The Economics of Pharmaceuticals in Central and Eastern Europe: A Focus on Generics, Research, and Development

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***Abstract*—**The cost of health care delivery continues to increase at alarming levels in the world. Public health departments, health institutions, government agencies, and other key health stakeholders continue to work towards controlling and minimizing costs of care while increasing access and quality. A major contributor driving the cost of health care is pharmaceutical expenditures among others such as technological advances and uncoordinated care. The following article reviews health economic considerations as they relate to health system capacity to provide efficient and low cost care. The authors focus on economic implications for the pharmaceutical industry in Central and Eastern Europe.

***Keywords*—**Economics, health care delivery, pharmaceuticals, markets

I. Introduction

HEALTH care services and products provide a significant portion of a country's Gross Domestic Product (GDP). The economics of health in a given country infuse many factors contributing to the public good such as workforce employment, medical supplies and device development, and the social good of health that improves productivity of citizens. The health care industry is complex in that business practices and financial sustainability of organizations is dependent on community health status, provision of care, scarce resources, a multi-disciplinary, diverse skilled and unskilled labor force, and patient satisfaction. According to the World Bank (2014), the percentage of GDP for several countries in Central and Eastern Europe is below.

	2010	2011	2012
Czech Republic	7.4	7.5	7.7
Hungary	8.0	7.9	7.8
Poland	7.0	6.8	6.7
Slovak Republic	9.0	7.9	7.8

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As part of the health care expenditures in a country contributing to rapid increases in cost are pharmaceuticals. According to the World Health Organization (2014) the global pharmaceuticals market is estimated at $300 billion dollars a year with anticipated increases to $400 billion in three years. Of this market, the ten largest drug companies control over a third of share with profit in many cases of thirty percent (World Health Organization, 2014). Herman (2014) identifies nine major factors that are impacting the health economic including:

- Physician, facility, and drug costs
- Expensive technologies and procedures
- Fragment and uncoordinated care
- Lack of cost consideration from patients
- Fee for service
- High administrative costs
- Unhealthy behaviors
- Expensive end of life care
- Provider consolidation

This paper focuses on the drug costs considerations as it relates to health care in CEE and reviews the role generics, research, and development has on the economy.

II. Healthcare Environment, Market Structure and Concentration in Europe and Central and Eastern Europe

Several multinational companies dominate the pharmaceutical industry. In 2012, 66% of the global pharmaceutical market was divided between the top 20 pharmaceutical firms (Evaluate Pharma, 2013). The biggest pharmaceutical companies play a crucial role in medicine innovations. For instance, a study conducted by Munos (2009) reveals that 50% of the new molecular entities introduced in the market since 1950 have been discovered by 21 companies which were all belonging to the top 15 pharmaceutical firms in 2008 (cited in: Kiriyama, 2011). The share of the top pharmaceutical groups

is expected to drop by one percentage point by 2018 mostly due to the competition from emerging countries (Evaluate Pharma, 2013; EFPIA, 2014 (a)). The European pharmaceutical industry is the 5th largest sector within the European Union accounting for 3.5% of the total EU manufacturing value. This sector is divided between two types of suppliers. The first one corresponds to the originators companies, which are active in R&D. The second type of suppliers corresponds to generic companies, which can produce and sell pharmaceuticals once the patent of these products is expired (EFPIA, 2014 (a)). The market for generic products is growing faster than the one for originators due to the expiry of many drug patents and the tightening of national health budget, which push governments to promote generics. Research and Development plays a crucial role in the pharmaceutical sector. In 2010, the pharmaceutical sector employed more than 113 000 highly specialized professionals in Research and Development activities (EFPIA, 2014(a)). The Pharmaceutical industry is also the sector, which has the biggest ratio of R&D expenditures to net sales (European Commission, 2011). In 2011, R&D expenditures accounted for 15.1% of net sales in the pharmaceutical sector compared to 9.1% for the software & computer services sector (EFPIA, 2013). Cost of new innovation is also very high and only few realized that without innovations there would be soon no generics. The cost of drug development represented respectively 149 and 344 millions of euros in 1975 and 1987, it amounted to 868 million of euros in 2000 (EFPIA, 2014(a)). Today, this cost is evaluated to more than one billion of euros. It takes on average between 10 to 13 years to launch a new drug on the market (EFPIA, 2013; EFPIA 2014 (a)). According to a report from the European Federation of Pharmaceutical Industries and Associations (2013, p. 6): "on average, only one to two of every 10,000 substances synthesized in laboratories will successfully pass all stages of development required to become a marketable medicine". It is a high risk business adventure with extremely high initial investment and very low probability of success.

Due to this phenomena and continual rising cost of drug development, the major pharmaceutical companies are under competitive pressures due to the expiry of the patents on their best-selling pharmaceutical products. Once a drug is coming off patent, competitors can sell cheaper generics composed of the same active ingredients than the drugs sold by originator companies, which considerably affect the profit of the latter. For instance, Pfizer was expected to lose around 10 billions of dollars of annual revenue due to the expiry of the patent on one of its top selling drug (atorvastatin) in 2011 (Wilson, 2011). A recent report also reveals that 230 billion of sales are threaten by patent expiries from 2013 till 2018 (Evaluate Pharma, 2013, EFPIA 2014 (a)). EU pharmaceutical industry is transforming its current business strategy in order to reduce its costs and to capture new markets, mainly overseas. Numerous Mergers and Acquisitions activities have enabled pharmaceutical firms to make economies of scale and to diversify their future drugs' patents portfolio (Blanc, 2014; EFPIA 2014 (a)). They also increasingly carry out clinical trials in Eastern European, Asia, and Latin America in order to reduce the costs of R&D. A study from Ernest and Young (2010) estimated that pharmaceutical companies outsource between 30% to 35% of their manufacturing activities and 25% to 35% of the clinical trials overseas (Kiriyama, 2011). For Europe, pharmaceuticals are a major source of competitive advantage and a key driver of future prosperity. The pharmaceutical industry has a higher trade balance than any other high-tech sector with an annual surplus of €80bn. Employment productivity is highest in the pharmaceutical sector. The sector outperforms all other leading industries in terms of both value added and turnover per employee. R&D industry invests around €30bn in R&D in Europe annually, making Europe an integral part of the life science eco-system and they directly employ around 700,000 people – many of whom are highly qualified scientists with the highest multipliers of indirect employment (EFPIA, 2014(b)). Maintaining health will be a major economic challenge for Europe in the coming decades. Smart investment in healthcare is definitely one way to maintain economic performance. Chronic diseases account for 75% (over €700bn) of Europe's healthcare bill and are responsible for up to a 7% GDP loss in some EU countries. Key risk factors for chronic diseases (age, adult obesity, urbanization rates) are all projected to increase. Early and effective use of medicines improves outcomes and reduces costs in the rest of the system. EU governments spend a far greater proportion of social expenditure on sickness and disability transfers than on unemployment transfers. As such, ill health is a far greater constraint on national economic budgets than unemployment. Societal changes – an ageing population and increasingly unhealthy lifestyles – present two key challenges for the future. An ageing population worsens dependency ratios and increases the prevalence of age-related disease (predicted two-fold increase in late-stage Alzheimer's to 7.5m by 2050), whilst demographic/life style changes will result in an increased incidence of cancer (400,000 new cases projected between 2010-2020) (EFPIA, 2014 (b)). Europe also needs to regain leadership in life sciences through focusing on an ambitious mission of tackling the challenge of chronic disease. Europe has 32% of the world's top 100 clinical and pharmaceutical academic institutions, compared with 56% in the US and 12% in the rest of the world. Europe should aspire to improve this performance. A new generation of public-private partnerships focused on a mission of improving the quality and efficiency of health outcomes in chronic disease could yield multiple benefits in terms of: providing a new focus for mission-oriented science; helping improve the financial sustainability of health systems through making the biggest cost driver more efficient and improving the attractiveness of Europe as a location for further private sector investment (EFPIA, 2014 (b)).

The challenges facing CEE can be categorized in three categories: financial crisis, economic crisis, and sovereign debts crisis (EFPIA: CEE TF. Brussel, 2011). The implications for patients as a result are several. Europe's perspective on healthcare risks is changing. Health outcomes become increasingly irrelevant in the face of budgetary pressure. International organizations, ie. Organization for

Economic Co-operation and Development, have become much more influential in decision making around healthcare, but focusing narrowly on reducing spending. These considerations often do not take into account the potential harmful effects of these cuts to patients. Stronger cooperation among national health authorities within Europe and higher risk of spillover effects from one country to another, or from one country to the European level, of policies that damage patients access to innovative treatments and increase health inequalities. Within this healthcare environment, opportunities tied to demographic changes are displayed. From 2007 to 2050, the European average age is projected to increase from 38.9 years of age to 47.3 years of age with those over 65 years of age increasing from 16 % of the population to 28 % of the population complimented by an increased life expectancy from 76 years to 82 years (BIPD, 2008).

Two major dilemma exists within the healthcare environment. The first, healthcare as a strategic investment for the future has been an ongoing debate in particular as it related to the demographic changes. The intention to improve healthcare delivery in order to maintain a health labor force in growing economies is critical. This has been a high priority in all political decisions. The second, to consider healthcare as a "consumption" item during the budgeting process and reduce spending. Cost often becomes a more important factor than better health outcomes.

III. ECONOMIC AND MARKET DYNAMICS

The economic evolution and market varies from CEE countries. According to IMF (2011), the crisis had differential impact with slow decline in 2012 with the exception of Slovakia of 3.3% of GDP at constant prices. Both Hungary 1.8% to 1.7% and Poland 3.8% to 2.9% saw decreases in GDP growth at constant prices. It is important to note the 2009 health significant losses of GDP growth for Slovakia and Hungary, while Poland showed positive growth of 1.6% (IMF, 2011). The annual growth rate in 2010 for Slovakia and Poland were less 2010 compared to 2008, while Czech had no variance, and Hungary saw slight increases.

The CEE market overview for pharmaceutical innovative market value evolution realized steady increases from 2009 ($9.49 billion USD) to 2013 ($11.70 billion USD). Generic market value evolution also saw increases from 2009 ($10 billion USD) to 2013 ($13.1 billion USD). The rate of increase in generic market value over the innovative market was significant over this period of time.

In the Czech Republic, temporary reimbursement for highly innovative medicines was present. Electronic auction utilizing transparent methodology and procedures was emphasized. The Czech Republic referenced the "Pharmo-economics Regiser" to support accountability and transparency. In 2010, a market-wide 7% cut in drug prices and reimbursement reductions were in effect (Stefancyn, M. et al, 2011). The authors further reported the generic drug market developed as a rate or around 12% in 2010 and developed at a slower rate between 6-8% from 2011-2013. The growth rate of the innovative medicine market to slow around 4-6%.

In Poland, access to pharmaceutical innovations had been significantly insufficient. This remains one of the major challenges for the country's health care system. The growth of innovative markets was modest between 2011 – 2013. In 2010, generics controlled 75% of the total market (Stefancyk, M. et al, 2011).

Less than 1% of Hungary's GDP is spent on pharmaceutical research and development each year (Stefancyk, M. et al, 2011). The Hungarian system uses the reference pricing system which prescribes cost effective therapies with generic rather than brand names. Because of the country's difficult economic situation, rapid growth on the pharmaceutical market will not be possible in the next few years in Hungary.

The expected growth rate of generic medicine in Slovakia will continue to exceed that of their counterparts through 2014. As a result of reference pricing rounds, the price of several hundred medicines have been reduced with many of them being innovative medicines. There is more generic market support rather than innovative. A new reference pricing system has been in place in which drug prices are set at the second lowest price in a basket of prices of all European Union countries. This lead to increases in the generic prescriptions instead of brand names. Slovakia is the most promising country for generic market growth with an estimated 9-11% growth compared to Hungary, Poland, and Czech Republic with 5-6% growth (Stefancyk, M. et. Al, 2011).

The compound annual growth rate (CAGR) in Czech and Slovak Republics was estimated at 5% through 2013 and 2-3% in Hungary and Poland during the same time (SAFS, 2011). The development of these markets can be threatened due to the economic crisis and effects from 2009-2010 and continual restrictive measures from the Ministries of Health and governing authorities. A high risk of parallel export and import of product also poses a threat.

IV. ECONOMIC AND MARKETING IMPLICATIONS FOR PHARMACEUTICAL INDUSTRY

The economic and marketing implications for the generic pharmaceutical industry in CEE is significant. The strategy to present first on the market, keep competitive prices, and patient co-payments low in comparison to other generic competitors is critical. A strong business development model with at least four to six new launches each year can support this model. As for research and innovation, the protection of patents and belief in established brands is essential. Price flexibility and providing discounts for wholesalers can serve as effective strategic practices. Industry leaders should re-think current business models to have a more efficient and low cost pharmaceutical model is critical to include product line extensions.

V. CONCLUSION

There is a great opportunity for generic drug market development as part of GDP for health care expenditures and to support lower costs products. The rising costs of health care globally, specifically pharmaceuticals, have raised concern for

health economics and health system leaders. With a focus on low cost, effective prescription drug usage, pharmaceutical leaders can bridge the need for market growth and while offering lower cost products to patients and payers.

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