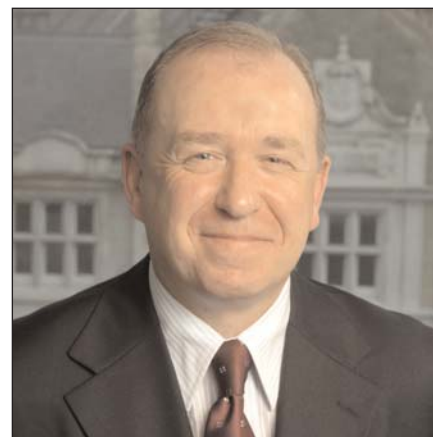


Parallel Medicines Distribution

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The article on counterfeit medicines by John Ferguson from the ABPI, in the Whit issue of *Science in Parliament*, contained a number of alarming inaccuracies about a so-called “link” between parallel medicines distribution and counterfeiting.

While counterfeiting is the manufacture and distribution of illicit products by unscrupulous businessmen, parallel distribution is:

- wholly legitimate;
- actively encouraged under the Treaty of Rome’s free movement of goods principles;
- fully licensed by national competent authorities; and
- delivers significant benefits to the UK economy.

What is parallel medicines distribution?

Parallel distributed medicines are medicines that are legally imported into the UK exclusively from other EC member states, repackaged for local markets and made available to patients through healthcare providers. Parallel importers are required to apply to the Medicines and Healthcare products Regulatory Authority (MHRA) for a licence for each individual drug they import.

Parallel imports provide patients with access to the latest drugs at lower cost and save the government and taxpayers money, which can be invested in other parts of the health service.

Parallel importation of patent protected medicines is for the time being restricted to the 15 EU countries. It does not take place from accession states such as Poland or the Czech Republic, or outside

Europe such as China, India or the United States.

Is it legal?

The UK parallel import industry has operated legally and safely in Europe for more than thirty years. It is actively encouraged through the EU’s founding Treaty of Rome which established a single, internal market through which goods, services, people and capital could freely pass. Parallel distribution in medicines is one of the best examples of genuine free trade across Europe that delivers real benefits to member communities.

How large is the market for parallel imported medicines?

Approximately 66 million packs are distributed annually in the UK (Jan-Dec 2005)¹. In 2002 the value of the UK market was estimated at approximately £1,300 million², though the market for various reasons has reduced in the interim.

One in seven prescriptions dispensed in the UK is parallel imported and 90 per cent of all pharmacists source some medicines in this way.

Economic benefits

Parallel distributed medicines generate savings for taxpayers as they cost the government less. Patients benefit as they have access to the latest drugs at lower cost. Pharmacists benefit as they can make additional savings by buying parallel trade medicines. In fact, many community pharmacists would struggle to stay afloat without the contribution made by parallel distributed medicines to their bottom line.

Direct savings from parallel distribution are estimated at up to £228 million, or 17 per cent of medicines expenditure³ of which approx 60 per cent passes to government and taxpayers and the balance to independent pharmacies.

Indirect benefits exist but are harder to quantify and may well be higher than the direct savings; these benefits include increasing competition which encourages pharmaceutical manufacturers and wholesalers to reduce the prices of domestically sourced products. Where no generic medicines exist, parallel distribution provides the only competition for branded medicines.

Both direct and indirect savings play a major role in containing the spiralling cost of medicines. In other parts of Europe, for example Germany, governments are promoting increased use of parallel imports to reduce pressure on the public health budget.

Quality and safety - our top priority

The MHRA will not allow a licence to be issued unless the imported and UK products are essentially therapeutically similar.

There are stringent rules governing the repackaging and marketing of parallel medicines just as there are for manufacturers. Every imported pack is subject to rigorous checks for every variable of strength, formulation and origin during processing. All imported packs have to be opened to accord with the requirements of the MHRA’s labelling guidelines, and to insert English-language patient information leaflets. Where packs

are opened, however, they are fully resealed before marketing. All facilities are regularly audited and subject to on-the-spot checks at any time.

No link between parallel trade and counterfeiting

There has never been a case of counterfeit medicines entering the UK supply chain through parallel trade. This fact is supported by the MHRA's head of intelligence, Nimo Ahmed, who says that there is no evidence of counterfeit medicines entering the UK supply chain through parallel imports.

This fact was reiterated by former Health Minister Jane Kennedy who dismissed any link with parallel imports, saying in July 2005 there was "no evidence to suggest that licensed parallel trade provides any more of an opportunity to introduce counterfeit medicines into the country over non-parallel traded products".

Parallel trade also has the support of the major high street chemists. David Loudon, Dispensing Category and Locations Manager at Boots, says that most community pharmacies in the UK have been providing prescription only medicines imported from the EU for many years and Boots believes they play an important role in maintaining continuity of supply. "We believe that parallel imports have an excellent safety record and that there is no evidence to link them with incidents involving counterfeit medicines entering the UK supply chain."

Maintaining the integrity of the supply chain

Although there has never been a case of counterfeit drugs linked to parallel trade in the UK, BAEPD members are committed to maintaining the integrity of the supply chain to ensure patients are protected.

Parallel trade is highly regulated with a series of safeguards to protect patients.

Parallel importers only import from fully licensed and MHRA-approved wholesalers, whose national wholesaling credentials have been audited. Long-term supply relationships developed over many years are in place, which provide trustworthy provenance of the goods. In the vast majority of cases medicines are imported direct from the exporting wholesaler (who has in turn received his supplies direct from the laboratories), repackaged by BAEPD member companies, under the supervision of MHRA-registered Qualified Persons, and distributed direct to the wholesaler or retail pharmacist. Best practice guidelines are conditional on BAEPD membership.

In fact, we believe parallel distribution acts as an additional safety measure. Whilst counterfeit product thankfully remains remarkably rare, we have frequently identified manufacturers' errors during the repackaging process.

If product recalls are required, parallel distributors perform these as efficiently and comprehensively as any other pharmaceutical distributor. We work closely with the MHRA to recall drug batches where necessary. Batches are traceable back to their European source.

Playing our part to help beat counterfeiters

We are committed to doing everything we can to assist in the fight against counterfeiting, providing our traditional and completely legal supply chains are not threatened. The BAEPD is part of an NHS-led taskforce examining bar coding and other ways to improve medication safety.

However, we see the major threat in counterfeiting coming from online sales, not parallel trade. Internet sales are effectively unregulated and have no quality assurance. We believe efforts should be concentrated in this area, a view supported by Government and the MHRA. Everyone involved in the industry needs to maintain vigilance at all times if we are to ensure patients are protected.

Parallel trade under threat

The benefits brought by parallel trade are currently under threat. What John Ferguson's article does not address are the lengths manufacturers are prepared to go to prevent parallel trade. Quotas are one way the industry has sought to restrict supplies and put pressure on the parallel medicines business. While imposing quotas is officially illegal under European law, drug companies know it will take many years for the EC to act. There have also been attempts to introduce dual pricing, a practice which we believe is also illegal and currently being challenged in the courts.

Manufacturers also claim that parallel distribution reduces investment in research and innovation. However, in May 2001 the European Commission found that contrary to claims by the then GlaxoWellcome, there was "no convincing evidence" that parallel trade affected the firm's R&D budget. The latest EFPIA (European Federation of Pharmaceutical Industries) annual report shows that pharma companies' spend on R&D has increased by 171% (1990-2004), with overall sales up 167% in the same period. Another recent report: *Health at a Glance: OECD Indicators 2005* reveals that pharmaceutical spending is a key driver of OECD health budgets. In most countries, growth in pharmaceutical spending has outstripped growth in overall health spending – in some cases by a factor of two.

Conclusion

While manufacturers continue to look for ways to limit our business and tarnish the reputation of BAEPD members, we will continue to operate in a proper, fair and legitimate manner – defending our rights and our reputation for the benefit of patients and taxpayers throughout Europe.

¹ IMS data: 1/1/05-31/12/05

² Benefits to Payers and Patients from Parallel Trade, York Health Economics Consortium, May 2003

³ Benefits to Payers and Patients from Parallel Trade, York Health Economics Consortium, May 2003

Richard Freudenberg is Secretary-General of the British Association of European Pharmaceutical Distributors (BAEPD). The BAEPD represents 14 of the largest licensed parallel distributors in the UK and is responsible for the promotion, protection and development of parallel trade and fostering the highest professional standard of practice and conduct amongst members.