

**WRITTEN STATEMENT TO HHS TASK FORCE ON DRUG IMPORTATION,
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BY

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Mr Chairman, members of the HHS task force on drug importation

Thank you for inviting the European Association of Euro-Pharmaceutical Companies, which I represent, to submit its views. The EAEPC is the professional representative body for parallel trade in medicines in Europe. We currently have over 70 firms from 16 European countries as members, from a region of 28 member states and a population of 450 million that is now the world's largest trading bloc. Several of our member companies have been in business for over 20 years, and some are among the top-10 pharmaceutical suppliers to their national markets.

I must emphasise at the outset some of the differences between parallel trade, as practised in Europe, and personal importation – whether by mail order, via the Internet or on foot – that has been the basis of US experience to date.

Ours is a mature, highly regulated industry developed with considerable investment that is strictly business-to-business. EAEPC member companies have no dealings with the public. We supply only wholesalers and/or pharmacists, it being the latter group's professional decision whether parallel trade is dispensed to the patient or not.

All product types are suitable for parallel trade – any pharmaceutical dosage form, cold chain products including vaccines, as well as diagnostics, OTCs, parapharmaceuticals, etc - whereas distance selling is applicable to repeats of chronic medication only.

With parallel trade the product's origin, quality and storage conditions can be assured. The chain is a closed one. Only authorised products are purchased from authorised wholesalers in one European country and sold to authorised distributors in another. Can the same be said of distance selling?

Parallel trade is offered as a rewarding alternative to wholesalers and pharmacies, whereas cross-border E-pharmacy seems to have a strongly negative impact on the business of local distributors.

Legal Basis

Parallel trade with prescription medicines is completely legal in Europe. This was reaffirmed as recently as January 2004 by the European Commission in a new Communication (COM[2003]839). It has been underpinned by an unbroken series of almost 30 judgements of the European Court of Justice (ECJ) dating back to the mid-1970s.

It takes its basis from one of the cornerstones of the near 50-year old Treaty of Rome: the free movement of goods within the Single Market. This now consists of the 25 member states of the European Union (EU) plus three former European Free Trade Area states (Iceland, Liechtenstein, Norway) that together form the European Economic Area (EEA).

The description 'parallel trade' is preferred, in a European context anyway, to 'parallel import' or 'parallel export' as our members source and sell products exclusively within the EEA, a market with no internal borders

Regulatory Controls

A framework for regulatory control was given to national regulatory authorities across the EEA by the first Commission Communication on the subject (C115/5, *Official Journal*, 6 May 1982). During subsequent years almost every member state introduced its own abbreviated marketing authorisation procedures for incoming parallel trade based on the Communication and, in 1998, the European Medicines Evaluation Agency followed with a special procedure for notification of parallel distribution of centrally-authorized medicines (EMEA/H/30313/98, Rev 2).

To obtain an abbreviated marketing authorisation, the product must

- be sourced from an EEA country, and
- have a current full marketing authorisation in the source country, and
- show no therapeutically-significant differences from a product covered by a full marketing authorisation in the country of destination.

The following are the conditions for authorisation:

- No parallel-traded product may be marketed until specific authorisation is given.
- The authorisation is valid for five years, but is renewable.
- It requires an extensive regulatory check and payment of a fee.
- Authorisation must be for the same indications, contraindications, side effects, dosage, route of administration as for the product with the full marketing authorisation in the country of destination – patient package inserts are mandatory and must contain identical information in the language of the country of destination.
- The trader must check each incoming lot and record origin, quantities received and batch numbers. In certain cases, the authority will require batch testing.
- The shelf life in the country of origin shall apply, though it cannot be longer than the shelf life accepted in the country of destination.
- The trader is subject to the normal obligations for all authorisation holders as regards adverse reaction, abuse and defect reporting, and provision for product recall.
- The regulatory authority will inform the full marketing authorisation holder in the country of destination that a parallel trade approval has been granted on his territory and the name(s) of its country of origin.
- The parallel trade authorisation is published in the country's official gazette.
- Any change in the conditions for authorisation require the filing of a variation application, with the product quarantined until this is approved.

In addition to product-specific marketing authorisations, parallel traders in all countries of destination have to hold EU manufacturing authorisations to allow them to conduct relabelling or repackaging operations (as is usually the case). This means that just as with main-stream pharmaceutical manufacturers, parallel traders have to comply with Good Manufacturing Practice guidelines, employ a special EU 'qualified person' (who personally takes legal responsibility for the safety of the procedures), and be subject to periodic inspection by the regulatory authorities.

If they supply pharmacies, traders also have to hold an EU wholesale dealing authorisation. Conditional on this is compliance with Good Distribution Practice, employment of a responsible person, and periodic inspection.

Under manufacturer liability provisions, parallel traders in several countries have to maintain substantial insurance cover. This has never once been needed.

Repackaging Issues

Though repackaging is more costly it is generally preferred by parallel traders as it produces a more professional result than merely over-stickering the original carton with the essential label information in the language of the country of destination. Surveys have shown repackaging is overwhelmingly preferred by pharmacists and it also improve compliance by patients..

However, it is very common for trademark owners to object to repackaging or its style, claiming that parallel trades are merely seeking a commercial advantage through it. The ECJ (linked cases C-443/99 and C-143/00, April 2002) has concluded that replacement packaging 'is objectively necessary...if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as a result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products'. In other judgements (i.e. cases C-427/93, C-429/93 & C-436/93), the ECJ has defined the allowable conditions for repackaging:

- the product inside the packaging must not be affected;
- the new packaging must clearly state who repackaged the product and the name of the manufacturer;
- the reputation of the trade mark or its owner must not be damaged; and
- the trade mark owner must be given adequate prior notice before the repackaged product is put on sale and, on demand, be supplied with a specimen of the repackaged product.

How it Works

Parallel traders purchase surplus medicines from established pharmaceutical wholesalers in countries where the medicines are cheaper. In many cases, the business connections between the two parties go back many years. If the trader holds a marketing authorisation in the country of destination, he adapts the packaging/labelling to local requirements, in accordance with national law and ECJ decisions, before selling to wholesalers or direct to pharmacies, in parallel with the same medicine sold by the domestic trademark owner (i.e. the manufacturer or its local licensee).

Guaranteed Savings from Parallel Trade

Quite simply, parallel trade is a cure for governments and consumers looking to pay less for drugs. Parallel trade can only be realised in case of demand and demand would only exist if the prices offered by parallel traders were clearly lower than those for equivalent domestic products. As a result, a number of European governments require pharmacists to inform patients of the availability of cheaper synonyms, including parallel-traded forms, or to supply these on their own initiative as long as the prescriber hasn't specifically blocked this step and the patient doesn't object.

How savings accrue vary by country:

- In the UK, the National Health Service recovers via the 'clawback' mechanism the average saving it estimates pharmacies have realised from their total parallel trade purchases.
- In Austria and Ireland, a parallel-traded product must offer savings to the state before it is added to the reimbursement list.
- 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, Swedish and Finnish governments oblige pharmacists to dispense parallel-traded forms when certain levels of savings are possible.
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For almost 30 years, parallel trade has delivered with absolute safety lower prices to payers in a growing number of European nations: the Netherlands, the UK, Germany, Denmark, Sweden, Norway, Finland, Ireland and Austria.

Independent experts at the UK's University of York (www.yhec.co.uk) – one of the world's best-known and respected centres for health economics – estimated direct savings from parallel trade in 2002 in just 5 EU countries at €631 million (the equivalent of \$745 million at current exchange rates).

Even more important, though less easy to quantify, are indirect savings from parallel trade's competitive effect. The trade is the only form of price competition with new, innovative but increasingly expensive medicines that are under patent. 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.

Common Myths About Parallel Trade

'Pharma should be exempt from EU free movement rules because with medicines unlike other goods governments set prices, not companies'

Contrary to widespread assumption, companies marketing medicines in Europe are not entirely at the mercy of prices fixed by the national payer. Most multinationals in fact pursue a proactive policy of price discrimination. As commercial enterprises, they naturally aim to obtain the highest price each national market will bear and so discriminate

between countries to reflect differences in the ability and willingness to pay. Price differentiation is known to yield higher profits than uniform pricing.

Manufacturers' selling prices for new drugs are either freely set, as in the UK and Germany – the two largest destination markets for parallel trade – or negotiated between the manufacturer and the payer with the company given real input and flexibility. Today no European country uses inflexible pricing formulae. Companies also control the sequence of launches across Europe so as to limit the opportunities for the authorities to depress prices in major markets through the application of international price referencing.

Drug manufacturers are getting bigger through M&A, and the bigger the company the stronger its negotiating power. It might even be true to say that decisions taken in New Jersey have greater weight on drug prices in Europe today than those taken by governments in its national capitals.

The pharmaceutical industry would like many to believe that strict government price control impose universally low prices in the likes of Belgium, France, Italy, Portugal and Spain. That incoming parallel trade already benefits two of these countries (Belgium and Spain), is about to start following a change in the law in France, a change which our Portuguese members would also like to see duplicated in their country, is proof positive that industry's claim is untrue.

'It Acts as a Channel for Counterfeit or Substandard Products'

Parallel traded medicines are the products of the original manufacturers. They are either identical with the regular domestic version, or with very small differences in colour, etc. which have no therapeutic consequences, as verified by the regulatory authorities. If a manufacturer criticises a parallel-traded product it amounts to criticism of its own product.

There is very little evidence that counterfeit medicines at all are traded in Europe, and no evidence whatsoever that any counterfeit medicine has ever reached a patient as parallel trade. Last July, in a written parliamentary answer, the German Federal Ministry of Health said it 'did not know of any case where medicines with counterfeit contents were brought on the market by an importer since the introduction of imported medicines'. Pharmaceutical parallel trade has been ongoing in Germany for over 20 years, and last year its market penetration exceeded 7%.

One isolated but unconfirmed case of a counterfeit in the UK, 15 years ago and prior to the introduction of Good Distribution Practice, was found via the normal testing procedures employed by a parallel trader before product release to pharmacies took place. In practice, the only checks made on a medicine after it leaves the manufacturer are those conducted by parallel traders. Hence, if counterfeits are a concern, the risk is less with parallel trade than with domestic products.

'Leads to Product Shortages'

There is no evidence of any link between outgoing parallel trade and product shortages. However, some steps to counter parallel trade have precipitated shortages. The problem of shortages is neither new nor restricted to countries with outgoing parallel trade.

In most EU member states, including the major parallel 'exporting' markets of France, Spain and Greece, wholesalers have a 'public service obligation' written into national law. This obliges them to supply all customers within their territory with a high percentage of orders from stock within a short time frame. Even in the absence of such a legal obligation, there are voluntary codes of conduct with the same aim, plus the real fear that if a wholesaler does not prioritise his local pharmacy customers, a competitor will move in and take the business, perhaps permanently.

'Loss of Profit Hits R&D Spend'

Diversion of sales from one European country to another has not led to the research-based industry cutting back on R&D. Capital investment hasn't been affected either.

After specifically investigating the issue, the European Commission found no causal link between one major manufacturer's losses from to parallel trade and its research investments (Commission decision of 8 May 2001 on GlaxoWellcome's dual pricing system in Spain). Moreover, the Commission added, 'these losses are too insignificant to affect these investments to a considerable extent...losses stemming from parallel trade could just as well be deducted from the company's other budget items, such as marketing costs'. Even manufacturers' own estimates show parallel trade penetration across the EU in 2002 at only 4-5% of the total pharmaceutical market, and it has certainly declined since then. Actual losses are seriously over-estimated.

Manufacturers' Counterstrategies to Parallel Trade

Many of the large multinational pharmaceutical manufacturers devote disproportionate efforts to obstruct the free movements of goods in Europe, with the sole intention to limit if not eliminate parallel trade with their products.

Whereas in the past, market segmentation moves (inter-state differences in brand names, formulations, pack sizes or strengths), narrow pan-European price corridors and even claims of inferior quality of their own products abroad were common, today's emphasis is on limiting the availability of stock through the application of supply quotas systems. According to the European Commission, they have received notification of these from no fewer than 15 manufacturers, resulting in over 40 antitrust complaints pending with the Commission .

With the quota allegedly based on historical purchasing levels, wholesalers in affected countries cannot buy sufficient stock to expand their market share nationally or to meet sudden surges in demand. In some cases, they cannot buy any stock at all. Shortages are inevitable, with consequent risks to public health, extra demands on doctors and pharmacists, and anxiety amongst patients.

Summary

European experience shows that parallel trade...

- makes available original, innovative products at lower cost
- includes internal supply chain assurances and external regulatory checks for patient safety

- provides both direct and indirect cost savings for third-party payers and consumers
- enhances competition
- acts as a counterweight to the monopoly situation of patent protection
- gives pharmacists and patients a choice
- avoids governments implementing other, more interventionist and more market-distorting cost containment measures
- creates new businesses and new jobs, and (unfortunately)
- provokes an extremely powerful backlash from Big Pharma

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