

IMPACT OF THE CRISIS ON THE PHARMACEUTICAL MARKET IN THE CZECH REPUBLIC AND HUNGARY

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Abstract

The pharmaceutical industry is one of the industries being most influenced by political changes. It is an industry which can both help and - without strict regulations – can also harm people. “Big pharma”, as the biggest players on the pharmaceutical market are often named, is going through changes and it needs to react to the global economy demands, healthcare reforms, educated consumers and new diseases. Firms are preparing new, country-specific strategies and models to be able to take advantage of any new opportunities the given market should offer.

Key words: generic prescribing and substitution, healthcare, legislation, pharmaceutical industry

1. Introduction

Pharmaceutical industry is a frequent topic of the economic news in connection with the free health-care systems in particular countries and following concepts: prescription and substitution, new fees, non-transparent prices, changes of reimbursement, ethical issues and so on.

Most governments intervene in the market of pharmaceuticals in order to assure the quality, safety, efficacy of medicinal products and access to the needed care for all citizens (Davidova et al. 2008).

In January 2007 the European Union was expanded by another two members and therefore forced to harmonise the healthcare policy. Nevertheless, the area of pricing and reimbursement policies still remains

fragmented under sovereign national healthcare institutions and governments (Kazakov 2007).

In the 90's the Czech Republic and Hungary were leading countries for foreign direct investment in Central and Eastern Europe. Pharmaceutical, automotive, software and life science sectors were contributed by a high amount of capital investment. The availability of cost the effective skilled labour, high quality infrastructure and EU harmonious regulations were the main reasons for the fast growth of the Czech and Hungarian industries (GBI 1999-2013). The situation has now changed and firms are facing a significant decrease of profit because of the economic crisis.

The present paper has a comparative character and focuses on the Hungarian and Czech pharmaceutical markets, healthcare policies of the countries, reforms, new trends, products and ethical issues. The aim is to give overall information about the similarities and contrasts of the pharmaceutical sector in two countries with a similar historical background which are happening due to the economic crisis. In my paper I focus on the following research questions: Are the markets more similar or different? What are the new trends? What are the core laws that affect the pharmaceutical industry? Will these two countries maintain the good position?

The Czech pharmaceutical market

a) History

If we talk about pharmaceutical industry in the Czech Republic we need to mention the first 3 companies that actually built the sector. We are talking about Zentiva (formerly called Léčiva), Galena which was bought by SPOFA (United Pharmaceutical Establishment) and Lachema from Brno that was at the peak point in the 80's of the 20th century. All 3 companies were bought by a foreign investor (Dušek 2009).

SPOFA was established in 1946 because of the nationalization of manufacturers from Germany. The peak point was in the 80's and in the same time there were composed 13 companies among them we could find Zentiva and Galena. In this period SPOFA could produce 540 medicaments and 20 new ones every year. Due to the cooperation with communist countries SPOFA suffered a big loss. In the 1989-1990 SPOFA was partly denationalized and torso was denationalized in 1993. The torso became a public limited company. In 2008 the company was in liquidation (Rusek 2004).

During the 90's of the 20th century, the situation in the Czech market has changed due to privatization and the entrance of foreign investors. The Czech market was opened and foreign companies were coming in. Czech

companies did not have sufficient capital and technology to survive in the open market and therefore the majority were bought by foreign companies.

The Czech Republic is one of the most successful transition economies in terms of attracting foreign direct investment (FDI). The main focus has been on increased public funding for industrial research and a new set of incentives aiming at FDI attraction. The economic crisis slowed down the increase of FDI and therefore the pharmaceutical industry turned towards the generic substitution. In 2011, the inflow of FDI reached almost EUR 4000 mil. (CIG 2012) These investments mostly went to automotive industry but the pharmaceutical industry was on the 16th place in terms of FDI flows.

b) Market description

The Czech Republic had 10, 5 mil. inhabitants in 2012. The value of the Czech pharmaceutical market in 2011 reached CZK 58.724 billion (USD3.114 billion), as calculated on the basis of medicines delivered to pharmacies and other healthcare facilities, in ex-manufacturer prices (a pharmaceutical item is the amount equal to the amount of the weighted average disclosed price of the pharmaceutical item), according to the information presented by the Czech State Institute for Drug Control (SÚKL). The market value fell slightly in 2011 by 0, 21% compared to the previous year (SÚKL 2012).

In terms of volume, there was a 2.37% y/y reduction in the number of packages distributed to pharmacies and healthcare facilities in 2011, with the total reaching of 297.14 million. There was a rise of 10.85% in sales of prescription medicines to pharmacies and healthcare facilities in the fourth quarter of 2011, with the total value reaching CZK13.49 billion (IHS 2012).

Headline Expenditure Projections:

- Pharmaceuticals: CZK80.71bn (US\$4.56bn) in 2011 to CZK79.74bn (US\$4.26bn) in 2012; -1.2% in local currency terms and -6.7% in US dollar terms. Local currency forecast moderately revised upwards due to stronger reported growth in Q112.
- Healthcare: CZK298.26bn (US\$16.86bn) in 2011 to CZK299.85bn (US\$16.01bn) in 2012; +0.5% in local currency terms and -5.1% in US dollar terms.
- Medical Devices: CZK28.03bn (US\$1.59bn) in 2011 to CZK28.47bn (US\$1.52bn) in 2012; +1.6% in local currency terms and -4.1% in US dollar terms (FMR 2012).

The growth of drugs sales in the Czech Republic is higher for generic drugs by 13,8% in 2010. The generic industry in the Czech Republic has bigger potential due to the expiration of patents, governmental cost cutting, etc. The generic segment reached the level which helped the Czech Republic not be affected by the economic crisis (Menčík 2012).

On the other hand original companies like AstraZeneca, GlaxoSmith-Klein, Baxter, etc. were affected more and the first step was the cut of working places in the Czech Republic. There was a significant raise of unemployed people (EC 2012).

c) Legislation

a) Fees

In 2007 the Czech government introduced a number of fees to be newly paid by patients within the healthcare system: charging 30 CZK/visit, 30 CZK/prescription, 90 CZK/visit of medical emergency, and 60 CZK/day in hospital. The co-payment of patient was one of the reactions on economic recession in the Czech Republic. There was a strong public opposition against the fees, and some pharmacies decided not to charge the fees (Hall 2009).

b) Prices and margins

The Ministry of Finance sets the upper price-limits for pharmaceuticals and therefore prices may differ. OTC (over-the-counter) drugs are not a subject to the price regulation and this was the reason for sales decrease (Decree No 54/2008 Coll.).

The margins cannot exceed no matter how many distributors or pharmacies take part in the distribution of the product to the market and they are calculated for every single package of the product. The final consumer price consists of the ex-factory price (the price at the factory which does not include any other charges, such as the delivery or subsequent taxes, etc.) of the product, the real level of margins and VAT (currently 14% p.a.) (Law office Marečková 2012).

The introduction of reimbursement ceilings, blind bidding auctions and preferential prescribing are decreasing pharmaceutical companies' margins (FMR 2012).

c) Decision making

In the Czech Republic decisions about healthcare policies are made at the national or state level. The decision making is based on social solidarity. (Davidova et al., 2008).

d) Public health insurance

The government has set up the compulsory public insurance where patients are participating in the costs. From the 90's the Czech Republic has introduced free market model of healthcare expenditures whereas patients are participating (SÚKL 2008).

d) Ethics

Pharmaceutical companies have their own Codes of Ethics. At the national level, there exist the following Codes: Code of Ethics of The Czech Association of Pharmaceutical Companies (ČAFF) and Code of Conduct of The Association of Innovative Pharmaceutical Industry (AIFP).

e) Trend

After the economic crisis the pharmaceutical industry has not had an easy time. The cost-cutting was the main instrument for each government. This aimed at controlling the public health care spending. Price cuts, changes in co-payments and VAT rates on medicines, and promotion of generic medicines have been among the most frequent cost-containment measures in addition to the increased demands for the proof of value. The Czech Republic was one of the countries which were continuously reducing prices and modifying reimbursement rules. For the industry the economic crisis meant the change of the strategy, reduction of workplace and deeper cooperation with the government (Bolt 2012).

The Czech Republic has started to focus on generic drugs which will be continued in the future. The pharmaceutical sector is now occupied by generic medicaments by over 50% of the market in terms of value. The goal of the government is the reduction of drug expenses and promotion of the generic substitution. The industry has proposed help to achieve savings for the government which leads to competitive generic market and innovative medicines (Vogler et al. 2010).

As it was said, the industry is open to help in innovative medicines and therefore R&D has high potential because of well-equipped laboratories, professionals and high concentration of Universities. Some laboratories have achievements comparable to the leading European laboratories, mainly in immunology, rheumatology and medical chemistry. However, the biggest weakness of the Czech pharmaceutical market is getting the result to the stage where the international pharmaceutical industry becomes interested in. Therefore the number of patents is very low because the motivation of a researcher to apply for them is small. Thanks to international companies some new medicaments discovered and developed in the Czech laboratories have found their way to the market (Vaněček 2005).

The Czech pharmaceutical industry presented a new healthcare reform to restrict the entry of expensive healthcare into the market by imposing stringent regulatory rules. The Czech government plans to divert spending on expensive equipment and medicines and increase salaries of doctors (GBI 1999-2013).

In the past 10 years, and more after the economic crisis, the Czech pharmaceutical market has had to change significantly, from the aggressive style towards deep specialization, to less aggressive marketing and cooperation within industry. The companies slowly start to use sophisticated distribution channels, evaluate benefits of cooperation within industry, cooperate with other institutions, specialize in medication and treatments procedures, take the R&D to the virtual level, reinforce their activity in emerging markets, etc. (PWC 2011).

The Hungarian pharmaceutical market

a) History

Traditional industries in Hungary were the chemical and pharmaceutical ones that is why there have been established manufacturing companies that are working well. There were 3 big players at the beginning of the 20th century: Chinoin (owned by Sanofi Aventis), Egis (owned by French Servier group) and Richter Gedeon. Only Richter Gedeon has remained as a generic Hungarian flagship the rest were bought by foreign companies.

Hungary was a key supplier of pharmaceuticals to the former Soviet Union; the pharmaceutical industry is often described as one of the oldest drug industries in the region (Lickens et al. 2012). The Hungarian tradition in the chemical industry, the proximity of strong universities and research laboratories were strong factors in the decision of develop the R&D sector that could provide the talented workforce for companies (Lengyel et al. 2009).

Pharmaceutical production and export increased significantly in the 50's and 60's of the 20th century. Many license agreements with Western producers were signed in the 70's (Jablonski 2007).

Hungary was one of the leaders of the FDI in Central and Eastern Europe (CEE). The Pharmaceutical, automotive and development sectors have been receiving the highest amounts of capital investment. (Hungary 2006). In the first half of the 1990's, Hungary enjoyed the largest FDI inflows (initially in absolute terms but later only in per capita terms) of all the (former) transition economies. More recently, however, Hungary seems to have lost this position, with a decline in FDI inflows that started in 2002 and has continued since then (Sass 2004).

b) Market description

Between 2007 and 2010 the Hungarian authority took a different approach and included strong mechanism to control the volume not the price of the supply side. This move had significant warnings that could jeopardize the R&D pharmaceutical sector in Hungary. The consequence was the continuous

increase in the generic segment and fall in the innovative segment also the control of the volume caused the increase of expenditures by 25% (Hren 2013).

In 2012 Hungary had 9.96 mil. inhabitants. Hungary's population health indicators are among the worst in the CEE. The Hungarian pharmaceutical market value increased in 2011 to EUR 2.2 bn. annually, which was positive, but the total growth was 3.3%, which was less than in previous years. (PMR, 2012). Multinational companies would like to keep the companies in the Hungarian market but there is no room for growth (Lickens et al. 2012).

Headline Expenditure Projections:

- Pharmaceuticals: HUF691.61bn (US\$3.44bn) in 2011 to HUF643.50bn (US\$2.87bn) in 2012; -7.0% in local currency terms and -16.6% in US dollar terms.
- Healthcare: HUF 2,013bn (US\$10.01bn) in 2011 to HUF 2,003bn (US\$8.92bn) in 2012; -0.5% in local currency terms and -10.8% in US dollar terms.
- Medical devices: HUF117.09bn (US\$582mn) in 2011 to HUF117.95bn (US\$526mn) in 2012; +0.7% in local currency terms and -9.7% in US dollar terms (Espicom 2012).

The generic drug market increased by 12%, whereas the original market increased only by 10%. No significant increase of innovative medicines is expected (PMR 2011).

c) Legislation

a) Fees

There are no fees that patients need to pay in the public healthcare in Hungary. The reimbursement fees were decreased and the maximum total prescription fee per patient per annum of 16 667 HUF (55 EUR) was set (Peto et al. 2011).

b) Prices and margins

During 2007 and 2010 the first measure was introduced by a 12% statutory rebate/payback on reimbursed expenditures for branded and generic firms. In 2011 due to the financial crisis this rebate increased up to 20% for the duration of 3 years. This caused a high reduction of profit for pharmaceutical companies (Hren 2013).

The new wholesale and retail margins for reimbursed drugs entered into force in Hungary on 1st August 2012, under the amended Health Minister's Decree No. 5/2007, on the price margins of pharmaceuticals available with reimbursement. The maximum wholesale margin is 8% of the manufacturer price (previously 12%). With regard to retailers, the maximum margin is 27%, or HUF 990 (€3.6), up by 1% or HUF 140 (€ 0.5), in comparison with the prior provisions. (Kanavos et al. 2011).

c) Decision making

The Hungarian healthcare system is based on the compulsory national insurance model. (Gulácsi et al. 2002).

d) Public health insurance

The Hungarian government established an obligatory public health insurance which is financed by Health Insurance Fund Administration (HIF) and taxes (Borbás et al. 2011).

As a general rule, the Health Insurance Fund Administration finances the running costs from its separate budgets (Health Insurance Fund), whereas covering the capital costs are the duty of the owner of the health care institute, mainly the local governments. The fund consists of more than 20 sub-budgets according to the different types of services (general practitioners, out-patient care, acute and chronic in-patient care, etc.), and these sub-budgets are capped with a national budget ceiling (Boncz et al. 2004).

d) Ethics

In 2008 Hungary has created a new ethical code called: Code of Ethics for Pharmaceutical Communication.

e) Trend

Hungary is slowly becoming one of the most popular hot spots for pharmaceutical research in CEE but due to financial difficulties this trend has been frozen. Foreign-owned companies have intensive personal connections with universities; several researchers take part in higher education, academic life, etc. (Jablonski 2007).

Hungary also shows the friendly generic environment, having specific policies stimulating the prescription. That causes that during the recession it was not as influenced as the original environment was. Generic companies are still generating profit even with a high% of the rebate.

There is no place for exporters in the market and therefore local manufacturing companies are trying to move to other countries (CBI Market Survey 2010).

Political reforms between 2007 and 2010 in education causes outflow of professionals. Doctors, nurses, researchers are leaving the country because of very low salaries. The increase of wages in this sector is a necessity because the consequences have already been visible in many ways such as the decrease of health care quality, decrease of quality of skilled staff (Healy et al. 1997). The Ministry of Health starts a program in which residents can sign a contract and commit to stay at least 10 years in Hungary. The signature means that people will receive around EUR 350 a month extra, the monthly salary for doctor is EUR 400 per month (Lickens et al. 2012).

Due to the healthcare reform (Széll Kálmán plan) many structural transformations have started. The new law has effected pharmaceutical representatives, who provide the product information, more negatively because of the additional taxes. According to the data of GYEMSZI (Institute of Pharmaceutical Healthcare Quality and Organization Development) the number of sales representatives dropped from 2600 to 2100. This step was another decrease of the profit for the companies. In 2011 there was a double increase of the fee from 5 million HUF to 10 million HUF per annum (Kiss 2012).

The internet started to have a key role for Hungarian patients. The patients are constantly seeking for health-related information and therefore the new communication process on a basis of consultancy has been built among patients and doctors. More informed patients have higher expectations of the quality of healthcare, which results in the increase of the number of visits in the private sector of the healthcare system (Kiss 2012).

Due to the financial crisis the Hungarian government started to set very strict and mandatory rules which, in one hand, saved money to the government but, on the other hand, started to slow down the outflow of international pharmaceutical companies that do not generate profits. The fall of workplaces is as significant as the outflow of professionals.

Similarities and differences

Table 1: Similarities and differences of the Czech and Hungarian pharmaceutical market

Similarities	Differences
– Size of the pharmaceutical market – FDI income – Code of ethics – Specialization in generic business due to the substitution of law – Cooperation between the pharmaceutical industry and Universities – No room for other companies – Change of the business strategy	– Fees – Wages – the quality of health service – Healthcare reforms – the outflow of professionals, higher taxes for companies in Hungary – Deep specialization, less aggressive marketing, virtual R&D in the Czech republic – Internet consultation – “ePatient”

Source: Own work

Conclusion

In terms of pharmaceutical markets, many differences and similarities can be found between the Czech Republic and Hungary. Both markets are quite small but growing (slightly, though). Foreign direct investments for these two countries are very similar. The position for them in the region of Central Europe has been maintained because of the skilled workers, low salaries, R&D, etc. Legislation is very similar but in the Czech Republic the laws are stricter about advertisements, prescriptions and reimbursements. In Hungary the Szél Kálmán plan has changed the business strategy for many companies. It has become a difficult environment to operate in and maintain profits. The lack of cooperation between the government and companies caused the outflow of international companies in Hungary.

The background of science – universities and research laboratories – is making space for investment in the research and development. However, Hungary is contributed better by pharmaceutical FDI, whereas new devices and medicines are launched slowly. This is the reason for focusing on the generic segment of the pharmaceutical industry.

The traditional strength in building high-quality generic manufactures brought Richter Gedeon to the number one position among generic companies in Hungary. Due to different political attitudes, local companies could not be maintained on such a high level in the Czech Republic.

Due to low salaries, Hungary has been facing a severe ratio of emigrating medical experts. To rectify this, the government has taken some unpopular measures recently. Any graduate that enters an employment abroad after graduation is to pay back all the state-aided study fees. The generated antipathy will provoke even higher emigration, bringing pharmaceutical companies to grief; however, in terms of professional training the companies have always had good relations with experts, providing them with courses, seminars, etc.

The Czech market has started to develop new strategies of products specialization. While the pharmaceutical industry, based on original companies, has been stagnating, new medical technology has been emerging. In the last 4 years several new companies have been founded which are focused on the hematologic device development and manufacturing. On the contrary, in Hungary generic pharmaceutical industry has outstripped the medical device development.

The aim of the present paper is to provide the comparative review of the pharmaceutical industry in the 2 Visegrad countries after the financial crises. However, further studies are needed to see new trends in both countries.

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