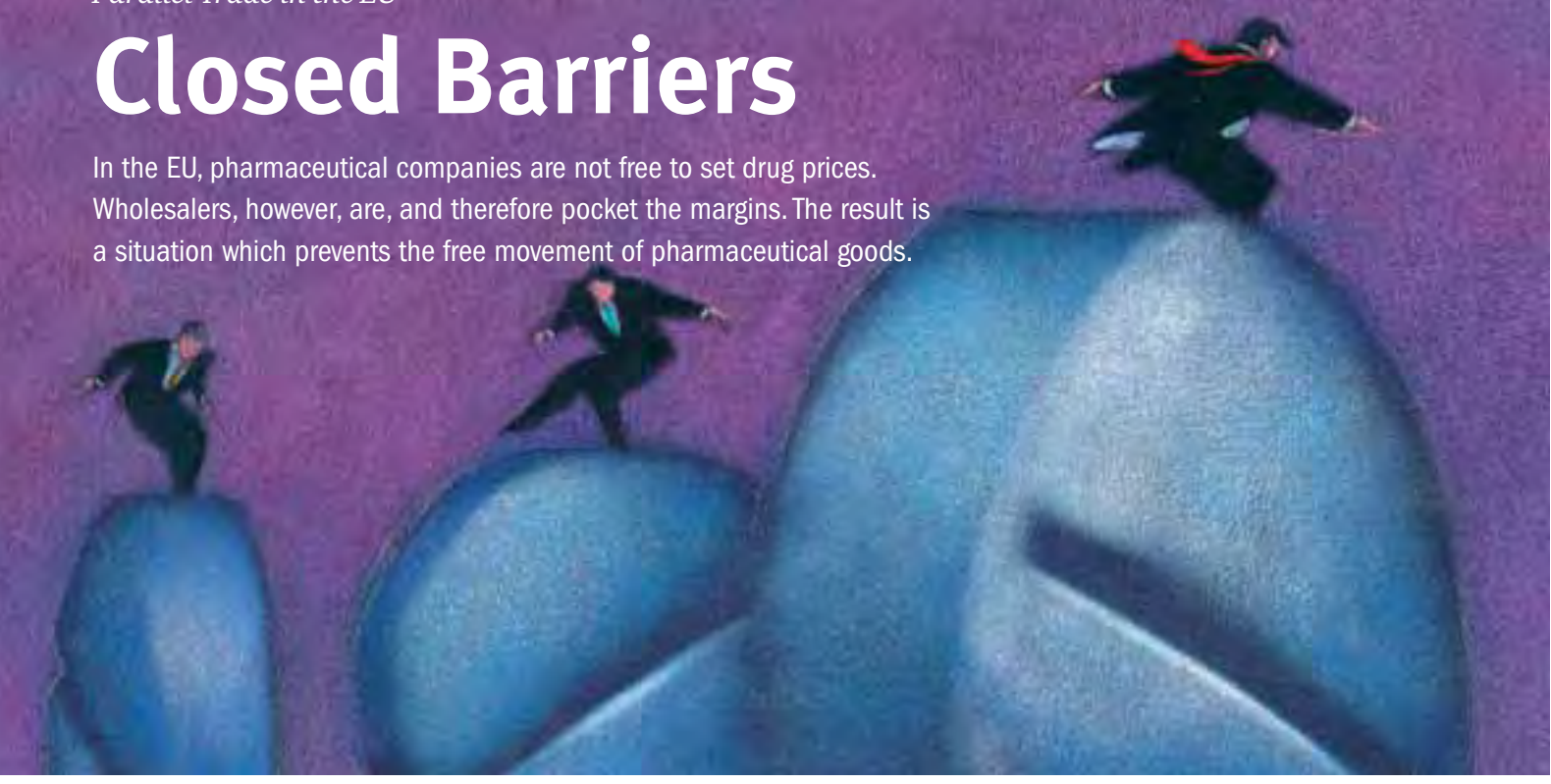
Parallel Trade in the EU

Closed Barriers

In the EU, pharmaceutical companies are not free to set drug prices. Wholesalers, however, are, and therefore pocket the margins. The result is a situation which prevents the free movement of pharmaceutical goods.



In abandoning trade barriers and establishing regulations that promote cohesion, the European Union created an environment that encourages parallel trade. Parallel trade occurs when products are traded within the EU, from a country in which prices are low to a country where they are high. The free movement of goods is guaranteed by the Treaty of Rome of 1957 (see next page below) and seen as a fundamental basis of a single European market. Parallel trade is thought to increase competitiveness by helping the most efficient producers to sell their products in EU-wide markets and was consequently a welcome side effect of trade regulation. The pharmaceutical industry, however, is less than delighted. This is because pharmaceuticals are not free to set drug prices and it is third parties, the wholesalers, who pocket the margins. In this article we will examine the impact that parallel trade has had on the industry and the consequences of a recent court ruling.

Wholesalers grab the profits

Despite perennial claims that drug companies are ruthless and profit-obsessed, they undoubtedly suffer more than other industries from parallel trade, as they have no mechanism for reaping the increased profits that the system produces (unlike wholesalers, who make extra cash by re-importing drugs). Wholesalers benefit from a scattered market of different prices in different countries. In this lucrative market, wholesalers are well organised into big international companies. As a consequence, part of the margin goes to the re-importer and not the producer who invested in research and development (R&D).

No single European market for the pharmaceutical industry

Whilst broadly supporting the idea of a single European market and standardised regulations to increase competitiveness with US and Asian markets, the pharmaceutical industry finds itself in a market a long way from being unified. Prices are regulated neither by the producer nor by market forces, but by national health regulations, which are subject to government control. This is because health care is left exclusively to national legislation, with not the consumer but the state or health care provider funding treatment and medication. In effect, prices are not set by the producer but by a representative of the consumer. The European pharmaceutical industry therefore remains one of the very few industries subject to government control while at the same time being entirely privately owned. Consequently, public health interests still lie mainly in the hands of privately owned companies, causing a dilemma for legislators: should they legislate for the benefit of citizens or for the commercial interests of the industry? Let's face it, commercial institutions, however beneficial their contribution might be, cannot act in the same manner as public institutions, since their shareholders must be their priority. Unsurprisingly, parallel trade is one of the main concerns of the pharmaceutical industry in the context of a unified European market.

Different health care systems

So what exactly is the difference between the pharmaceutical industry and other industries within the EU? In general, trade increases economic welfare by permitting consumers in importing countries to exploit the lower prices created by either more efficient or lower-cost producers in exporting countries. In the pharmaceutical industry, however, lower prices do not necessarily reflect higher efficiency or lower cost production but more aggressive regulation. Countries with a lower GDP tend to set lower prices for pharmaceuticals; differing health care systems also have an influence on pricinge policies. So what about the argument that parallel trade increases competitiveness in free trade areas? Many argue that competition law would make sense in a liberalised market; however, there is no such market for European pharmaceutical companies.

Let's look at parallel trade in more detail. In an ideal free market we can assume that the lowest price at which a product is sold is the price that the producer will get. In countries where the price happens to be higher, a parallel trader will import the product, which he has purchased at the lowest possible price elsewhere. This does not necessarily mean that the consumer will get the product for this or a similarly low price in his home country, as the parallel trader might decide to sell it for a slightly lower price than the producer is demanding in the high price country. However, this margin will go to the parallel trader and not to the producer. Transferring this model to the pharmaceutical industry means assuming that ten European countries will have ten different prices and that the pharmaceutical company will get no more than the very lowest price at which one of these countries offers its product. In effect, there is little or no incentive for a pharmaceutical to charge different prices in different countries.

Is this what we really want?

One could argue that this is just what we want: a cohesive approach towards competitive prices amongst all member states. Unfortunately, this overlooks several important facts. Firstly, and probably mostly importantly, nobody can force the pharmaceutical industry to sell its products in a particular market. So a pharmaceutical company might think twice before making a certain drug available in a low price market if the consequence would be lower revenues in all other EU member states, as it has to plan for the worst-case scenario that this market would supply all other markets. This in turn would exclude citizens of lower price countries from innovative treatment. Apart from ethical explanations, the reason that this does not happen is the fact that not only does no ideal single European market exist but also no ideal environment for parallel trade. Another argument against a policy of low and equal pricing is that the pharmaceutical industry loses out on refunding its immense R&D costs, with a huge margin of the profit going to traders who have neither invested in R&D nor otherwise contributed to the development of the drug. The pharmaceutical industry most likely would still be able to pay for its production costs, as these are usually low compared to earlier R&D investments. However, they would fail to accumulate revenues to invest in future innovation. Finally, living standards differ enormously throughout the EU. Cohesion is far from complete, so a 'one-size-fits-all' model of drug pricing is hardly appropriate.

Thus, parallel trade can be seen firstly as a conflict between the autonomy of member states to set pharmaceutical prices within their own country and the principle of free trade within the EU, and, secondly, the industrial policy goal of promoting innovative research and development within the Union on the one hand and the aim and need of the pharmaceutical industry to make profits on the other.

Pharmaceuticals protect their income

Here the pharmaceutical industry comes into the game, with various unsurprising attempts to protect their income. For example, some pharmaceutical companies are restricting their supply to specific countries whilst trying to hinder imports to other countries. Several legal cases arising from this strategy are still with the European Court of Justice, which is struggling to resolve the conflict. Pfizer has chosen a slightly different approach and decided that from June 2005 it would distribute its products in Spain directly to pharmacies and bypass wholesalers completely. This has already caused and is certain to cause further complaints from wholesalers and the Spanish pharmacist body, FEFE, that supply to patients might no longer be guaranteed. Pfizer, however, states that its new supply policy complies with all applicable Spanish and EU laws. Whether the law is being applied correctly is still not entirely clear. It is obvious why companies like Pfizer choose this approach. It would, however, have a huge impact on the industry and health market if many were to follow Pfizer's example. Pharmaceutical companies would need to build up in-house distribution systems and wholesale companies would become redundant or would at least face significant losses.

A Spanish case study

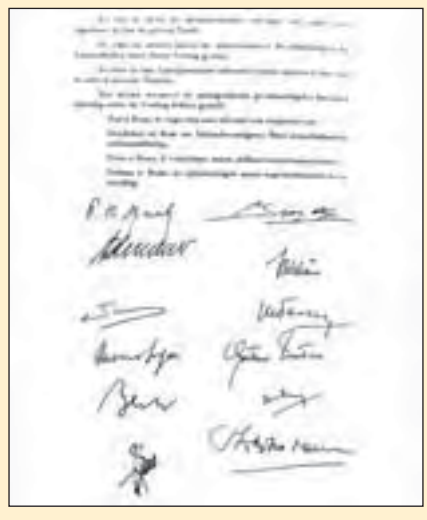
In 1998 a Spanish subsidiary of the GlaxoSmithKline group (GSK), one of the world's leading producers of pharmaceutical products, adopted new general sales conditions. These, stipulated that its medicines would be sold to Spanish wholesalers at prices tied to the national health insurance scheme, which would reimburse them. In practice, this meant that medicines reimbursed in other member states of the Community would be sold at a higher price than those reimbursed in Spain. This would make the parallel trade of these drugs less attractive and should therefore limit par-

The new Glaxo SmithKline headquarters in Brentford, Western London, UK.

Flashback: The Treaty of Rome, 1957

The Roots of the European Union

On March 25, 1957, the prime ministers of six European countries (France, West Germany, Italy, Belgium, the Netherlands and Luxembourg) laid the foundation stone for the European Economic Community (EEC). In Rome, they signed the *Treaty establishing the European Economic Community* (now generally called **the EC Treaty**; see right), with the aim of establishing a customs union, based on the "four freedoms": *freedom of movement of goods, services, capital and people*. Despite the widening of the Union from 6 to 27 member states, most decisions taken by the EU's institutions still rest on the legal basis of the 1957 EC Treaty. -WK-



allel trade between Spain, where the administration sets maximum prices, and other member states, in particular the United Kingdom, where prices are fixed at a higher level. GSK notified the European Commission of its plans in order to obtain either a statement declaring that the new sales conditions were allowed under Community competition law or a decision granting them an exemption. Not surprisingly the Commission quickly received a number of complaints about GSK's request from Spanish and European wholesalers' associations, which rightly feared losing their foothold on this lucrative market.

In 2001 the Commission decided in favour of the wholesalers, ruling that GSK's sales conditions infringed competition law and did not merit an individual exemption. It therefore ordered GSK to bring the practice to an end. The only positive outcome for GSK was that no fine was imposed because the Commission had been pre-notified of the new sales conditions. Given how serious this ruling could have been for the pharmaceutical industry GSK appealed to the Court of First Instance (CFI: an independent Court attached to the European Court of Justice) to annul the Commission's decision – and this took another five years.

The European Court of Justice's verdict

Finally, on 27 September 2006, the CFI made its long-awaited judgment on the Spanish pricing case. And, in contrast to the Commission, the CFI decided that the aim of GSK's pricing system was not to restrict competition even though it sought to limit parallel trade in medicines. The CFI found that the Commission did not take proper account of the specific nature of the pharmaceuticals sector. They acknowledged that, unlike in other economic sectors, the price of medicines reimbursed by national health insurance schemes is not freely determined by supply and demand, but is set or controlled by member states. For this reason, it could not be presumed that unrestricted parallel trade would reduce prices and increase the welfare of final consumers.

Although the CFI also concluded that the effect of the pricing system was to restrict competition, it found that the Commission did not examine with sufficient thoroughness whether the system might give rise to an economic advantage by contributing to innovation, which plays a central role in the pharmaceutical sector. Needless to say, GSK and the pharmaceutical industry are pleased with this outcome. However, EU law and procedures are nothing if not complex and this is by no means the end of the story. The decision does nothing more than put the ball back in the court of the Commission and member states of the EU. Neither can afford to neglect the interests of their citizens nor those of the pharmaceutical industry and will have to take into account the inter-dependency between both when they act. The existing conflict between member state regulation and EU regulation puts everybody in a state of uncertainty.

The crucial question remains: who is the main beneficiary of parallel trade? Does it support the welfare state? Does it provide health care at a more reasonable price? Does it increase competition and competitiveness? Does it encourage innovation?

It seems that none of these questions can be answered with a 'yes'.

Parallel trade increases...

Several studies have investigated parallel trade in the pharmaceutical industry and found a significant increase in trade over recent years. A recent study from the London School of Economics (LSE) under the leadership of Panos Kanavos goes further (Pharmaceutical parallel trade in Europe: Stakeholders and competition effects. *Economic Policy* 20, no. 44 (2005), pp. 753-798).

Photo: AHR

According to Panos Kanavos, an expert in international health policy, parallel trade neither stimulates competition nor drives down prices.

The study analysed the impact of cross-border brand-name prescription drug tradinge within the EU and looked at a range of high volume medicines from six major drug classes in six European countries between 1997 and 2002. Parallel trade increased without providing any benefits for health care stakeholders. The German health care authorities in 2002, for example, made identifiable savings of just 0.8% of total market costs; in Norway savings were 0.3% and in the Netherlands and Denmark 2.2%. The main beneficiaries of parallel trade, according to this study, are the parallel traders themselves. Their mark-up accounted for between 44% and 60%, equivalent to nearly €100 million in Germany and about €469 million in the UK - in total, more than €620 million. These revenues neither help health care authorities to save on expenditure nor the pharmaceutical industry to regain its investments in R&D. In fact, no benefit for patients could be identified, whose access to medicine seems unaffected by living in exporting or generally low-cost countries.

...but benefits are scarce

The study concludes that parallel trade in the pharmaceutical sector neither stimulates price competition nor drives down prices in importing countries. It also identified no significant evidence that parallel trade encourages price competition on an EU-wide basis. The authors concluded that parallel trade in the pharmaceutical sector will not lead to lower and equalised drug prices. They emphasize that product shortages might grow further due to pharmaceutical companies trying to protect themselves against the exports of their products from low-price countries. The study makes the point that decision makers must take into account patient welfare in all member states as well as the interests of research-based pharmaceutical companies.

In an LSE statement Kanavos remarked in 2005: "The study clearly makes the case for urgent further debate before any additional legislation in support of parallel trade is passed, at EU or country level".

However, nothing suggests a move in Kanavos's preferred direction. The CFI's ruling in the GSK case has annulled the Commission's previous decision but done little else, leaving the pharmaceutical industry in uncertainty about what would be a legally acceptable approach to deal with parallel trade. Its legality under Community law means that parallel trade will continue to reduce the profits of the pharmaceutical industry and the profitability of patented products. The pharmaceutical industry is likely, therefore, to continue to pursue a policy of restricting supply – an unsatisfactory solution for all involved. SILKE BLOHM

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