

## *newsletter*

# Parallel imports of pharmaceuticals

**Parallel imports of pharmaceuticals within the internal EU market can result in large reductions in drug expenditures. However, they are also associated with risks for the consumer because the official distribution networks and legal requirements are often purposely circumvented.**

### **Definitions**

In arbitrage processes, price differences that exist for the same product in different markets are used for commercial purposes. A differentiation is made between re-imports, parallel imports and lateral grey imports. In the case of re-imports, goods flow from the export country back into the country of origin (country of manufacture) when the price in the export country is lower than the price in the country of origin. Parallel imports refer to goods that flow from the country of origin into the export country parallel to and in competition with the distribution networks of the original manufacturer or the official trading company, frequently on an unauthorised basis. Significant differences in price may be due to the manufacturer's pricing policy or to tax requirements, for example. Hence, lateral grey imports may also exist between different export countries.

### **Legal framework**

Parallel imports of pharmaceuticals are permitted within the EU if the product in question is identical to or largely equivalent to another product which is already marketable in the importing EU state. Pharmaceutical makers produce and market drugs internationally, whereby the specific requirements for approval have to be met in each individual country. The sometimes extreme price differences for pharmaceuticals in conjunction with the upward trend in health costs and higher life expectancies are the economic driver of commercial parallel imports. Great Britain, Germany, Switzerland, Denmark and Holland are regarded as high-price countries, while Greece, Spain, Portugal and Italy are considered low-price countries. Two fundamental legal principles in the EU allow for parallel trading in pharmaceuticals and other categories of goods: the free movement of goods and the "exhaustion" of the rights conferred by patents and trademarks. Under the international agreement on trade-related aspects of intellectual property rights (TRIPS), decisions concerning the approval of parallel imports are at the discretion of the individual countries in question. In the EU, any product that is approved in one EU country may automatically be imported from one member state into another. This creates a multitude of arbitrage opportunities. National authorities may ban or restrict parallel imports if it is justified to do so in order to protect public health or industrial and commercial property (patents, trademarks) and the measures implemented are reasonable and necessary. Parallel imports from non-EU countries are prohibited. In the USA, parallel imports have thus far been insignificant as a consequence of restrictive distribution agreements. President Obama's Administration is planning to eventually allow pharmaceutical imports from developed countries. In Switzerland, parallel imports have been permitted since summer 2009, but pharmaceuticals are explicitly excluded.

**Pharmaceuticals** Often, goods legally produced in their country of origin are sold as parallel imports or re-imports by unauthorised third parties who by-pass the official distribution network or licence holder and purposely circumvent administrative and legal requirements. Pharmaceuticals that enter the market this way may harbour significant risks for consumers because the conditions necessary for protecting public health are not always adhered to. The market volume of parallel imports of pharmaceuticals estimated in the EU in 2006 was approximately USD 8 billion (Reuters Business Insight). Market shares were 7.7% in Germany, 15.2% in Denmark and 14.7% in Great Britain ([www.efpia.org](http://www.efpia.org)).

**Opportunities and risks**

The issue of parallel drug imports is being hotly debated. The possible advantages they may bring in terms of potential value added for the health industry, savings potential for consumers and comprehensive market supply contrast with possible negative consequences, in particular consumer health risks. Three studies have been published attempting to calculate this savings potential, which for some EU countries may be between EUR 100 and 600 million per year (York Study, 2003; London School of Economics, 2004; Odense Study, 2006). On balance, however, the parallel importers are the real winners, reaping about EUR 700 million in profit – mainly attributable to price mark-ups of between 44% and 60%.

The biggest risk here concerns drug safety, which is compromised primarily through increased transport and packing activities in the products' supply chain and the associated error-prone infrastructure. Every instance of manipulation of any kind harbours safety risks, e.g. through contamination, substitution, fraud or incorrect labelling. Parallel importers are not permitted to alter the original condition of the product itself, because parallel imported drug must be identical or largely equivalent to the reference product and this must be verifiable at all times; but, under current EU regulations, the parallel importer may change the form or type of packaging (repackaging), add another trademark to the packaging or customise the packaging. An estimated 140 million pharmaceutical packagings are thus modified in the EU every year and change ownership several times on the way from the manufacturer to the final consumer (EFPIA 2008).

The EU Commission also acknowledges the risks to drug safety in connection with parallel trade of pharmaceuticals, mainly in connection with the error-proneness of distribution channels, unclear new marking and labelling, incorrect package inserts, lapses in compliance with legal requirements, diminished effectiveness of product recalls and supply risks. The European Federation of Pharmaceutical Industries and Associations (EFPIA) studied problem cases of parallel-import drugs from 2002 to 2005. They found that, in particular, impacts on product quality, the health of the consumer, distribution bottlenecks, the effectiveness of product recalls and errors in new packaging (incorrect dosages, missing instructions for use and expiry dates, breach of originally sealed packages, incorrect warnings, misleading information, omission of information on side-effects, missing child-proof features, incorrect declaration of active ingredients) harbour risks of potentially serious health consequences for the final consumer. Also, in recent years, counterfeit versions of drugs have been detected with increasing frequency among parallel-import drugs and supposedly parallel-import drugs (<http://ec.europa.eu>).

Ultimately quality standards are impaired by inadequate controls of drug origin (e.g. unregulated Internet sales) in conjunction with the lack of pharmacist recommendations and medical supervision by a physician.

## Information for the underwriter

Parallel imports of pharmaceuticals are common and accepted practice in the EU. The safety of products that patients obtain through reliable, officially monitored distribution channels can be regarded as on par with the original product. However, parallel imports are also associated with substantial safety risks because high-investment logistical requirements can be circumvented, and are often purposely not complied with. This may result in liability risks and questions of drug safety for the original manufacturers. Products that are repackaged, for instance, may only be traceable with great difficulty in the event of a product recall or may not be traceable at all, and liability issues will be difficult to clarify in such cases. Parallel importers also do not conduct any product surveillance and can therefore only respond insufficiently to new findings, in contrast to the original manufacturer. Another added risk is the potential for counterfeit drugs to infiltrate distribution chains. Experts estimate that at present one out of every ten pharmaceuticals sold in Germany is counterfeit. It is therefore recommended that prior to concluding a cover agreement, the distribution methods and risk management of the manufacturer, the retailer or the pharmacist in question are thoroughly investigated and a careful risk assessment is made.

In the event of a damages claim (e.g. faulty quality, undesirable side-effects, missing or incorrect information) the party will first and foremost refer back to the original manufacturer/trademark owner. In most cases of personal injury, however, all parties involved in the distribution chain will be named in the claim. To this extent the commercial liability insurance of the wholesaler, the distributor and the pharmacist (or drug store or grocery store in the case of OTC products) may be affected. In view of the complex global network of wholesalers and pharmacies this factor is not negligible, given that indemnity limits may be quickly exhausted. A review of liability chains and liability exposure and the possibility of indemnity agreements is recommendable. Parallel imports may also trigger conflicts about patent and trademark rights (licensing fees, violation of competition). The fact that parallel imports can be offered more cheaply has consequences for the manufacturers' pricing policy, and manufacturers will usually attempt to assert their rights under patent, copyright and trademark law in order to prohibit parallel imports.

The internationalisation of production and distribution chains in recent years has on balance substantially increased the quality and safety requirements to which pharmaceutical manufacturers are subject. In contrast, parallel imports and the problem of counterfeit drugs impair the manufacturer's control over the distribution chain and consequently heighten safety risks. Under certain circumstances, the manufacturer may conceivably bear the full liability risk when the responsible party (e.g. the parallel importer) is domiciled abroad and is not subject to the legal system of the country where the manufacturer is located. Furthermore, some supervisory authorities are finding themselves confronted with international pharmaceuticals trading of a magnitude that in practice makes adequate official quality controls infeasible owing to a lack of resources.

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