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The impact of generic medicines on the European pharmaceutical market: The example of Poland

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Abstract

The impact of generic medicines on the European pharmaceutical market: The example of Poland

In this paper has been done a review of the existing situation on European pharmaceutical market. It was found that the Polish pharmaceutical market is quite different from other countries of the European Union. The share of generic medicines in Poland is the highest in the European Union. Quantitatively about 85% of the pharmaceutical market is composed of generic drugs. The social role of generics is expressed in their accessibility, affordable price, diversity and security for the most vulnerable part of the population — people with various health problems. It is impossible to overestimate the importance of generic medicines in both saving of the state's budgets and the rational use of public finances.

1. Introduction

The aim of this article is to provide an overview of the impact of generic medicines on both the European market and Poland, as well as competition and regulation in the pharmaceutical industry. The importance of pharmaceutical markets is considered here from two approaches. Thus, the purely industrial organization side of the business is not only taken into account but also its social role, as the access to medicines is highly important for people's quality of life. The fact that access to medicines is an indicator of health system development is highlighted here throughout research of the existing literature.

2. Theoretical framework of the research

Research by Prof. Steven Simoens mentions the future perspective of generic medicines in Europe. Two of his studies found that generic medicines discount the prices on the European pharmaceutical market from 20 to 70% off the wholesale price in France and up to 50% in the United Kingdom. Therefore the main factor which affects the price is the local regulations of the country. A number of experts in different countries were involved in creating such a pharmaceutical policy on the market which can provide a better quality of health care on the market.

3. Research methodology

As a source of information, a wide number of databases have been consulted: Eurostat, The Central Statistical Office of Poland, World Health Organization databases. This paper summarizes the data of technical reports by many experts and public organizations providing the analyses of pharmaceutical policy.

4. What is a generic medicine?

How do the medicines enter the market?

The process of creating of a new medicine can take from a few years up to a few decades. After conducting detailed research of the market, significant investments in new technologies, equipment, and their development, which requires some very precise engineering, pharmaceutical companies provide the medicines to the market.

At the same time, the manufacturing of medicines is always connected with legal regulations in the pharmaceutical industry. After pre-clinical and clinical trials it is necessary to prove the efficiency and safety of the drug, to perform a registration process and as a result, to release the new drug for sale.

Originally discovered and developed, a brand name for the pharmaceutical product can be provided to the market and the producer can apply for a patent for such medicines. Newly created medicine is considered as intellectual property and a producer can apply to the European Patent Office or in the case of Poland to the Patent Office of the Republic of Poland. Since July 6th 1998 European patent law relating to biotechnological inventions has been harmonized with member states. The Directive 98/44/EC — concerns the legal protection of biotechnological inventions.

“Patents are a key tool to encourage investment in innovation and encourage its dissemination” (https://ec.europa.eu/growth/industry/intellectual-property/patents_en).

A patent gives the opportunity to protect the pharmaceutical product from copying for a definite period of time. Nevertheless, there is no such patent that can firmly protect the original product from illegal copying.

In accordance with Directive 98/44/EC the standard period of a patent is 20 years: “At the applicant’s request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed” (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>).

After the expiration of the main period of the patent, it can be extended up to 5 years in order to recover the time spent on marketing and introducing the product to the market.

While the brand name of the original product has the protection of a patent, no one pharmaceutical company can produce the same product, as this creates a monopoly on the pharmaceutical market and as a result, unfair pricing.

After the term of the patent has expired, any pharmaceutical company is free to produce the same product without using the original name. This product is called generic medicine. Generic should be bioequivalent to brand-name medicine and contain the same active ingredient(s) in the same amount and in form.

Since no significant research is necessary for providing generic medicines to the market, clinical trials or marketing, the price for generic medicine can be reduced by 20% or more from the first year of entry into the market.

According to the opinion of manufacturers of brand medicines, a higher price for such medicines should recover not only the research and development costs, but also the costs of unsuccessful drug development that did not reach the pharmaceutical market.

How do generics have an effect on the market?

As there can be an unlimited number of manufacturers on the market of the same medicine — the price goes down. With the appearance of generics, the situation on the market is radically changing and competition arrives at a situation akin to a monopoly.

One of the perfect main market indicators is a lack of market concentration, which is related to industrial concentration, so the argument for a price reduction is that generic medicines create competition in the pharmaceutical market and that has a direct effect on pricing strategies.

Quantitatively the share of generic medicines on the Polish pharmaceutical market is 84%, but as the price of generic medicines is quite lower, this will take only 62% in qualitative terms (Figure 1).

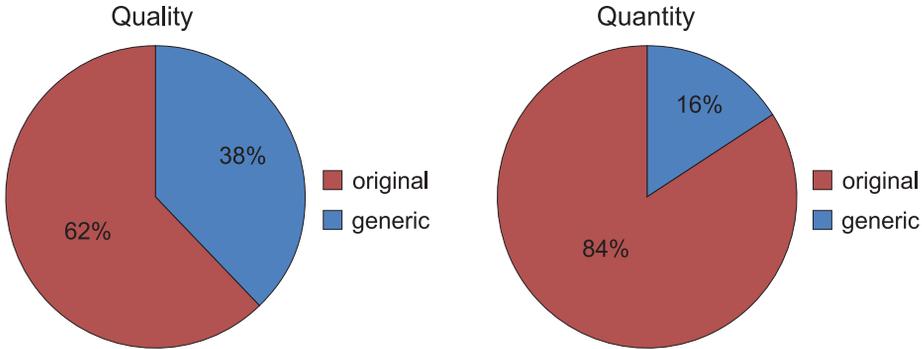


Figure 1. Share of original medicines and generics on the Polish pharmaceutical market, 2015

Source: <http://www.producencilekow.pl> (access: 31.12.2015).

As a result of the predominance of generics on the Polish pharmaceutical market — Poland has the lowest price for medicines among other countries of the European Union with the exception of Bulgaria — the average price for generic medicine amounts to 3.01 in euro (Figure 2).

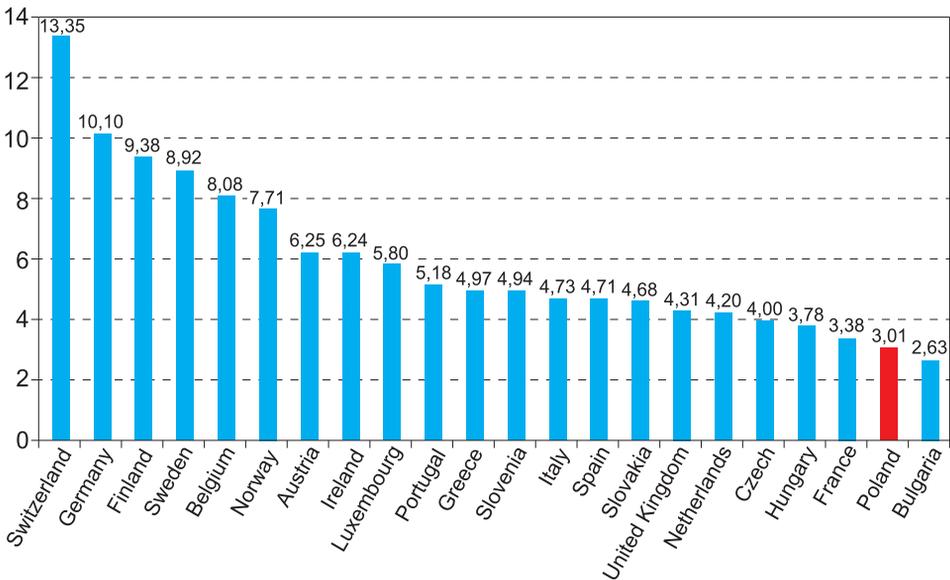


Figure 2. Average price of generic medicine (EURO)

Source: MIDAS MAT 2015/03, ExMan Prices EURO, Retail Market.

Nowadays generic medicines are promoted by different organizations, first of all by the World Health Organization (WHO). The Policy of the WHO is to provide access to medicines at affordable prices.

The World Trade Organization (WTO) is an international organization of 148 member countries dealing with the rules of trade. In joining, WTO members adhere to specific agreements (WHO Drug Information Vol. 19, No. 3, 2005). Among different agreements of the WTO, the most important for the pharmaceutical sector was Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement establishes minimum standards in the field of intellectual property (www10).

The Generic Medicines Group is a sector group of Medicines for Europe, representing generic medicines developers and manufacturers, which provide high-quality cost-competitive medicines to millions of patients in Europe and around the world (www6). This organization consolidates about 350 manufacturers of the biggest manufacturers of generic medicines.

The International Generic Pharmaceutical Alliance (IGPA), was founded in 1997 as an international network of generic medicines associations, which helps to ensure patient access to safe and effective generic medicines. The name of the organization was changed in September 2015 to the International Generic and Biosimilar Medicines Association (IGBA) to reflect the evolving nature of the industry (www3).

There are many more organizations which promote generic medicines, this means that the share of generic medicines will grow worldwide.

4.1. The capacity of the market for generic medicines in the European Union

Currently, the pharmaceutical industry is one the most developed and innovative, which gives to millions of people an opportunity to improve the quality of their lives, to lead a normal life even with chronic diseases, to defeat serious ailments.

No matter what state of health we are in or what age we are, we are each a consumer of pharmaceutical products — either prescribed medicines, over-the-counter drugs, or any health-related products.

Nowadays the population of the European Union is slowly growing, for on 1st January 2014 it was estimated at 506.8 million people (Eurostat Statistical Books, *Key figures on Europe 2015 edition*, p. 18). But at the same time we can see changes in its structure — its population becomes older.

An important element that affects the level of drug consumption is the proportion of the population with chronic diseases.

According to the latest data from Eurostat, the share of the population with a long-standing illness or health problem on average for the European Union for the year 2015 was 34.1%. This percentage includes all ages from 16 years old and for both males and females. For Poland, the share of population with a long-standing illness was 35.7%, which is more than in such EU countries as Belgium, Bulgaria, Denmark, Greece, Italy, etc.

Table 1. People having a long-standing illness or health problem, by sex, age, and educational attainment level, years 2011–2015 (in %)

GEO/TIME	2011	2012	2013	2014	2015
European Union (28 countries)	31.2	30.8	32.0	32.5	34.1
Belgium	26.1	24.5	25.7	24.9	24.5
Bulgaria	17.9	18.4	18.9	20.5	21.4
Czech Republic	30.6	30.0	31.5	31.5	34.1
Denmark	29.0	29.0	28.5	28.1	29.6
Germany (until 1990 former territory of the FRG)	36.7	36.9	38.3	38.7	42.5
Ireland	25.8	26.2	27.3	26.8	26.5
Greece	22.3	22.7	22.8	23.9	24.0
Spain	21.1	24.2	29.9	29.6	32.8
France	36.3	36.3	36.0	37.0	37.3
Croatia	36.7	28.7	30.5	30.6	34.0
Italy	25.3	23.4	24.5	24.7	24.8
Cyprus	32.1	32.1	32.8	32.0	32.5
Latvia	36.1	35.7	39.4	40.6	41.2
Lithuania	28.5	29.2	30.9	32.3	34.5
Luxembourg	20.6	19.9	23.3	22.6	23.1
Hungary	35.5	35.7	36.8	37.0	39.2
Netherlands	34.1	34.5	36.5	34.9	35.4
Austria	34.1	33.0	34.4	35.8	34.8
Poland	33.9	34.3	34.0	33.9	35.7
Slovenia	36.0	35.0	31.3	32.2	33.1
Slovakia	31.3	29.6	30.4	30.2	30.3
Finland	45.3	46.8	47.5	46.1	46.6
Sweden	32.2	33.9	35.2	34.8	34.4
United Kingdom	35.8	31.7	32.0	34.1	35.2
Norway	36.3	30.8	34.0	33.3	33.5
Switzerland	32.6	34.0	34.5	36.2	—

Source: Eurostat (last update 6.02.2017), <http://appsso.eurostat.ec.europa.eu> (access: 1.03.2017).

Price has an effect on the quantity of demand on the pharmaceutical market among different groups of society. It was found that the category which needs the most access to inexpensive medicines is people at the age of seventy and older. The affordable medicines for them — the basic condition for maintaining a decent quality of life and its expectancy. Due to the data of the Central Statistical Office of Poland (Figure 2) in the year 2014, 93.7% of the population of Poland under

70 has long-standing health problems, 93.5% of the population in this age has a chronic disease. This looks dramatic — no one can survive without access to medicines, moreover these medicines should be affordable for customers. The position for the category of the population aged 50 to 70 is rather complicated as well: 77.8% from this group has long-standing health problems and 78.9% has a chronic disease.

Table 2. Health status of the population of Poland in the year 2014

Specification			Age groups					
			0–14	15–30	30–50	50–70	70 and above	
%—value of variable SE — standard error								
Health status evaluation	very good	%	49.8	46.8	21.8	4.5	1.0	
		SE	0.8	0.9	0.6	0.3	0.2	
	good	%	41.5	44.5	57.0	38.3	17.1	
		SE	0.8	0.9	0.7	0.6	0.8	
	fair	%	7.5	7.2	16.9	39.9	41.3	
		SE	0.5	0.5	0.5	0.6	1.0	
	bad	%	1.1	1.4	3.7	14.0	29.9	
		SE	0.2	0.3	0.3	0.4	0.9	
	very bad	%	0.2	0.1	0.6	3.3	10.7	
		SE	0.1	0.1	0.1	0.2	0.6	
	Long-standing health problems	yes	%	26.1	26.7	44.8	77.8	93.7
			SE	0.8	0.8	0.6	0.5	0.5
no		%	73.9	73.3	55.2	22.2	6.3	
		SE	0.8	0.8	0.6	0.5	0.5	
Limited ability to perform activities	yes — severely limited	%	1.5	1.6	2.9	8.9	27.6	
		SE	0.2	0.2	0.2	0.4	0.9	
	limited but not severely	%	3.3	4.6	9.0	22.6	37.5	
		SE	0.3	0.4	0.4	0.5	1.0	
	not limited at all	%	95.2	93.9	88.1	68.5	34.9	
		SE	0.4	0.4	0.4	0.6	1.0	
Chronic disease	with chronic disease	%	26.5	28.0	48.2	78.9	93.5	
		SE	0.8	0.8	0.7	0.5	0.5	
	without chronic disease	%	73.5	72.0	51.8	21.1	6.5	
		SE	0.8	0.8	0.7	0.5	0.5	

Source: Central Statistical Office of Poland 2017.

Such a health status of the population creates a high demand on the European pharmaceutical market and particularly in Poland, with the needs of wide product differentiation and innovations at the same time. Moreover, health expenditure in the European market is expected to be higher due to the trend of an ageing population and a reduction in natural population growth.

Nevertheless, the share of public finance expenditure in Poland is one of the lowest in the European Union. For the year 2016, general government spending in Poland was 11,400 USD *per capita*. This can be provided because of the high share of generic medicines on the Polish pharmaceutical market (Figure 3).

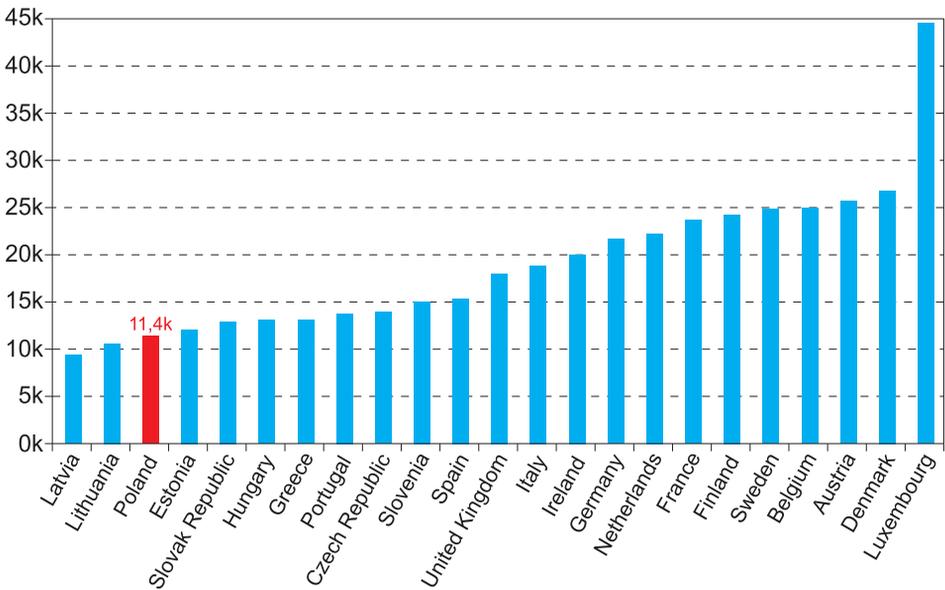


Figure 3. General government spending total, European Union, in Thousands of US dollars/capita, 2016

Source: OECD, <https://data.oecd.org/gga/general-government-spending.htm#indicator-chart> (access: 1.03.2017).

5. Conclusions

The results obtained show that:

- Generic medicines have a large impact on the pharmaceutical market as they enable a competition that brings down drug prices.

- Generic medicines that are affordable for people with low incomes have a high social value.

- Generic medicines improve welfare due to the fact that they capture a consumer surplus.

According to the structure of the population of the European Union, the demand for generic medicines will grow.

The entry of generic medicines onto the pharmaceutical market results in producers of branded medicines decreasing their re-investment of income to research and development.

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