many of them also applying for full or partial reimbursement from health insurance companies. The entire procedure of drug registration is managed by the State Institute for Drug Control (SUKL). SUKL enables an applicant the 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.

The other key intervention by the state in the drugs market comes in the shape of price regulation together with drug categorization. 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.

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