

Parallel Trade

*Helping to Make Modern
Medicines More Affordable for Europe*



*European Association of
Euro-Pharmaceutical
Companies*



Welcome from the EAEPC

Do you like the idea of saving money when making a purchase, especially if the origin and quality of the goods bought are unchanged and this can be assured? Anyone answering in the affirmative will find the idea of parallel trade attractive.

Payers for prescribed medicines in several member states – whether these are national health services, sickness funds or patients – are already convinced, since for over 20 years they have obtained real economies from the use of parallel trade. The products traded are those of the original manufacturers, sourced exclusively in Europe.

They are often produced in the same manufacturing plants and are sold through the same channels as essentially identical products marketed by the domestic trade mark owner.

The European Association of Euro-Pharmaceutical Companies (EAEPC), representing parallel traders in medicines across Europe, invites you to find out more in these pages.

A handwritten signature in black ink that reads "D. Macarthur." The signature is written in a cursive, slightly slanted style.

*Donald Macarthur
Secretary General, EAEPC*

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EAEPCC is a professional body whose primary aims are fourfold:

- ◆ *to safeguard free movement of medicines in the European Economic Area (EEA)* in line with Article 28 of the EC Treaty;*
- ◆ *to counteract any attempts at trading patterns prohibited by Article 81 EC (anticompetitive agreements) and Article 82 EC (abuse of a dominant position);*
- ◆ *to ensure the socio-economic benefits of parallel trade are recognised and acted upon; and*
- ◆ *to promote parallel trade as a means of completing the EU internal market.*

The pharmaceutical parallel trade industry is a European asset. EAEPCC member companies are all locally-owned small and medium-sized enterprises, yet several are amongst the ten leading suppliers of medicines to their national markets. As well as offering competition to the domestic trade mark owner, the sector is itself highly competitive, with up to 30 active players per country, each offering different terms. Together they provide employment to thousands of staff.

For further information on pharmaceutical parallel trade or on EAEPCC please visit www.eaepcc.org or contact info@eaepcc.org.

**consisting of the 15 member states of the European Union plus Iceland, Liechtenstein and Norway*

Key Benefits of Parallel Trade

Same Product, Lower Price

Parallel trade occurs when a distributor makes use of the difference in prices 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.

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

- ◆ *free movement of goods within the internal market and*
- ◆ *exhaustion of patent and trade mark rights,*

create an ideal opportunity for payers to benefit from pharmaceutical parallel trade.

The products that enter into parallel trade are surplus to local needs. Wholesalers in the supplying states 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.

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 Agency for the Evaluation of Medicinal Products (EMA). Parallel-traded products need marketing authorisations, and parallel traders must possess manufacturing authorisations if they make changes to the label or outer package demanded by local law. In most member states traders need wholesale dealing authorisations too.





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 trade can only be realised in case of demand and demand would not exist if the parallel trader did not pass on a large part of the price differential 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 trade would cease to exist, as would the trade itself.

Parallel trade offers a truly European solution to member states' healthcare funding deficits. It avoids or minimises the implementation of other, more interventionist or market-distorting cost-containment measures.

Patient Gains

Patients benefit directly from parallel trade 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, Norway, Portugal, Spain and Sweden.

Real 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 trade 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.



Basis for Parallel Trade

Parallel trade occurs when products are purchased in a country where they are cheaper and transported for resale to other countries where they are more expensive, in competition with the same product sold by trade mark owner, ie the manufacturer or its local licensee.

Parallel trade increases the effectiveness of the market and customers enjoy lower prices as a result. It helps to restrain costs in markets that are not very price sensitive.

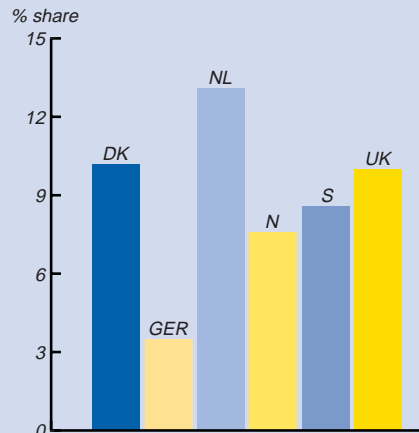
Parallel trade will exist wherever there are price differentials. It has been ongoing worldwide since goods were first traded and is found across Europe today with a diverse range of branded products (see table).

The overall level of parallel trade with medicines in Europe is unremarkable in this context. Various independent estimates on its market share by value have consistently arrived at a figure of just

footwear and leather goods	<5%
musical recordings	overall 5-10%, some releases up to 20%
motor cars	estimates up to 5%
consumer electronics	around 5%
domestic appliances	<5%
cosmetics and perfumes	around 13% for upper end of market
clothing	5-10%
soft drinks	0-15%
confectionery	<10%
alcoholic drinks	<5%

NERA and SJ Berwin & Co: *The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks*. Report for DG XV of European Commission. London. 1999.

2%. The extent of penetration of some national pharmaceutical markets, obtained from a variety of mainly industrial sources, is shown below.



In total, almost all EEA countries are involved, as the product source or the product destination; indeed, many countries simultaneously act, with different products, as both source and destination.

Parallel trade consequently boosts intra-Community trade. Indeed, the European Commission views it as decisive vehicle for the completion of the EU internal market in medicines.

Approximate parallel trade share of prescription medicine sales by value, 2000

Legal Framework

Parallel trade is completely legal.

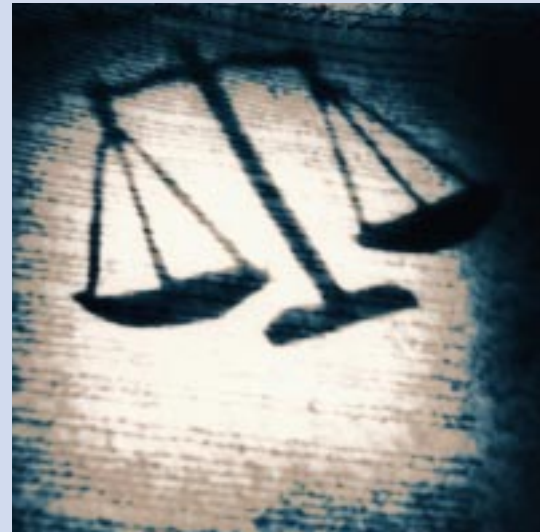
A core objective of the Treaty of Rome is the creation of a single, internal market through which goods, services, people and capital – the ‘four freedoms’ – can freely pass. Article 28 of the EC Treaty (formerly Article 30) provides that: ‘Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states.’

A direct consequence of free movement is the classic *Cassis de Dijon* doctrine of the European Court of Justice (case C-120/78), ie a product lawfully placed on the market of one member state must be allowed to circulate freely throughout the EEA.

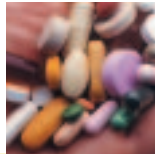
Pharmaceutical parallel trade in Europe is strictly limited - in terms both of where the products are sourced and where they are finally

sold - to within the EEA. Therefore the term ‘parallel import’, in a European context anyway, is now redundant. Trade between EEA states is no longer classified as imports or exports, rather it merely represents the free movement of goods within a single marketplace having no internal borders.

The products that are traded may be patented, or marked with the originator’s trade mark. Such intellectual property rights attached to goods are regarded as having been exhausted. The principle of exhaustion of rights (sometimes referred to as ‘the first sale doctrine’) is that once a product is legally placed on the market in a country within the EEA by the owner of the rights, or with the owner’s consent, the owner cannot use these rights to hinder the further sale of the product elsewhere within the EEA, except in very exceptional circumstances.



Regulatory Controls



The regulatory position with parallel trade arose from the *De Peijper* judgement of the European Court (case C-104/75). Each national regulatory authority should verify that a parallel-traded product was either identical with the version already marketed in that country by the domestic trade mark owner, or that any differences had no therapeutic effect, the Court said. In its subsequent 1982 Communication, the European Commission produced an advisory legal framework for a form of abbreviated marketing authorisation. All destinations for parallel trade now have national rules based on this in place.

Every parallel-traded product is required to have a marketing

authorisation issued by the national authority. Alternatively, a compliance check is used by the EMEA on the request of a parallel trader for high-tech or biotech medicines that have already received centralised, pan-European marketing approval by the Agency. Such products are, by definition, identical in every respect across the EU, with the Community marketing authorisation covering all linguistic versions of the label and package insert. As a result no further regulatory approval is necessary before parallel distribution takes place.

As one of the conditions for their marketing authorisations, parallel traders are required to keep records of the origin, quantity and batch numbers of all products they sell. This enables, if necessary, a product recall.



If, as is usual, parallel traders are involved in modifying the outer packaging to enable the product to enter the local supply chain then they need a manufacturing authorisation, with all the usual obligations this entails (eg employment of an EU Qualified Person, maintenance of Good Manufacturing Practice standards, periodic government inspection). Under manufacturer liability provisions, parallel traders in several countries are required to maintain substantial insurance cover, yet this has never once been needed.

Advantages to Social Security

Savings from the use of identical lower-priced parallel-traded products occur everywhere incoming



parallel trade is found. How these arise varies by country:

...In the United Kingdom, the National Health Service recovers via the 'clawback' mechanism the average saving it estimates pharmacies have realised from their total parallel trade purchases.

...In Ireland and Sweden, a parallel traded product must offer savings to the state before it is reimbursed.

...The cost difference between the domestic product and its parallel-traded equivalent is split between the dispensing pharmacist and the payer in both the Netherlands and Norway, and between health insurance and the patient in Finland.

...The German sickness funds and the Danish government oblige pharmacists to dispense cheaper synonyms, including parallel-traded forms, when certain levels of savings are possible.

In addition to direct savings, there is also general price erosion, benefiting all buyers in all markets. This is because parallel trade brings an important competitive element to bear, especially in the notoriously price uncompetitive

patent-protected segment, the part of the market that generics cannot reach.

The availability of parallel-traded products, or even just the threat of this, can result in lower prices for domestic equivalents than would otherwise be the case. Market prices are reduced and/or price rises forgone, and greater discounts or improved terms are offered to distributors by manufacturers.

Governments which cap reimbursement for multisource products are also able to set lower reimbursement ceilings when parallel-traded versions are available.

Advantages to the Patient /

Just What the Doctor Ordered

Advantages to the Patient

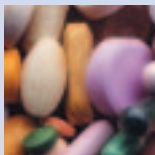
Patients as taxpayers or as members of health insurance funds have a clear interest in seeing their hard-earned contributions well spent by the statutory health-care system.

Modern, innovative medicines are often both more effective and more cost-effective than the older medicines they replace, but their prices may simply be too high, given budgetary limitations, to allow usage without some restrictions. If these are available in parallel-traded form, their price will be lower and more eligible patients may benefit.

In many European countries the majority of patients pay a share of the cost of prescribed medicines they consume, so use of cheaper parallel-traded products will mean lower out-of-pocket demands. Some member states also employ forms of reference pricing, in

which products are grouped and the amount reimbursed is capped at a maximum per group. If a parallel-traded product is dispensed the patient may avoid paying any excess payment that would otherwise be due.

With the growing use of so-called 'lifestyle drugs' as well as with oral contraceptives – products that are not widely if at all reimbursed - the consumer makes a direct saving from the cash purchase of a parallel-traded medicine on private prescription.



Just What the Doctor Ordered

It is accepted that a part of the medicines market in every member state – a part that makes a disproportionately large and growing contribution to overall

costs – consists of branded preparations under patent, where there is either no therapeutic alternative at all or only limited interchangeability in respect of particular patients. Different active ingredients within the same therapeutic category often affect individuals in different ways. Moreover, doctors, if persuaded by the merits of a brand, are reluctant to switch on cost grounds alone to even a closely similar variant because of the risk of lower efficacy, poorer tolerability or allergy. Patients, too, prefer the familiarity of their usual brand.

Parallel trade offers a real solution to the funding problem that all European healthcare systems increasingly face. It provides, along with guaranteed cost savings, the original products from innovative research-driven manufacturers, not substitutes or copies.

Frequently Asked Questions

Why Do Price Differences with Medicines Occur?

Pricing and access to reimbursement are national responsibilities throughout Europe. Willingness and ability to pay, medical and prescribing practices, the balance of supply-side/demand-side interventions, and even value judgments in healthcare differ, and therefore so do prices. Another factor is the policy of price differentiation by manufacturers. As commercial enterprises, companies naturally aim to obtain the highest price each country will bear.

How Does Parallel Trade Actually Work?

Parallel traders buy medicines from established wholesalers in member states where the products are cheaper. If the parallel trader has obtained a product-specific authorisation for the member state of destination, it can be resold there to wholesalers or direct to

pharmacies, in parallel with the same medicine sold by the manufacturer's subsidiary or its licensee. Parallel traders neither manufacture medicines nor interfere with the actual product, but merely adapt the labelling to meet local requirements according to national law.

How is free movement within the internal market compatible with price-fixing by national governments?

The European Court has stated that inter-state price differences with medicines cannot justify an exception from free movement, even if these differences result from price controls. Despite this, manufacturers say a correctly working free market entails the freedom to set prices.

This ignores today's reality:

- ◆ Only a handful of states still exert direct ex-factory price control on new medicines.

Instead, the preferred approach, adopted in various country-specific ways, is to limit access to reimbursement or to curtail payments made under it.

- ◆ Even where actual price control still exists, the authorities no longer employ inflexible formulae, and allow instead a true negotiation, by which a company's asking price is increasingly accepted, sometimes in return for offsets elsewhere.

Won't parallel trade deter the search for new cures?

Diversion of sales from one European country to another with parallel trade has not led to any cut-backs with pharmaceutical R&D. In fact, just the opposite; industry expenditure on this in Europe grew more than three-fold from 1985 to 1999.



*For further information on pharmaceutical parallel trade or on
EAEP C please visit: www.eaepc.org or contact info@eaepc.org.*