Parallel Trading in Medicines: Europe’s Experience and its Implications for Commercial Drug Importation in the United States

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Agenda

- Parallel trade and how it works in Europe
- What lessons can Europe offer to the United States on drug parallel trade?
  - Safety
  - Regulatory requirements
  - Gains
  - Can it make a difference
  - Overall welfare perspective
How does parallel trade arise in Europe? There are significant price differences due to differences in systems of drug pricing.

Prices per pill, DDD-adjusted in selected EU countries, 2002 in €

<table>
<thead>
<tr>
<th>Drug</th>
<th>UK</th>
<th>Germany</th>
<th>Sweden</th>
<th>Spain</th>
<th>Italy</th>
<th>Greece</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipitor</td>
<td>1.01</td>
<td>1.37</td>
<td>1.04</td>
<td>0.96</td>
<td>0.63</td>
<td>0.55</td>
</tr>
<tr>
<td>Zocor</td>
<td>1.25</td>
<td>1.06</td>
<td>1.02</td>
<td>1.19</td>
<td>0.74</td>
<td>0.62</td>
</tr>
<tr>
<td>Prilosec</td>
<td>1.60</td>
<td>1.77</td>
<td>1.83</td>
<td>0.43</td>
<td>1.50</td>
<td>0.84</td>
</tr>
<tr>
<td>Zyprexa</td>
<td>5.48</td>
<td>5.78</td>
<td>5.37</td>
<td>3.57</td>
<td>3.60</td>
<td>3.30</td>
</tr>
<tr>
<td>Paxil</td>
<td>0.93</td>
<td>1.16</td>
<td>0.85</td>
<td>0.80</td>
<td>0.77</td>
<td>0.69</td>
</tr>
</tbody>
</table>
How does parallel trade work in Europe?

High price country (e.g. Germany)
- Manufacturer → Wholesaler → Pharmacy

Parallel distributor

Low price country (e.g. Spain)
- Manufacturer → Wholesaler → Pharmacy
Incentives encouraging the use of Parallel traded medicines in Europe

United Kingdom
1. Discounts to pharmacy
2. Clawback

Germany
1. Quota to pharmacies for PI dispensing
2. Penalties for not adhering to quota

Denmark
1. Information on PI use
2. Mandatory substitution

The Netherlands
1. 1/3 of price difference accrues to pharmacy
2. Clawback encouraging pharmacies to procure more cost-effectively

Sweden
1. Information and PI substitution
2. Aggregate payment to pharmacy for work on generics and PI drugs
What lessons can Europe offer to the United States
Legal & regulatory issues

- Free movement of goods and regional exhaustion of rights within the EU only
- No (significant) modifications are allowed to the original product
- Public health considerations in export countries
- Simplified licensing by regulatory authorities
- Manufacturer must be kept informed that parallel importation is commencing
Product safety

- Importation allowed only by licensed distributors
- No (significant) evidence of counterfeiting
- Manufacturers can recall products if safety standards are under threat
- A number of problems with packaging, labelling, patient insert
<table>
<thead>
<tr>
<th>Brand</th>
<th>LS</th>
<th>PI</th>
<th>Acquisition price</th>
<th>Co-pay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GERMANY</strong></td>
<td></td>
<td></td>
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<tr>
<td>Zyprexa</td>
<td>80.9</td>
<td>76.7</td>
<td>46.2</td>
<td>10%</td>
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<tr>
<td>Prozac</td>
<td>115.7</td>
<td>104.1</td>
<td>64.9</td>
<td>Flat</td>
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<tr>
<td><strong>THE NETHERLANDS</strong></td>
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<tr>
<td>Zocor</td>
<td>44.3</td>
<td>38.6</td>
<td>18.9</td>
<td>0</td>
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<tr>
<td>Risperdal</td>
<td>108.6</td>
<td>95.8</td>
<td>46.6</td>
<td>0</td>
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<tr>
<td><strong>UNITED KINGDOM</strong></td>
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</tr>
<tr>
<td>Zocor</td>
<td>46.7</td>
<td>46.7</td>
<td>17.7</td>
<td>Flat</td>
</tr>
<tr>
<td>Zyprexa</td>
<td>153.6</td>
<td>153.6</td>
<td>88.0</td>
<td>Flat</td>
</tr>
</tbody>
</table>
Gains (2)

- Health insurance realises small benefits
- Consumers realise at most marginal benefits
- Distribution chain (parallel distributors and pharmacies) realise most of the benefits
- Manufacturers incur losses: Impact on R&D?
- Export countries may register product shortages: some (anecdotal) evidence
Can reimportation make a difference in the USA?

*Three dimensions*

1. Price structure
2. Product availability
3. Bypassing the distribution chain
Can reimportation make a difference in the USA?
Price structure (federal sector)

EU G5 comprises UK, Germany, France, Italy, Spain
WAC vs. FSS price: weighted average discount of top-50 selling products is 38%

Source: Kanavos et al, LSE, 2005
Can reimportation make a difference in the USA? Is there enough product available to be imported?

If Europe is a key source of imports to the United States, the following need to be considered:

- **Product availability**: not secure
- **Sustainable supply**: uncertain
- **Supply restrictions**: may apply (legally so)
- **Bypassing distribution (wholesaler) chain**: can occur (probably legally so)
Conditions that must be satisfied for consumers to benefit

- ... Must have incentive to seek lower-priced drug; insurance status and cost-sharing burden
- ... Must be aware that PI version may be available and actively ask at pharmacy
- ... Price differences between LS and PI have to be meaningful and be passed on to consumers
- ... Supply must be sustainable for benefits to be realised over time
- ... Perception of quality of PI drug must be the same