Parallel trade in medicinal drugs is putting the welfare of EU patients at risk

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The term 'parallel trade' refers to instances in which a product sold for a low price in one country is bought and transported to a second country in which the same product sells for a higher price, allowing for a profit to be made. **Joan Costa-i-Font** writes that the EU's single market has helped facilitate this practice in Europe with respect to the trade in medicinal drugs. He notes that one of the potential dangers of parallel trade is that shortages of certain drugs could develop in countries where prices are low due to companies buying up products and exporting them to more expensive markets.



Different regulatory regimes for pharmaceuticals result in significant differences in pharmaceutical prices across European countries. For instance, unrestricted pricing of medicines in Germany gives rise to higher prices compared to countries that regulate medicine prices such as Italy, Spain and France.

This would not be a problem if markets were segmented and prices were fixed (reflecting relative need and demand). However, medicines fall into products that are subject to single market regulations. Hence, some distributors find it lucrative to create a parallel distribution channel made up of products intended to be distributed in other European countries at lower prices. The latter gives rise to 'parallel trade', which was estimated to amount to €5,465 million (value at ex-factory prices) in 2012. Parallel trade accounts for up to 23 per cent of total medicine sales in Denmark, 10 per cent in Sweden, and around 10 per cent of sales in Germany and the United Kingdom, as shown in the chart below.

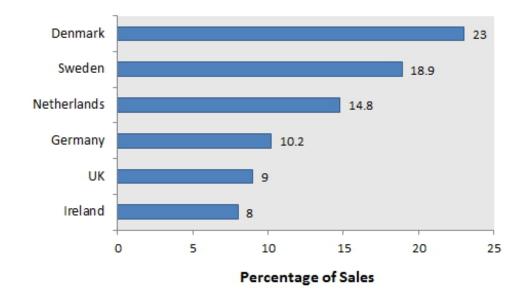


Chart: Percentage of 'parallel imports' in pharmacy market sales in selected European countries (2012)

Source: EPFIA

A parallel imported medicine may be distributed under a licence obtained through a simpler procedure than that for the initial marketing authorisation for the product, provided that the parallel sales do not pose a risk to public health.

The European Commission accepts that parallel trade is lawful based on the principle of the free movement of goods, provided that it does not pose a threat either to public health or to industrial and commercial property. European courts have repeatedly ruled against different strategies to deter the evolution of parallel trade. These include ruling against dual pricing or against vertical agreements between manufacturers and distributors that prohibit parallel exports, on the grounds that they violate Article 81 insofar as they constitute abuse of a dominant position.

In the European context, parallel trade can give rise to legal conflicts as medicines are regulated by each country in accordance with the principle of subsidiarity. Hence, unlike in unregulated markets, such differences in price cannot be arbitraged out directly, and can lead indirectly to inefficient price uniformity across European countries. This is what appears to be happening across Europe, which ultimately impacts on the welfare of low income and high need countries that could benefit from lower medicine prices.

Parallel trade is in this context regarded as 'regulatory arbitrage' and studies find it has only limited effects on patients and health insurance systems, and on the prevalence of lower prices. However, the question of who benefits from parallel trade is complicated by a large array of non-transparent discounts and rebates. Similarly, some companies have introduced strategies to alter the presentation of medicinal products in each country to increase the costs of parallel trade. Finally, if companies limit the distribution of a particular type of medicine it can generate shortages as products are exported from cheap markets to more expensive ones, creating serious problems in cases where a particular treatment is urgently needed.

Similar effects in North-America

Parallel trade also has importance outside of Europe: in particular, there have been frequent discussions with respect to the welfare effects of US-Canadian parallel trade for products that are available in both countries. In this regard the impact depends largely on whether pharmaceutical firms may legally ration supply to Canada.

In the case of the US, the question largely relates to whether they wish to maintain a system based on free pricing, or whether they prefer to move toward some form of price regulation that reduces the incentives for parallel trade to take place. In a joint statement in late 2006, several Canadian interest groups reacted to the possibility of legalised parallel trade by asking for an export ban to protect Canadian patients and Canada's drug supply.

Consequences of parallel trade

The inclusion of regulated and publicly funded goods and services such as medicines in the EU's single market has generated some important policy questions: namely whether we should allow arbitrage (parallel trade) to take place even when we know its wider effects may be undesirable.

The proliferation of parallel trade is encouraging the elimination of country specific price regulation and the adoption of single prices across Europe for new medicines. This is occurring in part as a result of strategic decisions by companies to launch new medicines in high income countries, and as a consequence of the adoption of 'external referencing', whereby prices in other, generally high income countries, are taken as a reference to set the price across Europe. A single European drug price is therefore increasingly becoming a reality, for better or worse.

Nevertheless, one area in which there are some potential benefits from parallel trade is that of generic medicines. Generic products are no longer under patent protection and refer to substances that launched some time ago, where the gains from keeping price regulation country-specific are less clear-cut. Some evidence suggests that strategies to reduce the price of generic medicines (such as by using reference price mechanisms) often fail to have the desired effect and in these instances the pressure from competition brought on by parallel trade could potentially play a role.

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Joan Costa-i-Font is an Associate Professor (Reader) in Political Economy at LSE. His research is on the economic analysis of welfare institutions, health, health care and aging, with a particular focus on Europe. He is co-editor of the *Applied Economics, Perspectives and Policy* (AEPP) journal.



