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Regulating Pharmaceutical Prices in the European Union

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Abstract

This case study aims to provide a better understanding of the necessity for regulation in the market for pharmaceuticals and to reveal the impacts of parallel trades in the European Union and how they may affect markets in the future. The pharmaceutical industry up to now has largely been regulated. Although the EU is a single market, it still has variable prices for pharmaceuticals. Consequently, the price gap and other EU-specific factors have created a great environment for parallel trades. The author has confined this study to the price regulations inside the EU before the enlargement in 2004.

Keywords: regulation, pharmaceutical market, European Union, parallel trade

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Introduction

There are a multitude of reasons for regulation as participating stakeholders pursue different goals. From the perspective of government the most important objectives of regulations are expenditure control, quality and access (Maynard and Bloor, 2003). Governments in the EU frequently offer a list of reimbursable drugs and provides access to them for anybody who might not be able to pay the full price. Thus, it is obvious that people's price sensibility plays an important role when governments attempt to regulate the market. Additionally, stringent development testing must be conducted – to comply with high quality standards – before a potential drug would reach the market in order to identify both potential positive and negative effects as well as side effects. The versatility of regulations is reduced to the scope of regulations dealing with pricing within the European Union.

Drug companies want to present themselves as entities which contribute to the improvement of the quality of life worldwide. They created various corporate slogans to persuade people of the necessity of their drugs, e.g., "Life is our life's work", and "We're part of the cure". The reality however suggests that these slogans are commercialized and introduced to obtain larger market shares in the market for pharmaceuticals rather than caring about the patients' health. Even though it is obvious that drug companies spend billions of dollars on research, it should not necessarily lead to predatory marketing. They undoubtedly could use – and largely use – legally allowed methods to influence governments that their products were the best alternative to be subsidized.

The companies in this sector will continue to fight for and to protect their market shares, even if they may endanger the patients' lives. Numerous cases were brought to court, where the patients won the lawsuit – sadly – usually after huge negative impacts on human lives. Still they would rather follow aggressive tactics trying to lower the initial cost of developing new drugs. (Un)surprisingly innovative drugs may have no other effect than the ones developed earlier, but companies replace them in order to generate higher profits through price skimming strategies. The replacement happens as long as the older products

continuously reach a price – as prices fall gradually – that is near to their marginal costs (Reekie, 1997). When a new drug appears in the market after obtaining approval, the drug manufacturer may not care about the proper dosage, but wants to boost the profit and the impact of the newly introduced drug on their balance sheets. They rarely care about the so important and many times emphasized balance of the human body (Olivieri, 2003). Only recently has more attention been devoted to traditional (also herbal) drugs which as a result face a huge growth in demand. Unlike profit oriented companies, producers of such pharmaceuticals have a solid base of production with thousands of years old approved herb and of natural techniques (Jia and Zhang, 2005).

Regulation in markets have been established for a long time. While Smith described in his theory a self-regulating mechanism as an “invisible hand”. In addition, neoclassical economists already had insisted that the existence of “invisible hand” was vital. Maynard Keynes stated in his book “The General Theory of Employment, Interest and Money”, that the uncontrolled price mechanism would not work, so it was normally in disequilibrium and that should be corrected by the government.

On the contrary, the monetarists argue that there is no need for intervention since they only have short-term effects and in the long-run may even lead to a potential negative effect on the price level and on the GDP of the specified country or group of countries. These arguments blur in the case of public interest, such as health (Palley, 2005). In this case actually the public goods are meant to be available for everybody at an affordable price. For that reason governments attempt to negotiate with suppliers of pharmaceuticals in order to reach a consensus related to the state-subsidized pharmaceuticals (e.g., reimbursement schemes).

Parallel trade in the European Union

This kind of legalized business is possible within the boundaries of the European Union as one of the major pillars, namely the free movement of goods and exhaustion of related rights, and is provided by the Treaty of Rome to the parallel exporters. Exporters buy the authorized pharmaceutical products in countries, where the price is significantly lower than in

the target country; then they repack the products if necessary, and supply to the countries with higher prices. They simply undercut the prices of the target countries. This activity is not new in the EU. Exporters have certain advantages besides simply the cost advantages. They usually do not need to go through a second marketing authorization procedure. But, of course, the pre-condition is that the product is identical or almost identical with the local product in the target member state, where this product has a same standard as the imported one.

Before a medicinal product is placed on the market of any country in the EU, it must obtain marketing authorization. This requires the detailed information of the safety, quality and efficacy of the given product. In the EU the authorization can be issued either by one of the national regulatory authorities in accordance with Directive 2001/83/EC or by a centralized authority in accordance with the Regulation 2309/93/EC (EU 2001). The latter one allows the exporters directly to purchase the product and sell it, since it refers to the entire EU market. The states' reimbursement system – that will be exploited – gives only the allowance to specified packages of the certain drug and, therefore, the package has to be modified with the official language for the product information. Occasionally even the package size has to be changed.

Parallel traders are often faster than manufacturers in launching their products in a particular European market. Initially the manufacturers did not count on such a rapid re-importation of their products since they believed that the traders also need significant time to evaluate the market, and determine the profit potential. However, this happened in the early phase of the parallel exportation, and since then parallel traders have become more and more sophisticated and quick. They even may be able to identify the future blockbusters before the manufacturer or the wholesaler launches them and they obtain licences rapidly. Since they sell directly to wholesalers, they can process the deals fast and load up stocks often before the manufacturer can step into the national market with the new product (Haigh, 2002).

Several years ago, the threshold was supposed to be at 20% price difference, but the IMS Health (Haigh, 2002) has discovered remarkable cases as well, e.g., importation of

pharmaceuticals having higher prices on paper in the source country than in the country of importation. This certainly was not understandable at first glance, but investigations discovered that the primary purchaser in the source country was a hospital and these particular medicinal products were discounted at these institutions. It was the hospital stock which was sold at a higher price in the other country (Haigh, 2002).

In 2004 there were 25 countries between which these products can be dealt in parallel. Manufacturers simply tried to spread the belief that their items have different quality according to the pricing. Accordingly, they attempted to make people believe that the products having lower prices in other states also have inferior quality compared to the products which they put into the market by themselves. But the products were and are most of the times identical and the only difference might have been that the package and/or package size was/were designed in a different way. The European market has the same high quality requirements everywhere, which must be fulfilled by the manufacturers.

Currently not just the sales of branded products suffer from the lower profits, but the traders also found the way of making more money by non-branded, generic, drugs. On parallel trades the off-patent products mean a certain threat as traders cannot sell their products so easily due to the high competition among generic products. Still when the parallel trader found a way of supply from a source country, where the price is a little lower, the product found its market in the – still high-priced – market. Through their re-importation activities the price gaps among countries have been narrowing and probably – but not necessarily – will lead to a single common market price in the future. Parallel traded pharmaceutical products are of quality and well-packaged. They cannot be distinguished from the branded products coming from the manufacturers through their actual distribution network. The market has been growing and reached about 5% of the total European market in 2002 as Figure 1 reveals.

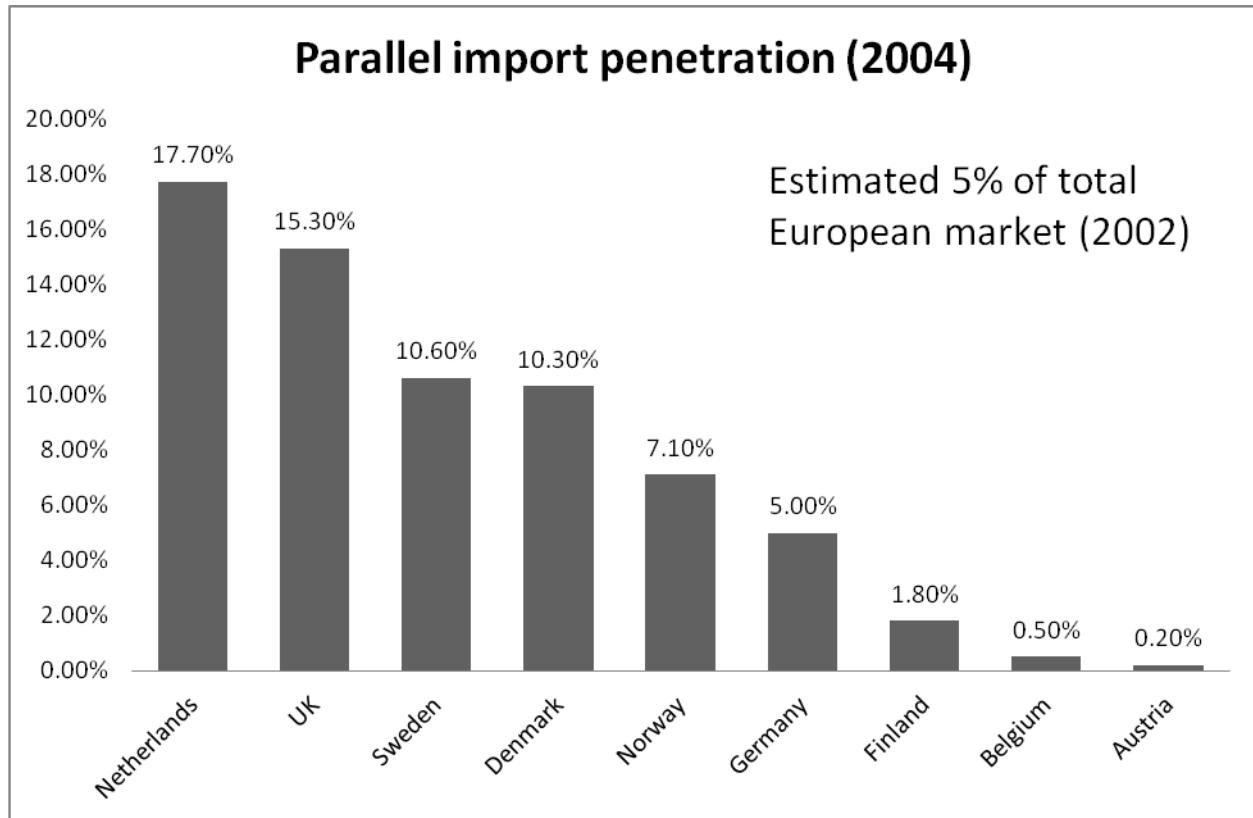


Figure 1: Parallel Import penetration (EAASM, 2007)

This European phenomenon is growing and will probably become a global one in the future. After parallel trades reach a significant level governments have tended to introduce different regulations to tighten parallel trades or to reduce price differences between parallel-traded pharmaceuticals and products that came through the traditional distribution channels. Accordingly, parallel traders pulled out slowly from one market and attempted to tap into other markets. The high growth represented by Figure 2 for Greece accounted for its parallel export share in its market for pharmaceuticals. The growth in Sweden slowed down while the UK and Germany reported the highest growth between 1998 and 2002 (Kanavos et al, 2004).

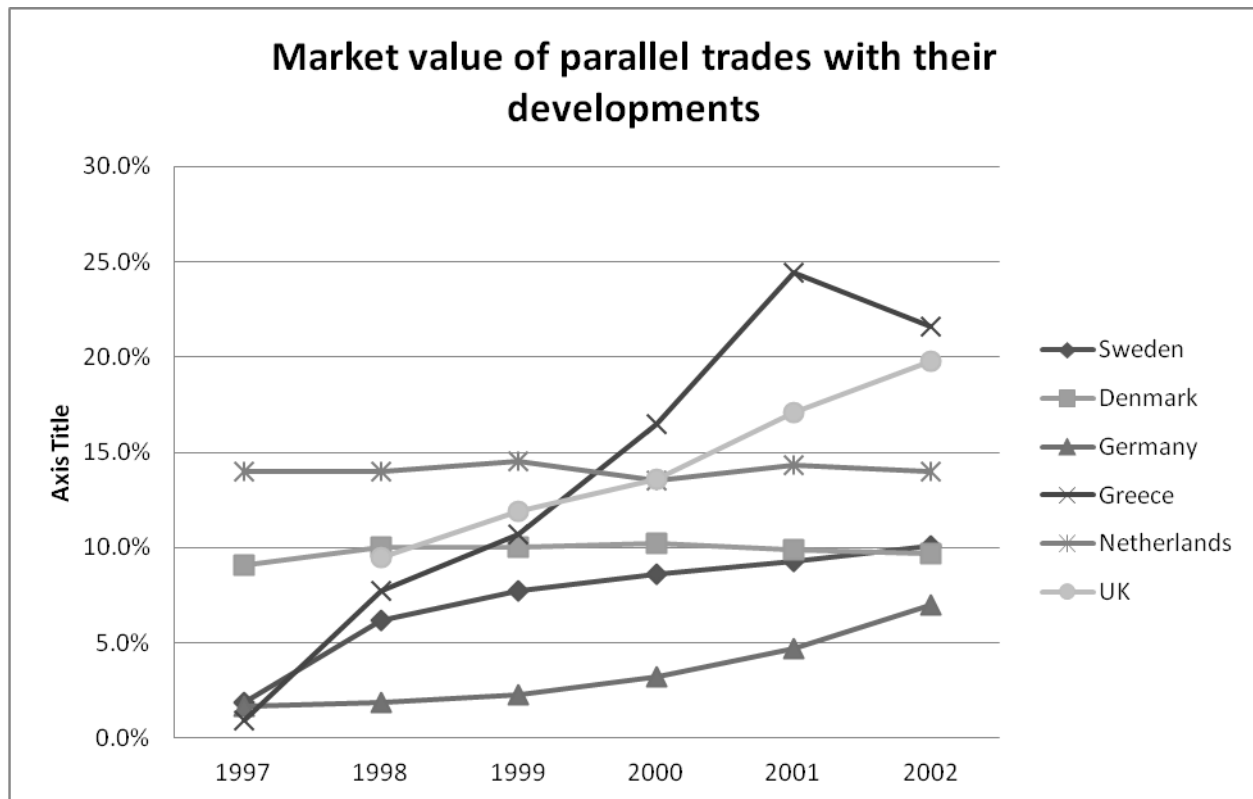


Figure 2: Development of market share in parallel-trades in a few EU countries (Kanavos et al, 2004)

Not only price matters

Most of the regulation schemes of pharmaceutical markets – introduced by governments – are so complex, that even experts have problems in using them properly. Any intervention in the price setting mechanism driven by the “invisible hand” may only have short term effects and might not lead to the expected low prices at the highest general welfare. Nevertheless, governments in welfare states have to contribute to the satisfaction of demand in a socially sensible industry such as the pharmaceutical one significantly. From this point of view a combination of price reference schemes and profit control systems like PPRS seems to be the most effective and consumer-friendly, even if they may not be transparent enough (Ess et al, 2003).

Parallel trades became the consequence of complex and diverse price regulations within the European Union. The parallel trades exploit the loopholes in the law of the EU and if one market shows unfavourable tendencies traders seek for other opportunities, i.e., a solution of the problem concerning parallel trade is rather impossible during the following years. Besides, parallel trades can contribute largely to a single price or at least to less difference in prices. Danzon and Towse (2003) argue that confidential contract between the demand and the source side could wipe out parallel trades in order to maintain profit and to be able to develop new pharmaceuticals. Whereas both sides may be correct, the author considers parallel trades as not the real source of danger while fake pharmaceuticals are and the trades just started through the globalization process. This is likely to affect the major markets of the pharmaceutical manufacturers in the future largely (Balfour et al, 2005).

Although price is a major factor, it is not the only factor for the parallel trading activities. Spain is considered as one of the cheapest states for medicinal goods and UK is as one of the most expensive states. But many times, where there is just a bit price difference, the items still can bring profit for the trader companies.

The factors, which a parallel trade can depend on:

- Product price
- The sales volume in the source country
- The sales volume in the destination country
- Price differences between the two countries
- The way to acquire the product – whether it is easy (Haigh, 2002).

Since not just the price difference is a necessary pre-condition, other pre-conditions also must be considered:

- It is important to determine the volume of supply for the particular product in the market of the destination country.

- Whether regulatory conditions allow to make an adequate profit in both, the exporting and the importing, countries.
- The transportation costs between the two markets.
- Legal and regulatory conditions to allow the importer to place the product on the host market.
- As last but not least the importance of the acceptance of the product on the market by the patients, pharmacists and wholesalers

After the parallel traders could make so much profit, the manufacturers looked for possibilities to fight back and took legal actions. According to the judgement in UK there is an important distinction between the application of trademark law and relabelled pharmaceutical products and the repackaging of those.

“With that background, the judge held that all repackaging was to be treated as harmful and would only be permitted where it could be shown to inflict the ‘minimum collateral damage on the [trademark and] should be as unobtrusive from a trademark point of view as possible.’ The judge considered that at least two forms of packaging satisfied this requirement”:

- Imitation Packaging: Packaging whose design imitates the design of the original packaging in all ways, but for the features have no trademark significance e.g., translation of the words from German to English.
- Blank Packaging: Completely plain boxes telling nothing except the proprietor’s trademark. (Wearing et al, 2004)

When can a manufacturer oppose repackaging?

As mentioned above, the court also investigated different cases and made a way of repackaging still available. Whether the pharmaceutical producers can oppose the activities of traders successfully or not depends on the following factors:

- Whether the parallel trader considers itself as the proprietor of the trademark and whether it gave a prior notice that the repacked pharmaceutical product will be put on sale, is a sample supplied?

-> If not, the manufacturer is entitled to oppose the marketing of the repackaged pharmaceutical product.

- Is the package design so that it protects the legitimate interest of the owner of the trademark?
 - Does the repacked product have any effect on the original condition by advertising it?
 - Is the repackaging adequate so that it does not cause any harm for the trademark (e.g., the packaging must not be defective, of poor quality or untidy; 'de-branding' and 'co-branding' must be avoided)?

-> If not, the manufacturer is entitled to oppose the marketing of the repackaged pharmaceutical product.

- Does the package show clearly, who repacked the product itself and who is the manufacturer?

-> If not, the manufacturer is entitled to oppose the marketing of the repackaged pharmaceutical product.

- "Would the trademark proprietor's exercise of his rights amount to a "disguised restriction on trade" (i.e., would it contribute to the "artificial partitioning" of the markets between Member States)?"
- Is a repackaging "objectively necessary" for the parallel importer to obtain an "effective access" to the market of the importing state?

-> If not, the manufacturer is entitled to oppose the marketing of the repackaged pharmaceutical product (Wearing et al, 2004).

But if the above written criteria are met the manufacturer is not entitled to oppose the marketing of the repacked product.

Questions

- 1) What are the current developments of parallel-trades in the EU?
- 2) Consider if there is any imitation of parallel trades of pharmaceuticals on other continents. If there is, what are the similarities to the European case?
- 3) Are price regulations necessary in a market like the markets for pharmaceuticals?
- 4) Are governments able to lower or stem the increase of their pharmaceutical expenditures by regulating their pharmaceutical industries?
- 5) Do parallel trades reduce price differences between countries? Do the prices lead to a better price control?
- 6) Does parallel trade contribute to welfare at the end?

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