

## Q&A on parallel distribution in Italy

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### What is parallel distribution?

The European economy is built and underpinned on the creativity of entrepreneurs taking advantage of the wealth of opportunities generated by the internal market. Parallel distribution of medicines embodies that European spirit. The activity is 100% legal and regulated under EU law and is encouraged by many governments and regulators in order to foster competition. It is an arbitrage business that consists in the legal activity of authorised wholesalers to buy products in one EU country to sell them in another, where the identical products are more expensive.

This process puts the parallel distributed product 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. All products handled by EAEPC members have national or EU regulatory approval and are exclusively sourced from and sold to European Economic Area (EEA) countries using authorised trade channels. Parallel distributors source medicines exclusively inside the EEA area and from authorised wholesalers only, and must ensure that these medicines have been in free circulation in the EEA. Parallel distributors must check each box of medicines in the process of repackaging, adding an additional layer of safety to the supply chain.

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 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 5 years.

Over time, the dynamics between countries can change. For example, the UK was a leading import market in 2004, but has seen its share in the market halve ever since. Sweden on the other hand saw its import penetration increase, following pharmacy liberalisation laws. Germany is currently the largest import market with around 10 – 11% market share. In Italy, parallel import represents less than 1% of the market. Parallel export in 2011 was estimated to have a €275 million share in the €11 billion pharmaceutical wholesale market.

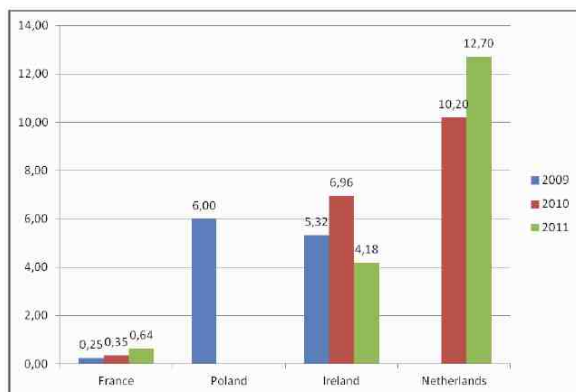
### What is the impact of parallel distribution?

Parallel distribution would not exist if it did not deliver a cheaper alternative, thus generating savings. Parallel distribution makes expensive, innovative medicines more affordable for patients and governments. Data released in 2013

show that the industry has continued to provide about half a billion Euro savings year on year in the 2004-2009 period, a trend that is likely to be sustained.

Price differentials have decreased in past years, but may again widen under budgetary pressure of payers. Also, parallel distributors regularly expand their portfolio of products, not least to escape volume restricting supply management quotas that manufacturers roll out on wholesalers. This is meant to limit the overall capacity of the sector to supply excess stock to parallel distribution.

Table 1: A comparison of direct savings in 4 PI markets for 2009, 2010 and 2011



All figures are in €m and for Poland ECB historical exchange rates were used to calculate the values. Direct savings data for Poland was not available for 2010 and 2011 or for the Netherlands in 2009.

It is no longer contested that parallel distribution provides savings to payers and patients. How much these savings are depends on the design of national reimbursement rules. For example, in Germany, pharmacies must dispense 5% of their turnover on parallel distributed products. This mechanism generates about €300mn in savings per year for the sick funds. In Italy, in contrast, there is no rational reimbursement for parallel imports, despite a call for action several years ago by the Competition Council and the parliament's finance committee.

### About the EAEPC

The European Association of Euro-Pharmaceutical Companies (EAEPC) is the representative voice of

the pharmaceutical parallel distribution in Europe. Through national associations and individual company membership it today encompasses 88 firms from 23 countries in the EEA. EAEPC members handle about 70% of the volume of parallel imports in the EEA. In Italy, its member association is AIP, consisting of 7 companies handling 90% of the country's parallel import volume.

The parallel distribution industry is an asset to the European Union. EAEPC member companies are mostly privately owned small and medium-sized enterprises, yet several are amongst the ten leading distributors of medicines in their national markets.

The contribution of parallel distributors to the European pharmaceutical market lies in an extremely innovative distribution system. The fact that medicines can become subject to parallel trade when price spreads between markets are excessive, has had a disciplining impact on manufacturers' launch prices. Moreover, the parallel distribution industry in Europe employs between 10-15,000 individuals, many of them highly skilled, in jobs directly and indirectly linked to the sector in Europe, often located in geographically disadvantaged regions.

### Medicine shortages are a fact, but what is the role of parallel distribution in this?

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. 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.

In certain situations, it has become clear that manufacturers' management schemes can constitute a threat to supply security and patient interests, because of tight volume quotas or their refusal to only supply certain wholesalers. Parallel distribution, on the other hand, can help to alleviate shortages by meeting demand through imports.

In Italy, in addition, there is a public supply obligation, meaning that all wholesalers should in principle be in a position to receive goods from the manufacturer in sufficient quantity to deliver to their clients. Fulfilling ordinary orders of wholesalers, in combination with their public service obligation, in itself should provide the right balance to preventing drug shortages.

### What is the situation in Italy?

Medicines exports have been singled out as the principal cause for shortages. There are, however, two major problems with this claim:

1. There is no clear definition of shortage in Italy, making it impossible to establish that shortages are, in fact, occurring. For example, Assogenerici has claimed that there is a shortage when there is no therapeutic alternative. However, most of the medicines currently 'missing' in Italian pharmacies are available in generic form and could be substituted.
2. Putting the blame for medicine shortages squarely on parallel exporters mistakenly simplifies the issue and will not help alleviate the serious problem shortages can cause for patients.

### What could be the cause for shortages?

Independent researchers birgli recently published a study on the causes of medicines shortages,

commissioned by the EAEPC. The key finding of the report is that the pharmaceutical supply chain is highly complex and vulnerable, meaning that possible causes for shortages are multifaceted and manifold.

birgli further 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:

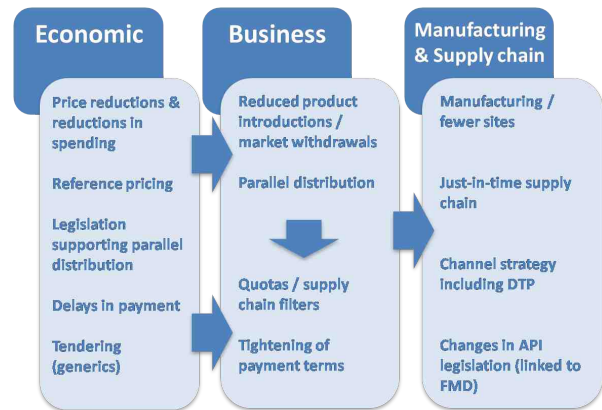
- shortages affect generics, as well as patented brands, although there is very little parallel trade with the former, and;
- shortages also appear in countries, which are totally unaffected by parallel distribution, such as the US and Switzerland.

Possible causes include:

- **Product withdrawal:** as part of austerity measures in recent years across European countries, dramatic price cuts and reduced state-spending on medicines have impacted the business decisions of pharmaceutical companies to reduce costs and streamline manufacturing. This has led 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. The result has been that currently only very few facilities supply a substantial share of the world's demand. The negative impact of this trend on medicine supply is twofold:
  - 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.



*birgli report, 2013*

- **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 for pharmacies by national healthcare systems, due to the overall economic situation in some debt-ridden countries, has led 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 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 Commission and the European Court of Justice have ruled that these measures were unfounded, instead constituting a direct restriction to trade. For example, the introduction of notification requirements in Spain has led the Commission to issue highly specific requirements for such notification rules to be allowed.

- 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.

*In other words: a clear definition of the terms shortages and a measurable scope of the problem are required. In addition, the adequacy of the proposed measure to solve the problem must be demonstrated.*

#### **What is the solution?**

1. The criteria for determining a shortage must be objective and transparent.
2. A notification from the originator on low availability of a product should be made available through the AIFA website in time.
3. Enforcing the public service obligation: MoH/NAS should inspect pharmacies with a newly applied Wholesaler Licence, to check

adequacy of GDP rules, including the feasibility of shared warehouses.

4. Combining the Italian government's current sophisticated tool to track and trace pharmaceutical products throughout the entire distribution chain and AIFA's regional pay-back system would provide all necessary information on the availability of medicines.
5. If a restriction on exports is established, there must be proof that certain products are short in supply and exports are a primary cause and not only aggravate the situation. This must in addition be a temporary measure that should be limited to medicines for which there is no alternative therapeutic option available. Generics are in fact an alternative.
6. Establishing a list of 'all non-exportable products' constitutes a de facto restriction to trade and is prohibited by European law. Such a list should be accompanied by a requirement for manufacturers to eliminate any supply quotas on wholesalers for the listed items. This should be enforced by AIFA.