



E A E P C



Parallel Distribution

Making modern medicines more
affordable for European citizens

About EAEPC

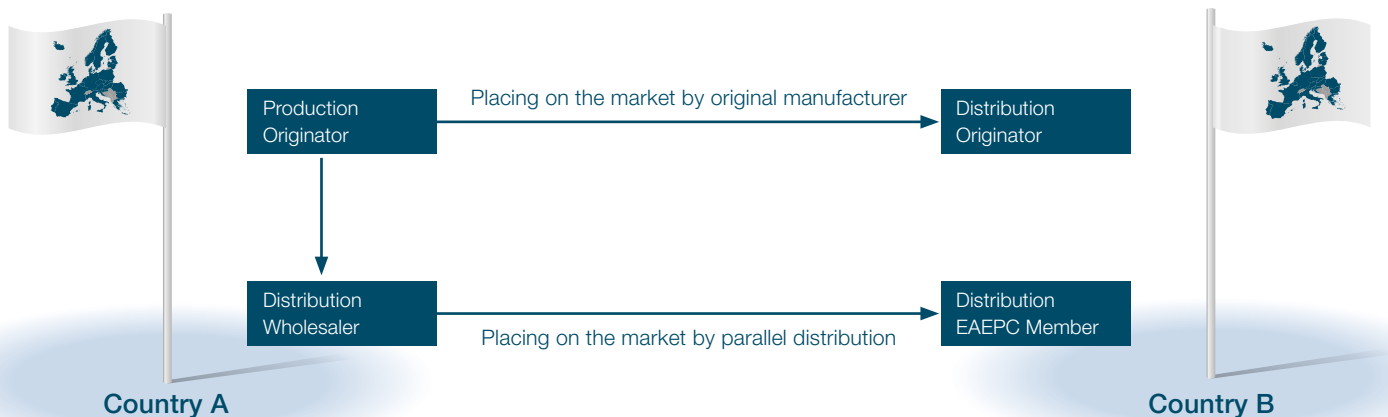
The European Association of Euro-Pharmaceutical Companies (EAEPC) is the only Brussels-based non-profit organisation, which brings together the European licensed parallel distribution industry, championing the industry's achievements and the benefits of its products.

Through the direct membership of 14 national associations and 21 individual companies, it encompasses over 100 parallel trading firms from 23 countries in the European Economic Area (EEA), representing around 80 percent of the overall industry. EAEPC member companies are all locally-owned small and medium-sized enterprises.

What is Parallel Distribution?

Parallel distribution of pharmaceuticals stems from price differentials between different national markets within the European Economic Area (EEA). Parallel distributors buy

products marketed by the original manufacturer at a lower price in one country and sell them at a higher price in another country.





How does Parallel Distribution work?

Parallel distribution occurs when products are purchased in a country where they are cheaper and transported for sale to other countries where they are more expensive. The parallel distributed medicine provides competition to the identical medicine sold by the manufacturer or its local licensee. The price advantage left should be passed on to the social health insurance system or national health service.

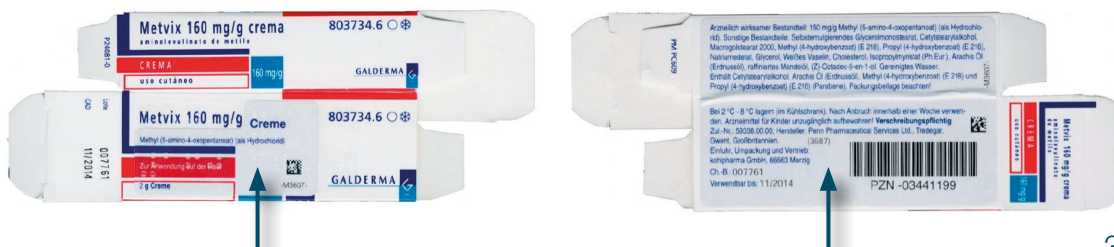
But the way this is effectively happening depends on the reimbursement systems chosen by the Member State. The EAEPIC promotes the policy that the benefits should reach the payers.

With a specific authorisation from the government in the country of destination for the medicine, the importer can sell it to wholesalers or direct to pharmacies. The importer must meet costs associated with regulatory compliance, purchasing, transport, warehousing, insurance, repackaging, quality assurance, distribution and promotion.

Reference Product



Direct Import



How safe is Parallel Distribution?

Parallel distribution is uncontrovertibly safe. Even if their supplies cross EEA internal borders (which manufacturers often consider a 'complex' supply route), the supply chain of PD is resilient in terms of quality assurance as well as against the entry of falsified products into the legal supply chain. Several business routines make up this result:

- a. Parallel distributors are subject to the same regulatory requirements as manufacturers of branded or generic products and undergo regular controls by the competent national and European regulatory authorities.
- b. Importers do not manufacture any medicines themselves, nor open the primary packaging.
- c. Importers buy finished medicinal products from exporters who are well-established and authorised pharmaceutical wholesalers.

d. They do not deal directly with the consumers either, rather the parallel distributors' customer is another licenced wholesaler, a registered pharmacy or a dispensing doctor.

e. All transactions are conducted through officially authorised and controlled trade channels.

f. A wholesale business or a pharmacist simply has one more source to purchase medicines from, which enhances the robustness of the medicines supply chain when manufacturers try to curtail supplies.

Parallel distributors can perform product recalls as quickly and effectively as any other participant in the medicines supply chain. Exporters and importers both apply internal supply chain controls including product verification and supplier verification and audit, and must meet stringent external regulatory checks to guarantee patient safety.

Parallel distributors take pride in being reliable, responsible and professional business partners for wholesalers and pharmacists in community and hospital practice. In particular, EAEPC members follow a strict and long-standing Code of Operational Conduct and good practice guidelines for parallel distribution to which all members have subscribed.

The EAEPC is dedicated to ensuring the European supply chain remains free of counterfeit medicines and is actively engaged in the on-going debate. Pharmaceutical inspectors have several times highlighted the ability of parallel distributors in their repackaging operations to identify and eliminate suspicious packages before they reach patients – an effective line of defence in the fight against falsified medicines. EAEPC (and its national affiliates) are active in the implementation of the FMD; EAEPC is one of the 5 founding members of the EMVO (European Medicines Verification Organisation).

Benefits of Parallel Distribution

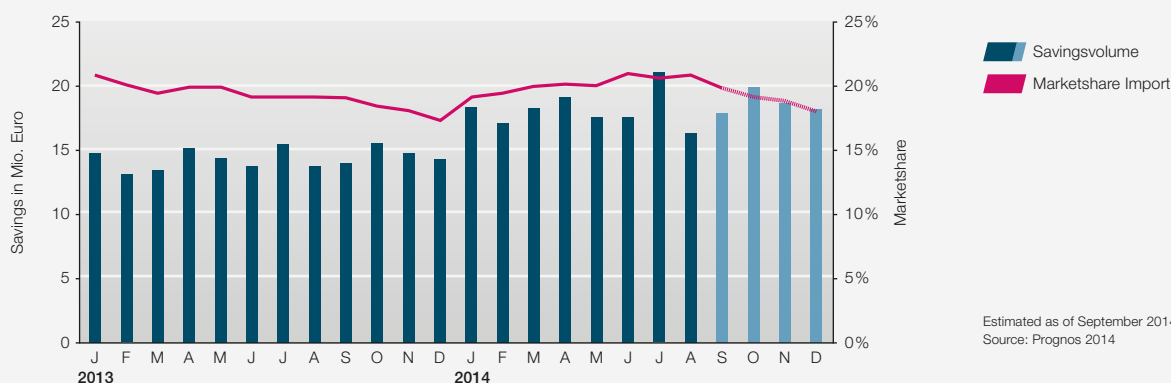
Parallel distribution of medicines provides significant savings to governments, health insurers and patients by making original, innovative medicines available at a lower cost.

A 2011 study (Ulrika Enemark and Kjeld Moller Pedersen, "Parallel imports of pharmaceuticals in Denmark Germany Sweden and the UK 2004-2009: An analysis of savings", Centre for Applied Health Services Research and

Technology Assessment, University of Southern Denmark) of only four EU countries found that parallel distribution generated direct savings to patients and social health insurance systems in excess of €440 million in 2004.

A 2016 study by Susan J. Mendez from the Melbourne Institute of Applied Economic and

Social Research found that in "sum, banning parallel imports leads to (i) an increase in variable profits for original producers and decrease for generic firms, (ii) an increase in government health care expenditures, and (iii) a decrease in consumers' welfare."



Study: "Import of Medicines: Savings in the German Health Care System"

Estimated as of September 2014
Source: Prognos 2014



Parallel distribution brings savings, competition and generates wealth.

Six key benefits of Parallel Distribution

1. Same Product, Lower Price

Parallel distribution occurs when a distributor makes use of the difference in price for the same product in two different countries within the EEA. It results in the payer and/or

consumer in the product's country of destination paying less for it than would otherwise be the case.

2. Guaranteed Savings

Most of the bill for prescribed medicines in Europe is paid for out of public funds by the various statutory social security systems. Parallel distribution can only be realised in case of demand and demand would not exist if the parallel distributor did not pass on a large part of the price difference after meeting his costs to these systems. The

price charged for a parallel-traded product is always less than that for the domestic version. If this were not the case, the entire *raison d'être* of parallel distribution would cease to exist, as would the trade itself. Parallel distribution offers a truly European solution to member states' healthcare funding deficits.

3. Opportunity with Medicines

The prices of many prescription medicines differ in different member states for a variety of reasons. This fact, combined with two basic EU principles (1) free movement of goods within the internal market and (2) exhaustion of patent and trade mark rights create an ideal opportunity for payers to benefit from pharmaceutical parallel distribution. The products that enter into parallel distribution

are surplus to local needs. Wholesalers in the supplying state are naturally obliged to meet domestic demands first; if they didn't, given the level of competition between wholesalers for pharmacy customers, they would not remain in business long. Most countries also impose, through national law or voluntary code, a so-called 'public service obligation' on wholesalers.

4. Patient Benefits

Patients benefit directly from parallel distribution either when they have to pay the full amount themselves or when reimbursement is partial and expressed as a percentage of the public price. The latter

situation applies, amongst other European countries, in Belgium, Denmark, Finland, France, Greece, Italy, Norway, Poland, Portugal, Spain and Sweden.

5. Safety Assurances

As befits their special position with the maintenance of human health, all medicines – including parallel traded ones – are strictly regulated by either national authorities or by the European Medicines Agency. Parallel distributed products need marketing

authorizations, and parallel distributors must possess manufacturing authorisations if they make changes to the label or outer package demanded by local law. Parallel Distributors need wholesale dealing authorisations too.

6. Intrabrand Competition

Almost all new medicines are protected by patents. A patent confers a monopoly and, by definition, a monopoly denies the right for the forces of competition to effectively work for the benefit of consumers. Parallel distri-

bution is the only form of competition to any specific medicine during the life of its patent. It provides wholesalers, pharmacists, prescribers, patients and payers with the ability to make a choice.

Why does Parallel Distribution happen?

The basic principle of free movement of goods within the EU and EEA creates an opportunity for parallel distribution in medicines. Once a product is legally placed on the market in a country within the EEA by

the owner of its trademark rights the owner cannot rely on these rights to hinder the further sale of the product within the EEA. Parallel distribution is likely to exist wherever there are price differentials.

Various estimates by independent economic consultants on the share of the pharmaceutical market in the EU taken by parallel-traded products put it at 2–3%.

Legal Basis for Parallel Distribution

Parallel distribution in general is based on the principle of free movement of goods and has contributed to the development of the Internal Market to the extent that more products at different prices move from one national market to the other and are thus available to the purchaser. Their legality has been recognised by the Court of Justice of the European Communities since 1976.

Parallel importation of a medicinal product is a lawful form of trade within the Internal

Market based on article 34 of the Treaty on the Functioning of the European Union (TFEU) and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 36 of the TFEU.

The Court has ruled (Case C 44/01 delivered on April 8, 2003 paragraph 63 of the judgement) that “in completing the Internal Market as an area without internal frontiers

in which free competition is to be ensured, parallel imports play an important role in preventing the compartmentalisation of national markets”.

The European Court of Justice has repeatedly confirmed that medicinal products are not exempted from the rules of the Internal Market⁹ and has condemned State measures, which restrict, without appropriate justification, parallel imports of medicines.



Parallel distribution brings market stability and benefits for patients.

Dual-Pricing and Challenges to Parallel Distribution

What is Dual-Pricing?

Dual pricing is defined as a two-tier price model, where two different prices apply to the same good depending on its final destination (normally a lower price for domestic distribution, and a higher price for exports).

This strategy has been used by pharmaceutical manufacturers to partition the European medicines market into closed national markets, thereby eliminating competition by parallel trade and maximizing profits.

By definition, price differences between national markets lead to arbitrage, or in the case of medicines to parallel trade. Dual pricing has the purpose to prevent price competition.

EU courts have repeatedly declared the anti-competitive use of dual pricing as unlawful.

Legal History of Dual-Pricing

Dual pricing was first introduced by Glaxo in Spain in 1998 and continues to be used by big pharma companies to ensure their market position.

In 2001, the European Commission, under Commissioner Monti, decided that Glaxo, in its contracts with Spanish wholesalers, had infringed Art. 101(1) TFEU.

In 2006, the General Court found that dual pricing does constitute an infringement of Article 101(1) TFEU.

In 2007 EAEPC filed a series of complaints with the Spanish Competition Authority regarding several dual pricing systems being operated in Spain.

Despite prior rulings the Spanish Competition Authority decided against conducting an investigation due to a "lack of prima facie evidence of an infringement".

In 2009 the European Court of Justice (ECJ) upheld the original assessment of the General Court that dual pricing was unlawful and violated Art. 101(1) TFEU.

In 2014, following nearly two decades of legal battles against dual pricing in Spain, the Spanish Supreme Court confirmed in a judgement of the Audiencia Nacional that dual pricing infringed Art. 101(1) TFEU.

The same year the Spanish Competition Authority finally opened a case to re-investigate.

Dual-Pricing today

Today, dual pricing continues to exist. Big pharma companies now try to claim an exemption based on Art. 101(3) TFEU. The pharmaceutical industry in Spain continues to use dual pricing distribution contracts, claiming the exemption under Art. 101(3) TFEU, damaging competition and patients in Europe alike.

Dual pricing obstructs the free movement of goods in the EU Single Market, one of the key pillars of European integration. While some EU countries continue to view dual pricing as a possible solution to medicine shortages, a 2014 "Analysis of dual pricing in Spain" conducted by inno AG (LINK) found that dual pricing "is harmful to Europe's sustainable competitiveness, its innovativeness and is in addition harmful to European consumers overall."



Medicine shortages are a fact.

But what is the role of parallel distribution in this?

Products entering into parallel distribution are surplus to the local needs. If local needs for certain medications are not met, wholesalers and manufacturers need to address the supply situation. It is important to note that the total market volume of parallel im-

ports has remained fairly stable at 5 billion Euro over the last 10 years. With the parallel distribution market stable and shortages having emerged over the last few years, it must indicate that there is another cause than trade. In certain situations of short-

ages it became clear that manufacturer's management schemes constitute a threat to supply security and patient interests. Parallel distribution can contribute towards supply and patient safety through imports.

Causes of shortages

Independent researchers birgli recently published a study on the causes of medication shortages in 2013, commissioned by EAEP. The study found that the pharmaceutical industry and medical supply chain was extremely complex and therefore exceptionally vulnerable for disruption, meaning small failures can have a big impact. The study found that there are 4 key causes of shortages:



1. Product withdrawal

Pharmaceutical companies regularly withdraw medication from markets when they perceive that the current conditions are no longer sufficiently profitable.

2. Production problems

With production facilities and processes having been streamlined over recent years, production has been concentrated on a smaller number of facilities making them more vulnerable for disruption; additionally a substantial amount of quality-related recalls over recent years has led to shortages.

3. Quota systems

Originally introduced by manufacturers to limit parallel distribution, the quota systems have now become a cause of shortages. Manufacturers supply quotas are often not flexible enough to quickly react to fluctuation in demand.

4. Reimbursement problems

The overall financial situation in some high debt countries has led to delays in national health system reimbursements to pharmacies, resulting in pharmacies being unable to settle accounts with wholesalers and wholesalers being unable to pay the producers. Additionally, in an attempt to reduce overall costs many wholesalers and pharmacies have eliminated buffer stocks leading to shortages if demand rises unexpectedly.

What impact does Parallel Distribution have on R&D in Europe?

There is no evidence that parallel distribution has a negative impact on R&D in Europe.

The costs of all parallel imported products are paid to the manufacturer at the price requested in the source market pricing principles allow for the recouping of R&D costs, hence every market pays for R&D.

Parallel Distribution represents a very small part of the total European pharmaceutical market, accounting for only around 3-4% of total sales.

Whilst innovation in the pharmaceutical industry is vital for the development of new medicines, R&D represents only around 15% of the budget of most pharmaceutical manufacturers. Manufacturers have higher expenditure in other areas, such as sales and marketing, where they spend almost twice as much as they spend on R&D.

Facts & Figures about the EAEPC and the European Parallel Distribution Industry

EAEPC represents over

100

SMEs

in

23

EEA countries

representing

80%

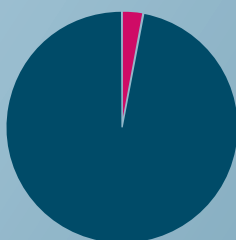
of the parallel distribution industry

Parallel imports equate to roughly 5 billion Euros of the total EU Pharmaceutical market per annum.

Number of parallel distributed medicines packages in Europe is estimated around 120-140 million packs p.a.

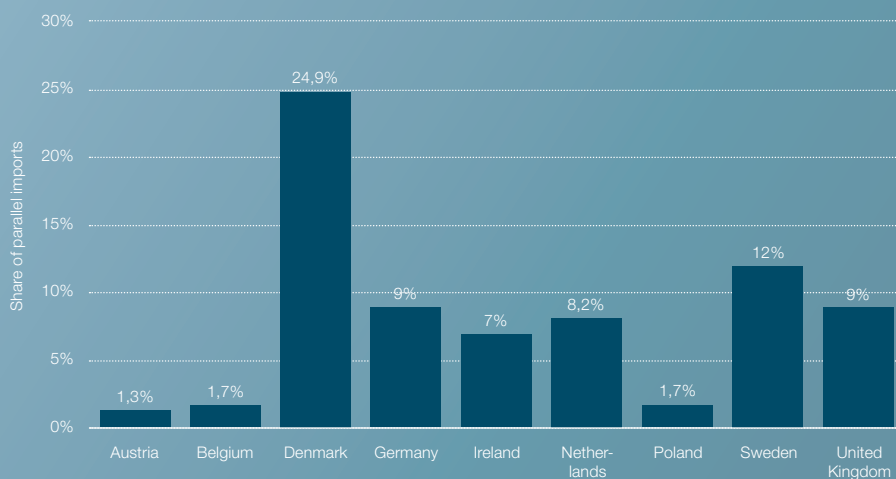
The Parallel Distribution industry in Europe employs between 10.000 -15.000 individuals, many of them highly skilled, often located in geographically disadvantaged regions.

Around 2-3% of the overall Pharmaceutical trade is conducted by the Parallel Distribution industry



Parallel Trade
Pharmaceutical Trade

Share of parallel imports in pharmacy market sales in selected European countries in 2015



Source: EFPIA
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