Drug Reimportation: Learning from the experience in Europe

National Medicare Prescription Drug Congress

Washington DC

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Differences between the US and Europe

US

- Personal reimportation occurs on a small scale (but attracts much attention)
  - Canada
  - Mexico
- Commercial reimportation is (currently) illegal

EU

- Personal reimportation occurs on a small scale
  - e.g. Czech Republic to Austria
- Commercial reimportation (parallel trade) is legal and big business
  - Worth c. €3.3bn in 2003, and growing at 20% p.a.
  - 20% of UK branded market

Who pays for medicines?

Dinner for three

- **The diner (the patient)**
- **The chef (the doctor)**
- **The third party payer**

But third party payers are different in US and Europe

Differences between the US and Europe

US

- There are many third party payers
  - HMOs
  - Managed Care Organisations
- Many patients have high co-pays
- Government (Medicaid, VA etc) has a relatively minor role
- There is a substantial out-of – pocket payer population, who are politically important
  - Will the Medicare drug benefit change this?

EU

- Universal health care coverage
- Provision by Governments/public authorities
  - Even when nominally insurance-based (eg Germany) they are effectively public institutions
- Low co-pays, mostly not related to price
- Out-of pocket payment is rare

Who cares about drug prices is different

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What is parallel trade?

- **Parallel trade is the process by which goods protected by an intellectual property right (e.g. patent or trademark) are placed into circulation in one market, and then imported into a second market without the authorisation of the owner of the intellectual property right in that second market**
- **It results from a clash of principles and practice**

Principle of free movement of goods within the European Union

Practice of price regulation by Member States

The principle of the free movement of goods is staunchly upheld by the European Commission, which over the years has ensured there is a strong legal framework

The legal framework

Commission Communication COM (2003)839

30 December 2003

Commission communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted

http://www.europa.eu.int/comm/internal_market/en/goods/art2830.htm

Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty

A simplified procedure

A medicinal product may be imported in parallel on the basis of a licence granted according to a 'simplified' procedure under which the applicant needs to provide less information than is required for an application for a marketing authorisation provided:

The imported product has been granted a marketing authorisation in the Member State of origin

The imported product is essentially similar to a product that has already received a marketing authorisation in the Member State of destination

This is the basis on which the Commission required the French authorities to provide a simplified procedure (although it is still not operational)

Revocation of the reference authorisation in the destination Member State does not invalidate parallel importation, unless the revocation was for public health reasons

Exhaustion of intellectual property rights

The owner of an industrial and commercial property right protected by Member State legislation may not rely on that legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right

There is a temporary exception to this rule for the accession states (except Malta and Cyprus)

Parallel imports are prevented from those Member States until the patent or supplementary protection certificates of the medicinal products concerned expire in the target Member States

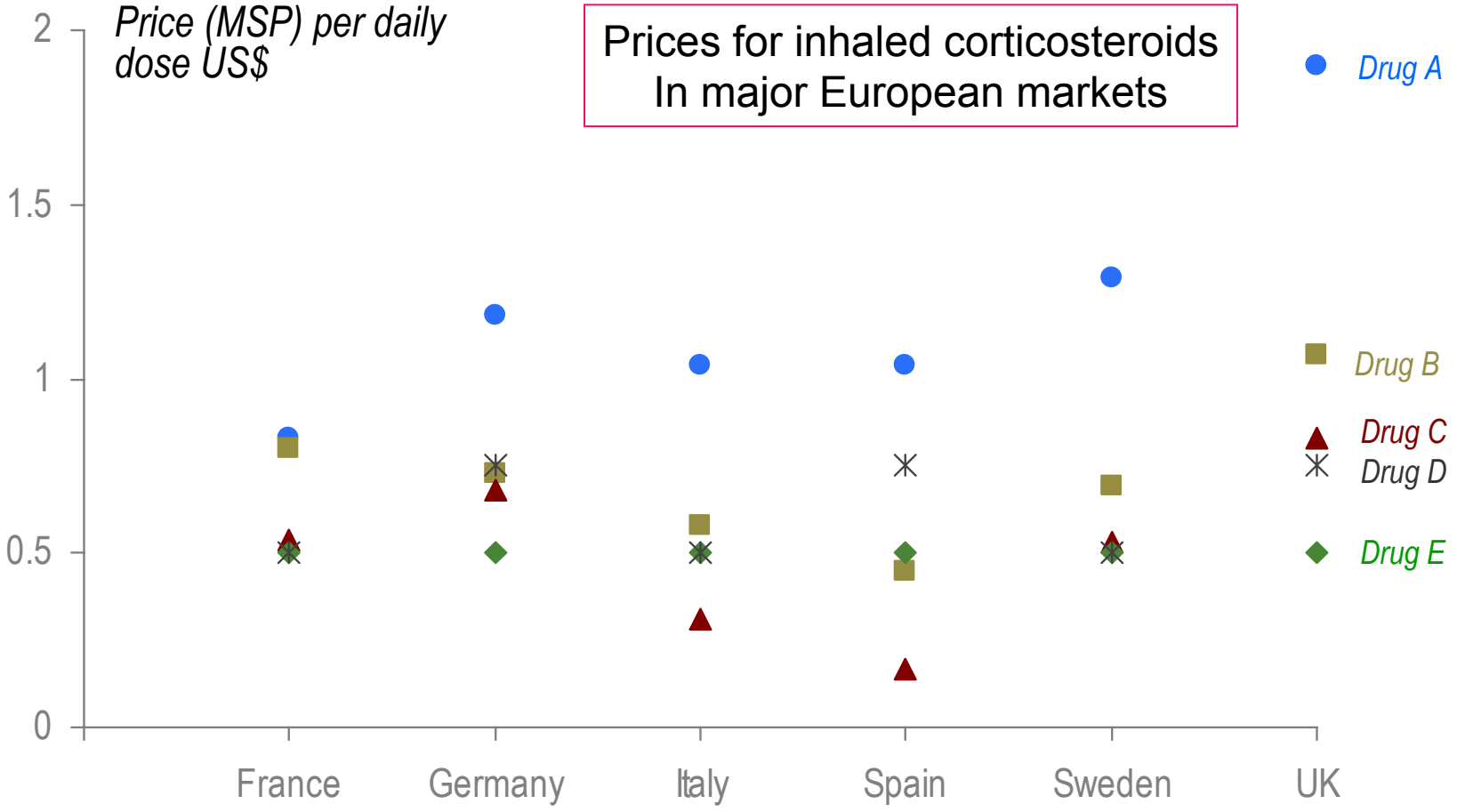
Repackaging is legal

The proprietor of the trade mark may not use his trade mark to prevent repackaging when:

- **The use of the trade mark right by the owner will contribute to the artificial partitioning of the markets between Member States**
- **The repackaging cannot adversely affect the original condition of the product**
- **It is stated on the new packaging by whom the new product has been repackaged and manufactured**
- **The presentation of the new package is not such as to be liable to damage the reputation of the trade mark and of its owner**
- **The proprietor of the trade mark receives prior notice before the repackaged product is put on sale**

The drivers of parallel trade

A price difference between the source and target markets is a necessary but not sufficient condition



The drivers of parallel trade

A price difference between the source and target markets is a necessary but not sufficient condition

Other factors are:

- Supply
  - Security of supply
  - Volume

What began as a small scale, “car boot” business has become an established and reputable trade. Kohl Pharma, a parallel trader, is now one of the leading companies in terms of sales in Germany

Averages are misleading

In the UK branded prescription market:

- 50% of PI is accounted for by 12 products
- 55% of PI is experienced by 4 companies

Leading products are disproportionately affected by parallel imports

- Average UK penetration 43% for top 12 imported products, compared with 13% for other products and 20% overall
- Includes the top 8 of the top10 selling products in the UK

Leading four companies are disproportionately affected by parallel imports

- Combined market share of 40%
- Average impact of 28% compared with 15% for others
- 8 out of top 12 imported products

Parallel trade is a symptom of success

The drivers of parallel trade

A price difference between the source and target markets is a necessary but not sufficient condition

Other factors are:

- Supply
  - Security of supply
  - Volume
- A secure legal and regulatory environment
  - This has developed over the years through a large body of case law
- Incentives to engage in parallel trade

Incentives to parallel trade

- **Economic incentives for pharmacists**
  - Pressure on pharmacy margins (many markets)
  - Pharmacy clawback (UK, Netherlands)
  - Mandated use of parallel imports (Germany)
- **Financial pressure on wholesalers**
  - Mandated reductions in margins in many markets
    - Pressures to source product more cheaply (importing markets)
    - Pressures to seek new (non-regulated) sales opportunities ((exporting markets e.g. Spain)

Why no parallel imports in France?

• Lack of regulatory infrastructure (no abbreviated licensing procedure)

• Lack of incentives. Cost containment focus has been on prices, not margins

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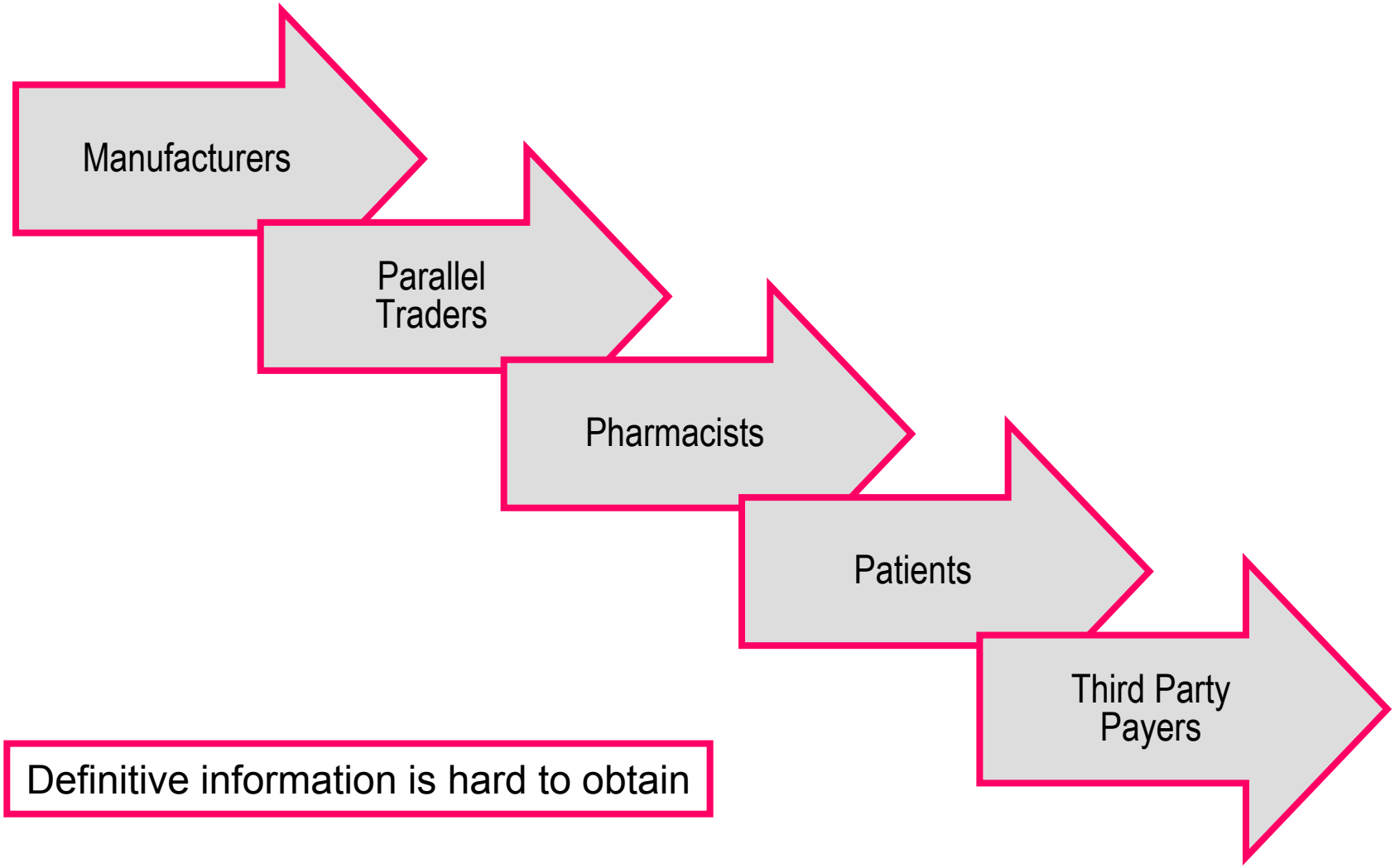
Who gains from parallel trade?



Definitive information is hard to obtain

Data from an empirical study

Based on parallel trade in Sweden 1994 to 1998, which accounted for 16% of sales of sample molecules in 1998

- The average price of PIs relative to original brands was 89%
  - i.e. a price reduction of 11%
- The average margin on PI products was 21% (range 9% to 39%)
  - "Rents to the PI firms … are therefore considerable compared to the price reduction in the home market"
  - The consumer surplus (i.e. the gain to payers) was SEK 150m
  - The rent to PI firms was SEK 188m

Source: The Price Impact of Parallel Trade in Pharmaceutical Products: Evidence from the European Union : Mattias Ganslandt and Keith E Maskus

Winners and losers

Global estimates of the impact of parallel trade are hotly disputed, but it seems clear that:

Manufacturers
- Lose the difference between the lower and higher selling price
- Run some reputational risk

Parallel Traders
- Reap substantial gains

Pharmacists
- Gain some financial benefit, but often under duress
- May have much of the benefit "confiscated" by payers

Patients
- Gain little financially (because of copay systems in Europe)
- May run some risk in quality and safety

Third Party Payers
- Gain some financial benefit, but:
  - probably not as much as they believe
  - a relatively small percentage of the total trade

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Implications for payers

- **A politically easy source of savings**
  - **Pharmaceutical companies are seen as extremely profitable**
  - **In any European market, most drugs are supplied by "foreign" companies (usually US based)**
- **Appeals to a basic sense of "fairness"**
  - **"Why should we pay more than our neighbours?"**
    - **Especially when living standards are comparable**
  - **"Why should companies make "excessive" profits out of sickness?**
- **Does generate some real savings**
  - **Estimates vary, and in some markets (e.g. Germany) are probably minimal**
  - **Savings of 2.4% of pharmaceutical expenditure in UK, and 3.2% in Netherlands, almost all derived from the pharmacy clawback[1]**

[1]Source: Panos Kanavos, The Economic impact of Pharmaceutical Parallel Trade: A Stakeholder Analysis LSE January 2004

Implications for Companies

- Loss of profit
  - Clearly established. The difference between the selling price in the source market and the list price in the target market comes straight from profit
  - Impact is biggest on biggest and most profitable products
    - E.g 60% of Zyprexa sales in UK and Germany parallel imports
  - "Brand equalisation" i.e. targeted discounts may help to reduce impact, but only at a discounted price
- Impact on funding for R&D
  - Claimed but never convincingly demonstrated
  - May in the long run force industry consolidation and increase efficiency
- Impact on internal company incentives
  - Distorts sales figures in both source and target markets

Implications for patients

- No clear benefits from lower prices
  - Structure of cost-sharing and copays means that patients are not usually aware of the price of medicines
  - "Only in Denmark are direct savings found, but these are marginal" (Kanavos)

In the US there are potential benefits for many patients

- May increase risks for patients
  - Repackaging is legal and regulated
  - BUT
    - There may be quality issues re labelling and packing
    - There have been (a few) instances of out-of-date stock
    - Risk of counterfeit stock entering the distribution chain has been alleged, but there are no proven instances

A strong regulatory framework is necessary

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Managing parallel trade

- **For new products**
  - Assess the risk, which is dependent on
    - Product characteristics (special storage requirements, short shelf life etc)
    - Primary market – hospital or primary care
    - Anticipated sales volume
    - Anticipated price differentials
  - Develop a pricing strategy to minimise parallel trade, but recognise the limitations of this:
    - Commercially, it may be better to take high prices when you can, and accept some parallel trade. This can be modelled and tested. The realistic options are to cap prices in higher priced markets, or refuse to launch in lower priced markets. Neither is commercially attractive.
    - Practically, it may not be entirely feasible. Relative prices change over time, as a result of exchange rate fluctuations (outside the Euro zone) and Government-imposed price cuts (most major markets over the last five years).

Managing parallel trade (2)

- **For products already in the market:**
  - Review the current pricing structures. Is there any potential to increase prices in low priced markets, perhaps with off-setting reductions elsewhere in the portfolio?
  - Manage the product to minimise parallel trade
    - Product differentiation
      - Brand
      - Packaging and pack sizes

Such actions must relate to real differences in the relevant markets, and not be simply to prevent parallel trade

    - Supply restrictions (quotas) in exporting markets
      - Must notify in advance, to avoid punitive penalties
      - Not yet ruled illegal (Bayer Adalat case)
      - May cause supply shortages in source markets e.g. Greece

May provide temporary respite, for two or three years

Managing the internal implications

- What is the nature of the problem
  - How big is the commercial impact?
  - Is it likely to grow?
  - Is it distorting priorities within the company?
    - Incentives and motivation
- Are there actions you can take within the company to minimise the distortions parallel trade causes?
  - For example, link incentives to prescriptions, not sales

It is important to look at the internal implications, as well as external action, to minimise parallel trade

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The political dimension

- Reimportation does little to add to efficiency or overall welfare benefit in Europe
  - Most of the benefits accrue to the trader
  - The costs are met by the research-based pharmaceutical industry
  - But the trade can be effectively managed for quality and safety
- The real problem in the US is political
  - **Access to medicines at affordable prices**
    - Especially for out-of-pocket payers (i.e. seniors)
- Reimportation from Canada can never overcome that problem at the national level
  - The Canadian market is less than 10% of the US market
  - Even 50% oversupply in Canada could only meet 5% of US demand
  - Companies can manage supply much better than that
- Will Medicare Drug Benefit be a better solution?