International Trade and its Impact on the Effectiveness of National Regulation in Pharmaceuticals

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Introduction and Hypothesis

- National regulatory authorities devise manifold expense control measures for pharmaceuticals. In most countries, however, costs for pharmaceuticals, especially for patented, branded and internationally traded drugs, keep strongly increasing. At the same time the concentration of the research based pharmaceutical industry has been steadily advancing. This study assumes a connection between the above parameters.
Introduction and Hypothesis

• National authorities devise complex and widely diverse regulations on pharmaceuticals
• Pharmaceutical firms are exposed to different sets of regulation especially by international trade of their products
• Different sets of regulation drive firm internal complexity; complexity costs are an important driver of industry concentration
• Industry concentration weakens competitive forces, leading to less innovation and higher prices for branded drugs
Introduction and Hypothesis

• As internationalization of industry activities proceeds, national regulation aimed at reducing costs for pharmaceuticals can have the unintended indirect effect of leading to higher drug prices in the longer run, thereby compromising the original goal.
Expenses for Pharmaceuticals

Table 1: Spending on prescription pharmaceuticals in selected OECD countries

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</thead>
<tbody>
<tr>
<td>US</td>
<td>226,758</td>
<td>10,3%</td>
<td>11,3%</td>
</tr>
<tr>
<td>Japan</td>
<td>60,144</td>
<td>17,3%</td>
<td>5,6%</td>
</tr>
<tr>
<td>Korea</td>
<td>13,398</td>
<td>16,4%</td>
<td>16,5%</td>
</tr>
<tr>
<td>Germany</td>
<td>39,523</td>
<td>13,3%</td>
<td>6,4%</td>
</tr>
<tr>
<td>France</td>
<td>30,819</td>
<td>13,5%</td>
<td>6,0%</td>
</tr>
</tbody>
</table>

SOURCE: OECD Health Data 2010
Expenses in Pharmaceuticals

- Expenses for pharmaceuticals have a high share of total expenditure on health and are growing briskly.
- The expense share for pharmaceuticals is especially high in Asian countries, e.g. in China amounting to more than 40%.
## Trade in Pharmaceuticals

### Table 2: International trade in pharmaceuticals in selected OECD countries

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<tr>
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</thead>
<tbody>
<tr>
<td>US</td>
<td>31,753</td>
<td>13,6%</td>
<td>50,013</td>
<td>17,7%</td>
</tr>
<tr>
<td>Japan</td>
<td>4,249</td>
<td>8,8%</td>
<td>9,154</td>
<td>9,8%</td>
</tr>
<tr>
<td>Korea</td>
<td>1,220</td>
<td>6,5%</td>
<td>3,792</td>
<td>12,7%</td>
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<tr>
<td>Germany</td>
<td>43,637</td>
<td>16,7%</td>
<td>34,582</td>
<td>18,6%</td>
</tr>
<tr>
<td>France</td>
<td>22,158</td>
<td>13,3%</td>
<td>17,700</td>
<td>12,7%</td>
</tr>
</tbody>
</table>

SOURCE: OECD Health Data 2010
Trade in Pharmaceuticals

- The international trade in pharmaceuticals is growing at a very high pace, which highlights the increasing exposure of pharmaceutical companies to different sets of national regulation.
- Besides by international trade the globalization of the research-based pharmaceutical industry advances in R&D, production and other fields.
National Regulation in Pharmaceuticals

• In any developed country the development, production and sale of pharmaceuticals is highly regulated

• Examples:
  – New packaging rules in Germany
  – Price setting regime in Japan

• Meeting the regulation requirements in a multitude of jurisdictions leads to many complications not only for the regulatory affairs departments of the respective firms, but in most other areas of the value chain like R & D, logistics and marketing
Pharmaceutical Industry Structure

• The industry structure of the international pharmaceutical business is marked by a steady trend towards concentration. Four-firm or eight-firm concentration ratios are increasing and competition measured by the Herfindahl-Hirschman Index is decreasing in important countries over the years.

• If measured not for the whole industry, but for drugs classed in the same therapeutic categories the concentration ratios are even higher.
Pharmaceutical Industry Structure

- High profile M&A activities in the pharmaceutical industry:
  - Pharmacia, Warner-Lambert, Searle, Upjohn and Wyeth all absorbed by Pfizer in the US
  - Merger between Merck and Schering-Plough
  - Astellas in Japan formed by Merger
  - MedImmune absorbed by AstraZeneca
  - Genzyme absorbed by Sanofi-Aventis
Pharmaceutical Industry Structure

• Scale and scope in R&D and marketing are an often cited reason for mergers
• The cost of R&D and marketing are strongly influenced by exposure to different sets of national regulation; regulations form thus an important underlying factor for industry concentration
• High industry concentration leads to reduced competition which in turn decreases the rate of innovation and increases the cases of monopolistic price setting for given products
Conclusions

• By influencing industry structure and behaviour, national regulations on pharmaceuticals can have long term unintended effects

• Stronger international harmonization efforts can soften those effects without compromising on safety and cost efficiency in providing pharmaceuticals

• Health care reformers in Asian countries, where expenses for pharmaceuticals weigh especially high, should carefully consider the effects of their regulatory regimes