

Economic impact of parallel trade on the selected pharmaceutical markets in the European Union

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ABSTRACT

One of the basic principles of European Union – free movement of goods, makes the phenomena of parallel trade in the pharmaceutical market possible.

Access to all medicines, including access to the most effective therapies is very important for public health. There are two important aspects strongly influencing access: drugs affordability and the presence of products in the market. The latter can be sometimes jeopardized by an excessive parallel export. Access to the newest pharmaceutical technologies can positively influence

quality of life of the society and thus, in the longer term, can trigger many positive consequences for particular markets and for the whole EU.

The aim of this article is to present the economic effects of parallel trade in the pharmaceutical markets in EU. Economic factors influencing presence, form and scale of parallel trade are presented, as well as its' macro and microeconomic consequences.

Key words: parallel trade, medicinal product, pharmaceutical market

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INTRODUCTION

According to European Union Treaty, free movement of all goods between every member state is allowed. It is almost unlimited, except for some extreme cases of a negative influence on some selected economies or common property.

Free trade is also related to pharmaceutical products present on the market in at least one member state. However, the differences between wealth of different countries, society income level, law regulations or reimbursement systems make drug's movement between some countries and it's further circulation much more complicated than in the case of any other goods.

This procedure, called parallel import, takes place simultaneously with distribution channels. It based on European Union Treaty resolutions both in the member states and the countries of European Economic Area.

1. Parallel import in the European Union

1.1. Parallel import on pharmaceutical market

The occurrence of the parallel import of pharmaceutical products in the European Union is common and results from price differences in different countries. The first product was sold in this mechanism in the Netherlands in 1975. The actual value of parallel import in the European Union is about 2 billion € per year [1].

When taking into account the countries of the "old" European Union, the lowest drug prices occur in Greece and Spain. These countries are the main source of drug import. The countries such as Romania or Bulgaria, have too little developed markets to become significant in the European parallel import, even despite the fact of low prices.

In the years 1996-2008, the value of drug export from Greece, counted as the percentage of the whole medicinal products sale, has increased five times. High export value caused drug shortages on Greek market. Therefore, National Drug Organization obliged wholesalers to satisfy local Greek market first. In 2001 it introduced the obligation to have 25% stock in comparison to the market needs and to inform National Drug Organization of every drug exportation regularly.

Spain is the main drug import source for Great Britain and Germany. It is the fifth-largest pharmaceutical market in Europe. Distribution channels are very fragmented, so margins for wholesalers under the Spanish healthcare system are thin, and all wholesalers claim they need to export [2].

The main recipients of drugs from the abovementioned countries are Germany, Great Britain, Sweden, Denmark or the Netherlands,

where drug prices are the highest. The British market of pharmaceuticals parallel import is concentrated a lot, because four leading companies have more than 52% of this sector, and they have reached this result by the distribution of only 15 medicinal products.

A similar situation takes place in Denmark, where half of the value is achieved by the sale of only three drugs, and 1/3 of the whole sale makes Orifarm the biggest importer in that country. In Finland, another leading parallel import recipient, one-channel distribution is characteristic – producers sell their products to only two wholesalers (Tamro and Oriola-KD). Such a system functions also in Sweden.

The German market is less concentrated: 50% of parallel import is made by 37 products, with eight companies experiencing 54% of all imports. The biggest among them are Kohlpharma and MTK-Pharma. In Germany functions a unique system, under which each product line from each supplier (the original German domestic brand and each of the parallel importers' versions) carries a unique seven-digit number in bar code form. This defines the reimbursement price for a pack, and savings from the parallel trade's lower cost go to the payer [2].

Parallel import market still develops in many countries. One of the best example is Polish market. Polish pharmaceutical market is the sixth most valuable in Europe [3], and the second among pharmaceutical markets in Central and Eastern Europe (Lithuania, Latvia, Estonia, Poland, Ukraine, Hungary, Bulgaria, Romania). Over the last five years the value of parallel import of pharmaceuticals in Poland has been growing at a very rapid pace, both in terms of participation in total pharmaceutical sector, as well as value. In 2011, after the first half of year, parallel import reached 95,4 million zlotys.

Despite of the dynamic growth of the pharmaceutical sector in Poland, the parallel import market of medicinal products exceeds the pace of development. In 2005 parallel import accounted for 0,01% of the pharmaceutical market, in 2009 was already 0,7%, and only in the first three quarters by 2010 it reached nearly 1,1% [4].

The rapid pace of pharmaceutical parallel import development also indicates the amount of licenses for this procedure. In 2005 there were 40 licenses, two years later 80, and in 2009 already 308 [5]. In 2010, 215 permits were licensed for the parallel import. Now, there are over 150 drugs from parallel imports available on the market [6]. This state results from the situation, in which the manufacturer informed of a intention of its pharmaceutical product parallel import, significantly lowers the price in the destination country that imports became unprofitable.

There are 19 registered parallel importers in Poland. The largest are Blau Farma, Delfarma, Forfarm, Inpharma and Inter Pharma. They have a 94% of the entire Polish medicines parallel import market. The greatest of these companies is Delfarma, which has about 45% of share in the market, that resulted in a net profit come to 3,6 million zlotys in 2009 [7].

In spite of the attractiveness of parallel import phenomenon in many respects, the increase of its popularity and the support provided to it by the governments of many countries, the value of parallel trade in pharmaceutical growth is goes down, and sometimes even decreases. It may be caused by the global financial crisis, which is taking place at present, but also by the producers' activities to limit the parallel import phenomenon.

1.2. Legislative regulations for parallel import

The first agreement marking the beginning of the European Union – European Economy Union Treaty enabled the existence of parallel import. It covered the matters concerning customs or situations restricting mutual trade. However, the most important statement is the one about the prohibition of goods importation and exportation limitations in all member states [8].

Maastricht Treaty from 1993, called European Union Treaty, as the foundation of the functioning of the European Union, is the next document regulating parallel import. By its rules, members of the European Community and European Economic Area are under the rule of free trade. However, this principle has some exceptions. Free trade restrictions are possible when there is a risk of the encroachment on morality, public safety, human's life and health, industrial and trade property and other issues mentioned in the Treaty [9].

The successive European Union Treaties haven't initiated any important changes for the issue of trade and parallel import between member countries.

In 1995 World Trade Organization applied an Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS allow each individual member country of the WTO to choose whether or not to allow parallel import into their local market [10]. The European Union, for instance, has chosen community exhaustion for all kinds of intellectual property rights, while it doesn't allow parallel import from outside the community.

Another important document about parallel import is European Community Commission Communication COM (2003) 839 final, which directly condemns all actions made to restrict parallel import by any of the member states, except

for health hazard situation or industrial and trade menace [11].

European Medicines Agency (EMA), the European Union agency coordinating and supervising medicinal products intended for human use on the whole Community territory, has introduced a number of ordinances regulating parallel import. The most important is the regulation issued in 2003 specifying issues about drug registration and repackaging.

1.3. The review of selected rulings of the European Court of Justice concerning parallel import

The European Court of Justice is a body of the European Union and its biggest authority in the matters of arguments and interpretation of law connected with pharmaceutical market. The main role of ECJ is to guarantee the proper use and interpretation of the European law in all member states and to settle controversial issues between them or some other parties.

One of the most important ECJ rulings concerning the bases needed to make parallel import possible is a sentence in case 8/74 Procureur du Roi v. Benoit and Gustave Dassonville from 1974. The European Court of Justice ruled that all the national regulations of member states which can restrict internal European trade in any way, are the limitation of free movement of goods inside EU, so they are divergent from article 28 of European Union Treaty.

In 2008 the European Court of Justice ruled in the case of GlaxoSmithKline's activities in Greece. In 2000 the company stopped delivering a group of drugs to Greek wholesalers explaining that it had been caused by too small production and its independence of Glaxo. Simultaneously, it started its own distribution of these drugs to Greek wholesales and pharmacies by its own company. Taking into account the fact that Greece is the leader as the source of parallel import in the European Union – 47% of imported drugs in the whole EU come from Greece [12], it obviously limited, and even stopped importing from Greece. Greek wholesalers brought action to ECJ, which found these activities illegal and divergent from article 82 of the European Union Treaty, which states that the abuse of a dominant position on market, for example by limiting production, markets or technological development to the detriment of consumers, is definitely illegal [13].

Another significant ECJ ruling connected with parallel import is the ruling from 2009 case between GlaxoSmithKline and Spanish pharmaceutical companies. GSK used double-prices mechanism on the Spanish market. This mechanism consists in the sale of some goods, and

in this case 82 medicinal products, by a producer on different price levels on the same market. GSK made a deal with Spanish wholesalers to sell drugs at higher prices to other countries of the European Union than to Spanish hospitals and pharmacies [14]. Such efforts have an obvious economic aim – profits magnification while causing losses to national health system, tax-payers or patients – and they are a clearly anti-competitive practice which gives rise to parallel distributors bloc on their national market [15]. The European Court of Justice ruled that such activities are illegal and divergent from article 81 point 1 of the European Union Treaty. In addition it ruled that every agreement between companies whose direct aim or effect has a negative influence on the competition on the European market is illegal [16].

The European Union support for parallel import is a phenomenon because it enables the improvement of competition in the pharmaceutical sector. Additionally, it is the only form of preventing monopoly in the case of drugs protected by patents. It is also connected with many law regulations, starting with drug registration, its repackaging, package and leaflet layout, and ending with the distribution process of imported drugs. Such a situation causes many contentions between producers and importers, often settled by ECJ. Despite the loss for producers, parallel import is a very desirable phenomenon, both from a macro- and microeconomic point of view, which will be shown in the next part of this article.

13. Economic factors influencing the phenomenon of parallel import

a. Economic reasons for parallel import

In the time of the patent protection of a given pharmaceutical product, price competition functions in a very limited range, and its intensity depends on the presence of substitutes and the level of ability to replace the original drug. Especially for highly specific products, this is due to the large investments in R&D, which is necessary to develop such products. The huge amount of resources necessary to discover a new molecule and the high level of risk associated with the inventive activity constitute a natural entry barrier that can perpetuate oligopolistic structures of the markets. The fact that only a small number of companies has the necessary resources to enter a potential market, and the presence of patent protection reduce and delay the possibilities of the penetration of the market by new entrants.

This analysis shows that interbrand competition can exert a poor pressure on prices during patent validity, thereby consenting to manufacturers to be price maker to a certain extent. That is why the stimulus of intrabrand competition, provided for by parallel trade during patent validity,

appears to be essential in order to balance the ability of companies with market power to charge excessive prices [17].

Although only parallel import of medicinal products under patent protection has been mentioned above, this phenomenon functions well also among generic drugs. In the case of this group of medicinal products, the determinant of parallel import is the difference in drug prices on different markets of the European Union.

b. The influence of drug prices and price policy on parallel import

Differences in the price of same drugs among member states constitute a generative factor for parallel import. For instance, in Germany, Great Britain or Netherlands prices are significantly higher than in Greece or Spain.

Therefore, the national pricing that creates opportunities for parallel trade on the European market of pharmaceutical products exhibits the characteristics of the third-degree price discrimination, the economic welfare effects of which can be either positive or negative depending on the circumstances. It is a situation when customers pay different prices for the same product for reasons that are unrelated to the cost of production or the quantity sold. The producer of a drug under patent protection functions as a monopolist. He uses this mechanism when he does not know the demand characteristic of individual consumers but he knows the demand of a whole group of consumers. That is why market segmentation and offer adaptation to its individual parts on the basis of price elasticity of demand for the given good are possible [18]. Every separated segment constitutes a separated market for a monopolist where he must adapt his activities properly. The consumers of an individual group pay the same price but the price differs between the groups – in this case the countries of the European Union. Prices are higher when the demand on a given market is less sensitive to price changes. This situation takes place in well-off countries but demand in poorer countries is much more dependent on price level [19].

The different price level of drugs in member states of the European Union does not depend only on demand susceptibility to price. Drug price controlling in every country also has a significant role. For example, in 2003 price setting under patent protection was almost unlimited in Germany and Great Britain. Other countries have introduced price limiting in different forms.

Another factor influencing the differences in drug price level is the difference in reimbursement services. By way of example, under the German reference pricing system a patient has to pay any amount in excess of the maximum reimbursement

price set by the government. However, in some other countries a patient has to pay some established amount regardless of the currently valid drug price. In addition, the government of every country has an influence on drug price differences because of its strong bargaining position to negotiate prices with patent holders [19]. Different requests for medicinal products on individual markets also have a big impact on price level, mainly because of different tax participation in drug prices. It varies from 5% to even 25% [20]. In

connection with different margins (only reimbursed drugs margins are controlled by the government) this factor can cause significant price differences on member states markets.

In many European countries supplementary regulations and facilities are applied to underline the attractiveness of products from parallel import and lead to its purchase. These actions are shown in the Table 1.

Table 1. Actions used in selected European countries to promote drugs from parallel import on pharmacy sale level

Action	Denmark	Germany	the Netherlands	Norway	Sweden	Great Britain
Pharmacy required to inform a patient of the availability of PI product	X	X			X	
Pharmacy quota on PI dispensing rates	X	X			X	
Financial incentives for pharmacy to dispense PI drugs			X	X		X
Financial incentives for dispensing lower-price drugs in general, including PI drugs				X	X	

Source: Kanavos P, Gross D, Taylor D: Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States, Washington 2005, page 11. Available from: http://assets.aarp.org/rgcenter/health/2005_07_trade.pdf [cited 2012 Jul 18]

In Denmark, Germany and Sweden a pharmacist is required to inform a patient about the availability of a parallel import, cheaper product and is also required to sell it if the price difference between the imported and domestic drug is bigger than top-down fixed difference. For example, in Germany this requirement is used when an imported drug is cheaper more than 15% than the domestic drug in the case of prices lower than 100 €, or when the difference is bigger than 15 € in the case of the prices over 100 €. Moreover, the governments of the Netherlands, Norway and Great Britain use additional expenditures to enlarge the participation of parallel import drugs in whole sale of pharmaceuticals [17].

c. Marketing and cost factors versus parallel import

Important economic factors which can affect the existence and the functioning of parallel

import of medicinal products are expenditures born by parallel traders, for example costs of transport.

For instance, if trade costs are very low or tend toward zero, the manufacturer cannot keep parallel trade in balance by raising the wholesale price [21]. In this case, parallel trade leads to an efficient re-allocation of medicinal products between two markets and there are no price differences in them and access to them, so there is also no difference between consumer's welfare. In a situation when these costs are relatively high, parallel import should become unprofitable, or even unattainable. In this case it isn't any danger for a drug manufacturer and he can set a price policy the most effective for him.

The level of parallel import depends also on marketing factors, especially distribution. On the pharmaceutical market a situation when distributor X invests in marketing activities on market A in order to increase the sale of a drug is typical. Later

he will charge higher margins on the sold products to cover his earlier spending. Other distributor Y uses low-costs policy and he does not undertake any marketing activities on market B. In this situation, even with the same wholesale price on both markets, the latter price will be higher on market A. Such a phenomenon creates the situation when parallel importers are very interested in purchasing the drug on market B and sell it on market A because of the already performed by a local distributor marketing activities. On market A supply will increase, product's price will be lower, because of both the presence of cheaper drugs from import and market saturation. On the contrary, on market B the price will be higher because of the increase in demand and lower amount of this drug on the market. In the consequence of these changes, distributor X will lose or at best his surplus will decrease but the charge of distributor Y will increase significantly.

Another factor which may influence the prices of particular drugs and the existence of parallel import is vertical price setting. This mechanism consists in an agreement between a producer and a retailer on the retail price recommended by the producer. In the case of pharmaceutical industry the producer sells drugs to an independent and sole foreign distributor on such a low price level which guarantees a desired retail price in a particular country [22]. By setting the proper foreign wholesale price, the manufacturer can establish and control the level of parallel import between these countries. This dependence works both ways – parallel import affects the wholesale price set by the manufacturer [21].

14. Economic consequences of parallel import

a. Savings and profit from parallel import

The economic theory suggests that parallel trade would stimulate savings both directly and indirectly. Direct benefits should derive from the lower prices paid by patients that purchased parallel imported products. The indirect benefits may potentially derive from the competitive pressure put on manufacturers by parallel importers, which drives down the prices of patented products, or decelerates the increase thereof. The empirical evidence provided for by the European Commission confirms the theory. It shows, that drug prices decrease rapidly in the case of the presence of drugs from parallel import [17]. This phenomenon brings benefits both for patients and a national health care system which pays for a big part of drugs.

For pharmaceutical companies an insurer in a health care system of some countries is a very important purchaser because of the enormous amounts of drugs bought by him. However, drug purchase on such a large scale is always connected

with earlier negotiations in order to decrease the price of medicinal products. The fact that there are products from parallel import on a given market gives the insurer an additional bargaining advantage due to the possibility to buy cheaper, imported drugs. Therefore, the producer is very often forced to decrease the price of his medications. This may, however, be positive for him.

In the situation presented above a producer and a distributor reach an optimum position and there is no reason to withdraw from the accepted conditions when the other party is operating because the price of the drug is decreased to the level which is satisfying for both parties. The insurer is satisfied with lower expenses on drugs and the producer ensures fixed income to himself thanks to the guarantee of the sale of a very big amount of medicinal products. Obviously, his income is lower than the possible initial income; however, the producer usually sets the price on the level which effectively prevents the import of the drugs from abroad. In this way, parallel import forces the producers to be more flexible in negotiations and to decrease the price of drugs in the future

For many entities, profit from parallel import of drugs, is unquestionable. However, in some European countries the decrease in the sale of drugs from parallel import has been noticeable in the recent years. This occurrence results from the changes in law regulations which produce different reactions among entities which operate on particular markets. For example, in Sweden in 2004 there have been introduced new regulations obliging doctors and health care system to use the cheapest generic drugs available on market. The cost of health care system diminished quickly because the price of generic drugs was lower than the price of original drugs but the proportion of the imported drugs in the general use of medicinal products decreased because special attention was paid only to generic drugs [17]. An additional factor which has reduced the level of the sale of medications from parallel import in the recent years is mass expiration of patents for many key drugs. It enables immediate appearance of generic products on the market, which causes additional competence.

b. The influence of parallel import on R&D activities

In the pharmaceutical industry a huge amount of money is invested in innovations which are one of the main factors determining the competitiveness of a given company in that economic sector. The necessity of the abovementioned activities results in the negative view of pharmaceutical companies on parallel import. Drug producers prove that they cannot

exercise their patent rights in full. The sale of a developed drug does not bring expected financial results, therefore companies are unable cover the expenses incurred on the research on a particular drug and the costs of the research on other innovative medications. The reason for this situation is that the target for the products from parallel import are most often reach markets with high drug prices and highly developed R&D sector.

Numerous economic analyses of various cases of particular drugs prove the arguments presented above. Additionally, in the situation when the government of a given country, due to the presence of cheaper medicinal products from parallel import, determines the maximum prices for particular drugs and when these prices are equal to or lower than the marginal cost incurred by the producer, the willingness and possibilities of pharmaceutical companies to invest in R&D will come to an end [23].

There are also theories according to which parallel import does not influence research and development negatively to the extent presented by pharmaceutical companies [24]. Over the recent years the cost of pharmaceutical research has increased whereas the number of studies has not decreased. On the contrary, the number of pre-clinical and clinical studies has increased. Interestingly enough, the biggest increase thereof has been noticed in Europe – in the heart of the criticism of parallel import and its alleged negative influence on innovations. Therefore, parallel import should not be presented as the main factor determining the income decrease of pharmaceutical companies and the decrease in financial resources for the research on innovations.

The development of innovations in pharmaceutical sector is the result of the interactions of many factors such as regulative issues, cost of research, patent law, the level of competition, profit expected from particular research, changeability of exchange rate, demand uncertainty and many other factors. Patent protection is only one of the factors which provide the producer with the reimbursement of the incurred costs. Extremely important are also the following issues: the ability to enter the market quickly and effectively, effective marketing, keeping an innovation secret, better customer service and effective sales chain [17].

c. Negative effects of parallel import

Parallel import may also cause negative effects. One of them is the problem of drug shortage in the countries with small prices of medicinal products. Medications imported on other markets come mainly from these countries. They are exported from that particular countries in large numbers, thus hampering the access to drugs for the

local patients. Therefore, many European countries, such as Belgium, Finland, France, Greece, Italy, Portugal or Spain, imposed on wholesalers the obligation to have in stock a big amount of all medicinal products and to provide them to all purchasers on the area of a given country in order to evade the situation presented above [2]. Drugs exported from a given country within the framework of parallel import are far more difficult to obtain and because of it their prices rise, which causes losses both on the side of individual patients and whole health care systems.

Medicinal products from parallel import may cause a certain degree of embarrassment, feeling of being misled or even dissatisfaction among patients. Usually packages of imported drugs vary from the original packages and the brand name is in many cases hardly noticeable.

Despite law requirements concerning parallel import of medicinal products, patients concerns may be justifiable to some extent. Medicinal products which leave the place of production are of the same, controlled by the producer, quality as other medications. However, this quality may be impaired during transportation between many entities or in the process of drug storage. Producers invest in quality protection during these processes in order to create, maintain and protect the reputation of a medicinal product developed by them. However, drugs from parallel import may be to some extent defective or even damaged because importers pay less attention to the control and the maintenance of drug quality in the postproduction processes, which results from the desire to limit the incurred costs but not only [25]. Parallel import may also cause the deterioration of the producer-distributor relations on a particular market. Distributors feel frustrated with the existence of an additional very strong competence and they expect producers to take some steps in order to eliminate that competence. It may also happen that the producer will have to buy from distributors a certain amount of drugs, often older drugs, because parallel import has caused the saturation of a market with a given medicinal product. Such situations lead to two-way accusations and in the consequence to lower profit for both parties.

CONCLUSIONS

The mechanism of buying a drug in a country where prices are lower and selling the same medication on a more expensive market causes a number of positive and negative economic consequences for many entities. The most visible effect is the existence of competence for a drug which is still under patent protection. When the same, however much cheaper, drugs appear on a given market, the producer is made to decrease the

price of drugs which have already been present on a market for a while. Those who take advantage of such a situation are patients who have the possibility to buy cheaper drugs and health care systems in the countries which initially had high prices of medicinal products.

The reach markets of the Western Europe, such as British, German or French market, are the place of the greatest intensification and development of R&D activities, among other factors because of better access to the most modern technologies and logistics solutions. However, due to high drug prices these markets are also the main target for the medications from parallel import. Because of the presented above process of forcing lower prices, the income of pharmaceutical companies decreases in an obvious way whereas a part of this income could be devoted to activities from the area of research and development in order to create new pharmaceutical products.

The arguments presented above indicate that there are many positive and negative effects of parallel import. They can be perceived in many ways depending on the different points of view of the entities. Therefore, it is essential to constantly monitor parallel import in the European Union and to adjust and update European law instantly in order to satisfy all the entities operating on the pharmaceutical market.

Conflict of interest

The authors have declared no conflicts of interest.

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