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Analiza importu równoległego leków w Polsce i jego wpływ na zdrowie publiczne

Streszczenie

Wstęp. Łatwy dostęp do tanich leków odgrywa znaczącą rolę w poprawie zdrowia publicznego. Zwłaszcza w czasach globalnego kryzysu niezmiernie istotne jest poszukiwanie tanich źródeł leków. Import równoległy (IR) może przynieść proste rozwiązania tej potrzeby społecznej. IR leków w Polsce jest możliwy od momentu jej akcesji do UE. Jednakże do chwili obecnej nie ukazała się żadna wyczerpująca praca naukowa dotycząca tego zagadnienia w Polsce.

Cel. Celem pracy była analiza zjawiska IR leków w Polsce, która posłużyła do opracowania modelu obliczeń oszczędności pośrednich i bezpośrednich, wynikających z tego zjawiska.

Materiały i metody. Skrupulatny przegląd literatury oraz analiza informacji publikowanych przez Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych oraz danych będących własnością IMS Health.

Wyniki. Do czerwca 2009 roku w Polsce zostało wydanych 445 pozwoleń na IR na wniosek 18 importerów. Leki z IR dostępne w Polsce są importowane głównie z Grecji, Republiki Czeskiej oraz Francji i są tańsze średnio 10%-60% od produktów pochodzących od producenta. Wartość sprzedaży leków z IR na poziomie cen producenta w 2008 roku wyniosła 82 mln PLN. W oparciu o przeprowadzone analizy ryku IR w Polsce opracowana została metodyka, która posłuży do obliczeń oszczędności wynikających z IR leków w Polsce w podziale na płatnika publicznego oraz pacjentów.

Wnioski. Znaczenie IR w Polsce wzrasta konsekwentnie w okresie ostatnich lat, a w kolejnych latach spodziewany jest dalszy wzrost jego udziału w rynku. Szczegółowa analiza oszczędności wynikających z tego zjawiska zostanie przeprowadzona we współpracy z europejskim ekspertem – University of Southern Denmark. Wyniki mogą zostać użyte do przekonania polskich decydentów, że IR może być źródłem znaczących oszczędności i nowych możliwości dla zdrowia publicznego oraz, że konieczna jest implementacja odpowiednich regulacji prawnych wspierających IR.

Słowa kluczowe: koszty leków, oszczędności, zdrowie publiczne, koszty opieki zdrowotnej, polityka zdrowotna.

Analysis of parallel trade of pharmaceuticals in Poland and its impact on public health

Summary

Introduction. Easy access to pharmaceuticals plays a very important role in public health improvement. Especially in times of global crisis it is amazingly important to look for cheaper sources of medicines. Parallel import (PI) can bring an easy solution to this social need. PI of pharmaceuticals in Poland has been possible since Poland became an EU member. However, until now no comprehensive, scientific paper about PI in Poland has not been published yet.

Objective. The objective of the present paper was to analyse the PI of pharmaceuticals in Poland in order to determine the calculation model for direct and indirect savings as a consequence of PI.

Materials and methods. Thorough literature review and analysis of information published by The Polish Office for Registration of Medical Products, Medical Devices and Biocidal Products and data owned by IMS Health.

Results. Till June 2009 the PI licences have been granted for 445 medicines in Poland for 18 parallel traders. Parallel imported products in Poland are mainly exported from Greece, the Czech Republic, France and, on average, they are cheaper by about 10%-60% than products from manufacturers in Poland. The value of sales, on the level of ex-factory price, from PI was PLN 82 million in 2008. Based on analysis performed, a methodology has been developed which will be used for calculation of savings from PI in Poland divided into public payer and patients.

Conclusion. Importance of PI in Poland has increased consequently during the last few years and in the next years further growth of its market share is expected. Detailed calculation of savings resulting from this phenomena will be conducted in cooperation with European experts in the discussed area – University of Southern Denmark. Obtained results can be used in order to convince Polish decision-makers that PI could be a source of substantial savings and new possibilities for public health and that it is necessary to implement appropriate directives supporting PI.

Key words: drug costs, cost savings, public health, healthcare costs, health policy.

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INTRODUCTION

Parallel import (also called parallel distribution or parallel trade) of pharmaceuticals is an important policy issue in many countries and is surrounded by controversy, in part due to many contradictory stakeholder interests, but also because theoretical literature shows conflicting results and the empirical literature is still scant, albeit growing [1]. Parallel import of pharmaceuticals has existed in Europe since the beginning of the 1970s and it is an important part of health care policy in European countries. Parallel import (PI) may be defined as goods legitimately produced under protection of a copyright, trademark or patent, that are placed into circulation in one country of the European Economic Area (EEA), and then distributed in another EEA country without the permission of the owner of the intellectual property rights [2]. For instance, it is permissible for parallel importer to purchase cheaper medicines in Greece and import them into Poland, where the product is more expensive, without the approval of the domestic trademark owner. We deal exactly with the same drug, manufactured by the same producer, with the only difference in packaging (due to repackaging process necessity). Parallel distributors are the only competitors in the market for branded innovative drugs, which are the most expensive in the market. Due to that reason pharmaceuticals from PI can have significant influence on Budget and budgets of particular patients – and in consequence on public health.

Parallel import can exist if four following conditions are met:

- countries between which parallel trade exists have free trade exchange;
- significant differences between prices exist;
- cost of transport compared with cost of goods is low;
- distribution of goods is separated from a producer [3].

In order to eliminate PI, innovative companies can use one, unified, same level price in all European markets. Nevertheless, it has been proved that diversity of prices generate higher profit than setting one common price for all the markets (so-called Ramsey pricing) [4].

In countries where parallel trade exist for a longer time (Germany, the Netherlands, the United Kingdom, Scandinavian countries) the market share of parallel trader pharmaceuticals is between a few and twenty percent. Also the amount of savings estimated in listed countries reaches significant levels. Additionally, governments of countries mentioned above have appreciated benefits resulting from parallel trade and due to this reason they have decided to implement different kinds of support for parallel importers.

The Poles have impediment access to medicines. In consequence many patients do not always buy all drugs prescribed by doctors [5]. Moreover, they pay for about 67% [6] of medicines out of their own pockets, which is one of the highest share of patients' co-payment throughout the European Union. The World Health Organization (WHO) has said that the health of citizens weakens dramatically when co-payment for medicines exceeds a 40% level [7]. Therefore, there is a relatively big area which can be explored and reclaimed by parallel traders. For those countries where relative access to pharmaceuticals is harder due to their high prices, parallel import can help patients to obtain easier access to pharmaceuticals, especially to modern ones, and to more expensive treatment.

Parallel trade of pharmaceuticals in Poland has been possible since Poland became an EU member in May 2004. However, the first parallel-imported drug was available on the Polish market more than one year later in 2005.

Besides seriousness of PI phenomenon until now there still has not been published an objective, scientific source of information about PI in Poland, especially concerning estimation of potential savings for society resulting from that phenomenon.

OBJECTIVE

The primary aim of the study was to investigate in details PI of pharmaceuticals in Poland, which served as a base for development of methodology for further studies dedicated to calculation of savings resulting from PI in Poland.

Further studies, not discussed in this article, assume also the preparation of appropriate market research among patients, pharmacists and parallel traders and the preparation of the proposal of reliable directives which can be introduced by the Polish Government. Results obtained through these studies will also be used to convince Polish decision-makers to implement appropriate model of support for parallel importers as a source of possible substantial benefits for public health.

MATERIALS AND METHODS

In order to analyse the PI phenomena of pharmaceuticals in Poland the author analysed information published on the website of The Polish Office for Registration of Medical Products, Medical Devices and Biocidal Products (URPL). The second part of the work was dedicated to extraction, processing and analysing of sales data gathered by IMS Health. The data were used to prepare PI statistics in Poland.

Based on principles of functioning of PI in Poland and thorough review of global literature the author has chosen appropriate methodology which will be used for further calculation of direct and indirect savings resulting from parallel import in Poland.

RESULTS

Statistics of parallel import in Poland

Since Poland entered the European Union PI licences have been granted for 445 medicinal products. Statistics regarding parallel import's licences granted in Poland in the last few years are illustrated in Figure 1 and Figure 2.

According to data presented in Figure 1 the number of PI licences in Poland was growing successively between 2004 and 2008. However, it is necessary to remember that granting of parallel import licences is not tantamount to launching those products on the market. Because of continual changes of products' prices on the market and fluctuations of exchange rates, part of products do not meet criterion of profitability necessary to launch product on the market. According to information obtained from Polish Organisation of Parallel Traders currently Polish wholesalers offer about 60 products from parallel import [8].

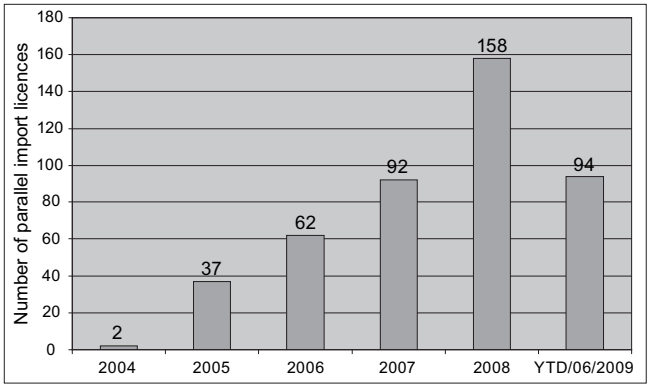

FIGURE 1. Number of PI licences granted in Poland in period of May 2004 – June 2009 (Based on data published by URPL).

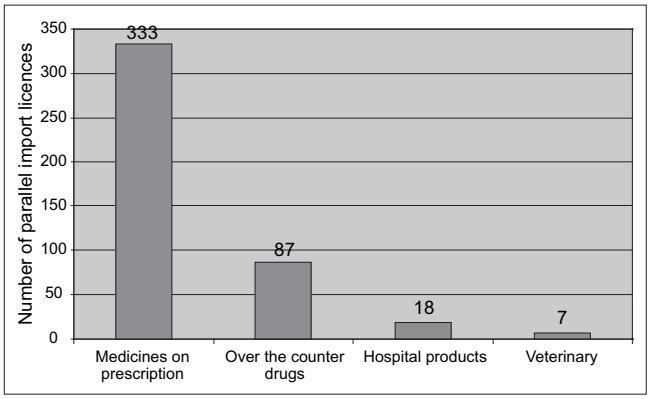

FIGURE 2. Number of PI licences for products from parallel import in Poland according to category of availability in period of May 2004 - June 2009 (Based on data published by URPL).

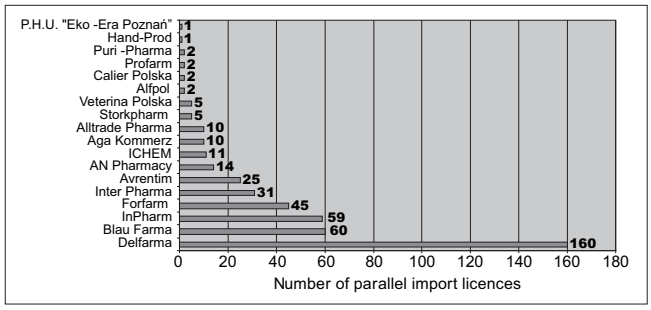

FIGURE 3. Ranking of parallel traders in Poland according to number of parallel import licences granted from May 2004 to June 2009 (Based on data published by URPL).

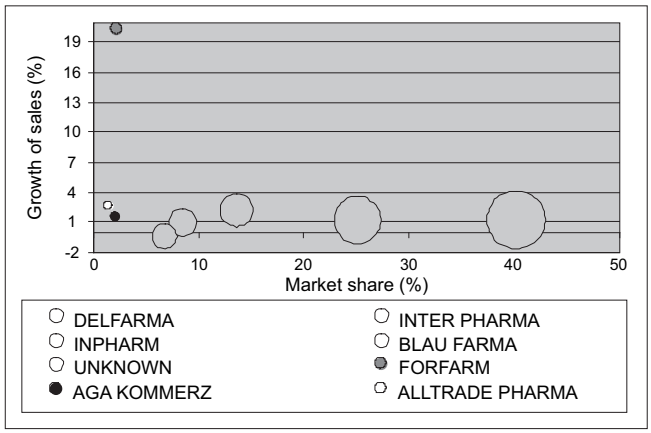

FIGURE 4. Ranking of parallel traders in Poland (sales value at ex-factory prices in PLN in 2008) (Based on data gathered from IMS Health).

Size of a bubble represents value of sales

According to data presented in Figure 2 prescription medicines and over the counter medicines cover 74.8% and 19.6% of granted parallel import licences in Poland, respectively. Hospital and veterinary pharmaceuticals have only 5.6% of the share.

Based on data gathered from IMS Health PI sales in Poland has been analysed taking into consideration category of anatomical therapeutic chemical (ATC) classification system.

The analysis of sales data shows that sex hormones (28.5%), cardiovascular drugs (20.4%), nervous system medicines (16.2%) and alimentary and metabolism pharmaceuticals (11.2%) are the major groups of drugs most frequently traded parallel and cover more than 76% of total PI sales in Poland.

The biggest sales in 2008 were observed for the following medicines: Aspirin, Aspirin C, Cilest, Detralex, Duspatalin, Eurespal, Harmonet, Marvelon and Mercilon. Analysing prices of pharmaceuticals from parallel trade available on the Polish market, one can observe that they are cheaper by about 10 to 60% than drugs offered by innovative companies.

According to the data from The Office for Registration of Medical Products, Medical Devices and Biocidal Products, there are 18 parallel traders who currently operate on the Polish market (Figure 3).

Figure 4 shows ranking of sales of parallel importers and their sales growth in 2008.

According to data presented in Figure 3 and Figure 4 Delfarma is the parallel trade leader in Poland. Delfarma is a wholesaler, based in Łódź, with 160 PI licences and about 40% market share. Warsaw-based companies: Blau Farma, InPharm, Inter Pharma and Forfarm also have significant position on the market. The rest of parallel traders have trace amount in total number of PI licences.

Pharmaceuticals offered by parallel importers in Poland are exported from a few countries of EEA, where prices of drugs are lower than in Poland and/or exchange rate to local currency is profitable for parallel traders. Those countries are: Greece (31.2%), the Czech Republic (16.2%), France (12.1%), Great Britain (11.5%), Hungary (6.3%) and Spain (6.1%). Figure 5 presents detailed information about the EU countries which are chosen by Polish parallel traders as a source of cheaper pharmaceutical products.

Parallel traders conduct unremitting research of new sources of cheaper drugs which are profitable for them. As a consequence of their actions one can see new countries like Italy, Germany or Slovenia on the list of countries which are the origin for parallel import.

Parallel trade has increased in Poland during the last few years. PI market share increased by 100% within just a year and a half (from 0.3% in December 2007 to 0.6% in July 2009).

Sales of PI in Poland has increased consequently during the last few years. The value of sales from PI reached a level of PLN 82 million in 2008 (sales at ex-factory prices).

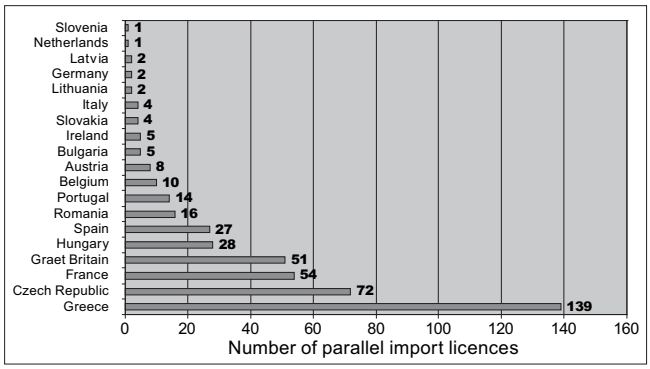

FIGURE 5. Ranking of countries which export pharmaceuticals to Poland through parallel import (number of PI licences in period May 2004 - June 2009) (Based on data published by URPL).

It should be stressed that the sales level of PI medicines in the first six months of 2009 has already reached almost PLN 53 million, which could be a promising indicator of further growth of PI sales in 2009 compared to the previous year. Detailed information concerning development of parallel trade market in Poland is presented in Figure 6 and Figure 7.

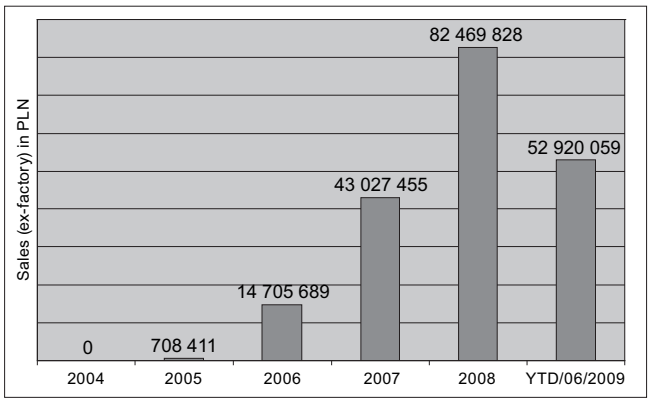

FIGURE 6. Parallel import market in Poland (sales value at ex-factory prices in PLN) (Based on data gathered from IMS Health).

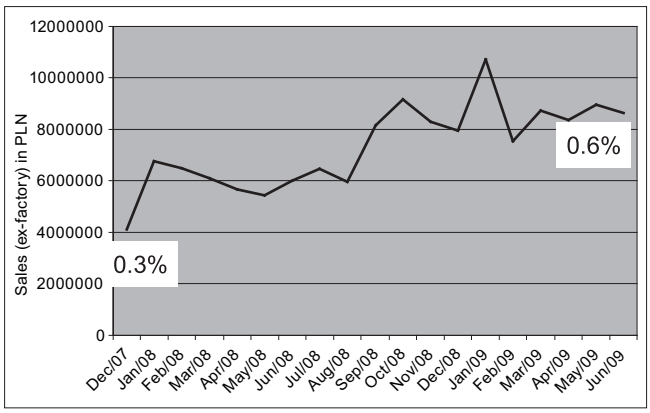

FIGURE 7. Parallel import market in Poland (sales value at ex-factory prices in PLN) (Based on data gathered from IMS Health).

Benefits of parallel trade in Poland

For the countries where PI has existed for more than 10 years the amount of savings has been estimated in a few studies. The savings connected with parallel distribution were calculated in three large studies: the University of York study (York study) [9], the London School of Economics (LSE study) study [10] and finally the University of Southern Denmark study (Danish study) [1]. However one can observe significant dissimilarities between research results which are brought about by the following:

– different methodologies used,
– different intentions of authors, and
– different time periods of surveys.

The detailed results of York, LSE and Danish studies' reports are shown on Figure 8.

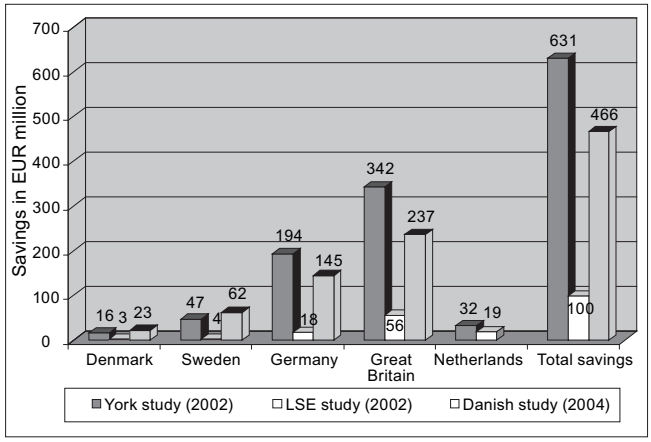

FIGURE 8. Estimated direct and indirect savings resulting from PI according to particular reports (EUR million).

Until now, an objective, scientific source concerning estimation of potential savings for society resulting from PI in Poland has not been published. However, according to analysis prepared by Delfarma, savings due to parallel trade in Poland were assessed on the level of PLN 30 million in 2007. Within this savings PLN 25 million is a result of indirect savings and PLN 5 million is due to direct savings [11]. Moreover, since July 2008 first drugs from parallel import are also on the reimbursement list. It also means savings for the National Health Fund, thus for all taxpayers.

Detailed literature review regarding parallel import in different European countries, meticulous analysis of studies concerning savings resulting from PI and deep understanding of PI principles in Poland lead us to decide on adjusting methodology used by Danish team for our further studies (calculations of direct and indirect savings resulting form PI in Poland with division into public payer and patients). Therefore, during the next several months preparation of detailed calculation of savings from parallel distribution in Poland during 2005-2008 in cooperation between Medical University of Warsaw and University of Southern Denmark is planned (part of the PhD thesis which is being prepared by the author).

DISCUSSION

Parallel import has more than 30-year-long history in Europe. Total value of parallel trade in Europe was estimated to amount to EUR 1,4 billion in 2008 [12], causing a substantial decrease of cost of treatment in the last few years. According to the reports concerning benefits of parallel trade this activity gives significant direct and indirect savings in national Budgets.

According to calculations made by parallel traders, estimated savings resulting from parallel distribution in Poland in 2007 are at the level of PLN 30 million. Moreover, since July of 2008, drugs from parallel import are on the reimbursement list. It also means some savings for the National Health Fund, and in consequence for all taxpayers. Additionally, it means that organisations responsible for health care system can invest saved money in new, modern treatments.

In the situation when in Poland many patients do not buy all drugs prescribed by their doctors due to lack of money, it seems to be an extremely beneficial idea to promote cheaper medicines from parallel distribution. Especially worse-off senior citizens seem to be the major group of customers interested in a source of less expensive drugs. Unfortunately, patients in Poland still have little knowledge about PI and its rules. Therefore, they are sceptical about medicines in white, less attractive and not advertised packaging.

CONCLUSIONS

In Poland parallel trade has existed for 5 years. Importance of PI has increased during the last period. PI market share has increased by 100% within almost one and a half year; however, currently its market share is still relatively low – 0.6%. There is a significant potential in parallel import development and the growth of its market share and value of sales could be expected in the next few years.

For many years subsequent governments of Poland and other countries all over the world have searched for a good solution for sufficient and equal health care. Unfortunately, the biggest problem to overcome is lack of sufficient amount of money. All specialists and Ministry of Health's advisors are constantly searching for areas of potential savings. One possibility is to decrease expenditures on drugs. PI appears to be a perfect solution for that problem. Using parallel trade a patient can buy drugs of the same quality which are substantially cheaper. Such an approach can be beneficial for both patients and the National Health Fund. Patients can save some money in their pockets and the NHF can use savings to support other activities in health care system in Poland in order to improve equal access to the best treatment for the whole society.

Unfortunately, the lack of knowledge among patients, lack of interest among pharmacists and lack of awareness of PI principles and benefits among decision makers inhibit faster growth of PI in Poland.

Therefore, it is necessary to build awareness of PI among different participants of pharmaceutical market and implement a reliable model of support for parallel importers by means of appropriate directives introduced by the Polish Government.

In order to convince decision-makers that parallel import could be a source of substantial savings a detailed study concerning savings is going to be conducted according to methodology selected in this study. The further analysis assume carrying out a market research among pharmacists, patients and parallel traders in order to deeply understand principles of functioning of parallel import in Poland.

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