# Parallel distribution and shortages – Q&A

**What is parallel distribution?**

Parallel distribution is the activity of authorised wholesalers buying products in one EU country to sell them in another, where the identical products are more expensive.

**Is parallel distribution legal?**

The activity is 100% legal and regulated under EU law, and is encouraged by many governments and regulators in order to foster inter-brand competition.

**Is parallel distribution safe?**

The practice is highly sophisticated and tightly regulated, and has always functioned in a manner ensuring the safety and integrity of the supply chain. All products handled by parallel distributors have national or EU regulatory approval and are exclusively sourced from and sold to European Economic Area (EEA) countries using authorised trade channels.

Prior to placing medicines on the destination market, parallel distributors must obtain a product-specific authorisation from the national regulator, or a distribution notice from the European Medicines Agency (EMA). Additionally, they must inform the trademark holder of their intention to import and provide information on the source country and a sample pack. This information also puts the original manufacturer into a position to anticipate trade flows and include this into his logistics planning.

**Parallel distribution in figures**

Parallel distribution represents a little less than 3% of the pharmaceutical market in Europe. Parallel imports equate to roughly €4.5 billion of the total EU pharmaceutical market per annum. The number of parallel distributed medicines packages in Europe is estimated around 120-140 million packs per year. The level of parallel trade in Europe has been stable over the past 6 years.

Over time, the dynamics between countries can change. For example, Sweden has seen higher imports since pharmacy liberalisation laws. Germany is currently the largest import market with around 10 – 11% market share.

The parallel distribution industry in Europe employs over 10,000 people in Europe, often located in geographically disadvantaged regions.

**What is the impact of parallel distribution?**

Parallel distribution makes expensive, innovative medicines more affordable for patients and governments. The parallel distributed product is put directly in competition with the same "originator" product provided in the destination market by the original trademark owner, generating savings for patients, governments, and health insurers alike.

How much the practice saves depends on national reimbursement rules. For example, in Germany, pharmacies must dispense 5% of their turnover on parallel distributed products. This mechanism generates about €300m in savings per year for the sick funds. In France, since a negotiated arrangement between the sector and the payer in 2011, parallel imported medicines are priced at a rate 5% lower than the price/reimbursement rate of equivalent originator products.

Parallel distributors also regularly expand their portfolio of products, not least to escape volume restricting supply management quotas that manufacturers roll out on wholesalers.

**How does the EU support parallel distribution?**

- Parallel trade is conducted on the basis of one of the EU's four fundamental freedoms: the free movement of goods. Under EU law, it is prohibited to restrict trade in goods between member states. Exceptions can be made on grounds of public health, but these grounds may never be used as a means of arbitrary or disguised discrimination.
- EU law also safeguards free competition within the EU single market. Companies are to compete freely and not limit each other's business activities, including by imposing unfair purchasing or selling prices, unfair trading conditions, limiting production, or limiting markets and technical development and thereby limiting the choice of consumers.
- In cases where EU Member States have attempted to limit parallel distribution, the European Commission and the Court of Justice have ruled that these measures were unfounded, instead constituting a direct restriction to trade. For example, the introduction of restrictions to the export of medicines in Portugal and Slovakia has led the Commission to issue 2 reasoned opinions as part of it infringement package in May this year.
- Following case law from the European Court of Justice, Member States must justify a restriction on the free movement of goods and demonstrate the existence of a purpose relating to the public interest, the need for the restriction in question, and the proportionality of the restriction in relation to the objective pursued.

**Medicine shortages: what is the role of parallel distribution?**

Parallel exports are often unfairly singled out as the cause for shortages. But putting the blame on parallel exporters mistakenly simplifies the issue. There are, indeed, a number of problems with this claim:

1. First and foremost, products entering into parallel distribution are surplus to local needs. If local needs are not met, there is a role to play for wholesalers and manufacturers.
2. Often there is no clear definition of shortages. This makes it impossible to establish how, when, and where shortages are, in fact, occurring – let alone find a solution for this problem.
3. It is important to note that the total market volume of parallel import has remained fairly stable at €4 – 4.5bn over the last 7 years. Shortages were no issue 5 years ago, so the fact that they are now, must indicate that there are other causes than trade.
4. In certain situations, it has become clear that stock management schemes imposed by the manufacturers in order to suppress parallel distribution constitute a threat to supply security and patient interests, because of tight volume quotas or refusal to only supply certain wholesalers. Parallel distribution, on the other hand, can help to alleviate shortages by meeting demand through imports.

**What could be the causes for shortages?**

Independent researchers birgli published a study in 2013 on the causes of medicines shortages. birgli argues that the process of delivering medicines to patients is more complex than is generally perceived and even a small failure in

one part of the system can have lasting consequences for the entire supply chain. This is further supported by their findings that:

- shortages affect generics, as well as patented brands, although there is very little parallel distribution with the former, and;
- shortages also appear in countries which are totally unaffected by parallel distribution, such as the US and Switzerland.

Possible causes include:

- **Product withdrawal:** as part of austerity measures imposed by many European countries, dramatic price cuts and reduced state-spending on medicines have impacted the business decisions of pharmaceutical manufacturers. This has lead to companies withdrawing certain products from the market, which in the current conditions are no longer sufficiently profitable – thus creating shortages.

- **Production problems:** in recent years many producers have streamlined their production facilities and processes, and have gone through mergers and acquisitions. This has resulted in a smaller number of facilities supplying a greater share of the world's demand. The negative impact of this trend on medicine supply is two-fold:

    - The global supply chain has become more vulnerable, as any incident that limits production in one of the facilities automatically impacts supply in a negative way, leading to shortages due to manufacturing issues;

    - Economies of scale and dependence on a limited number of players have not been beneficial to the overall quality of medicines: a substantial amount of quality-related recalls of medicines have led to shortages of supply.

- **Quota systems:** originally introduced to limit parallel distribution, quota systems have now become a cause for shortages. This is supported by findings of the French Competition Authority in July 2012. Manufacturer's supply quotas are often not flexible enough to respond quickly to demand fluctuations.

- **Reimbursement problems:** the lack of prompt reimbursement of pharmacies by national healthcare systems, due to the overall economic situation in some debt-ridden countries, has lead to pharmacies being unable to settle their accounts with wholesalers and to wholesalers being unable to pay the producers. These liquidity problems can have a negative impact on the supply chain, resulting in interrupted or delayed deliveries. Moreover, in an attempt to reduce costs further, wholesalers and pharmacies have decided to eliminate buffer stocks.

**How can parallel distribution contribute to the availability of medicines?**

The Matrix Insight Study on "*the Availability of Medicinal Products for Human Use*" commissioned and published by the European Commission in December 2012 highlights the positive role parallel distribution may play in ensuring the availability of medicinal products in the EU and EEA.

More specifically, the study:

- identifies a number of EU states as examples for where parallel distribution brings down prices and improves availability of medicines.
- identifies attempts to limit parallel distribution, such as the imposition of quotas, as negatively impacting the availability of medicines.
- questions whether obligations for wholesalers may become less effective in ensuring supply due to changing distribution models.

**What is the solution?**

To solve this shortages issue and improve the situation for patients in need of medicines, a number of steps need to be taken. Firstly, the criteria for establishing a shortage must be clear, objective and transparent. Only this way it will be possible to determine where the problem lies and how it can be solved.

In a second step, we strongly believe in the importance of a common understanding of how supply disruptions occur and evolve, and in the industry responsibility in developing proactive approaches to managing supply disruption. This is why, together with the European associations representing manufacturers of medicinal products, pharmaceutical wholesalers and pharmacists, we have agreed to collaborate on this issue and develop principles of good practice on medicines shortages information. We believe that supply chain stakeholders can, and must, play a role in working towards solutions.

Finally, the legality of parallel distribution and the principle of free competition within the EU single market must be upheld. In many cases, parallel distribution can actually act as solution to the problem as it opens up alternative supply channels to operators who can no longer get their products due to supply management practices such as quota systems or direct-to-pharmacy distribution (DTP) scheme. It is in the interest of EU competition policy and EU single market that anti-competitive behaviours such as supply quota systems be curtailed in order to allow European patients and healthcare systems the opportunity to benefit fully from the savings and availability generated by parallel distribution.