Competition in the off-patent biological market: Policies for biosimilars in Europe

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Promotors: prof. I Huys, prof A Vulto, prof P Declerck

Barriers to entry and use of biosimilars

- Lack of incentives
- Lack of knowledge
- No substitution
- IP rights
- Innovator's reach
- Complex development

Market potential incentivized companies and countries

Supply side:
Investment by companies

Demand side:
European countries implemented various policies

No country has high penetration in all biosimilars

<table>
<thead>
<tr>
<th>Country</th>
<th>Infliximab</th>
<th>Insulin Glargine</th>
<th>Etanercept</th>
<th>Rituximab</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>94.1%</td>
<td>5.0%</td>
<td>69.3%</td>
<td>36.5%</td>
</tr>
<tr>
<td>France</td>
<td>92.8%</td>
<td>5.4%</td>
<td>60.9%</td>
<td>36.5%</td>
</tr>
<tr>
<td>Germany</td>
<td>43.7%</td>
<td>7.3%</td>
<td>41.8%</td>
<td>36.5%</td>
</tr>
<tr>
<td>Italy</td>
<td>58.3%</td>
<td>1.5%</td>
<td>17.7%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Spain</td>
<td>44.9%</td>
<td>9.2%</td>
<td>5.3%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Poland</td>
<td>92.7%</td>
<td>5.4%</td>
<td>86.9%</td>
<td>-</td>
</tr>
<tr>
<td>Norway</td>
<td>92.7%</td>
<td>5.4%</td>
<td>86.9%</td>
<td>-</td>
</tr>
<tr>
<td>Finland</td>
<td>100.0%</td>
<td>24.8%</td>
<td>23.8%</td>
<td>-</td>
</tr>
<tr>
<td>Denmark</td>
<td>99.1%</td>
<td>5.0%</td>
<td>86.9%</td>
<td>-</td>
</tr>
<tr>
<td>Japan</td>
<td>86.9%</td>
<td>5.0%</td>
<td>86.9%</td>
<td>-</td>
</tr>
<tr>
<td>Canada</td>
<td>3.6%</td>
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<tr>
<td>US</td>
<td>2.8%</td>
<td>0.0%</td>
<td>1.6%</td>
<td>-</td>
</tr>
</tbody>
</table>

Pricing of off-patent biologicals – List prices

**Pricing of biosimilars:**
- % below price of originator
- Maximum price
- …
→ often combination of different pricing mechanisms

**Pricing of off-patent biologicals/reference products:**
- Price cuts for originators
E.g. Iceland: -20% on original ex-factory price after entry of biosimilar

Influence of mandatory price cuts on originator for sustainability of biosimilar market?

⚠ List prices vs actual prices after discounts and rebates


Pricing of off-patent biologicals – Tendering

Often by INN → no difference between treatment-naïve patients and on treatment

**Sustainability considerations:**
National – regional – hospital level
Multiple winners – single winner

Sweden
21 county councils

Norway
National tender

England
4 supra regions

Rotation system:
- Next region every 6 months
- Tender duration 2 year

Reimbursement of biosimilars

Approximately half of European countries use internal reference pricing

Limited information on methodology and process from authorities and literature

→ Questions

<table>
<thead>
<tr>
<th>Economic evaluation</th>
<th>Budget impact analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need?</td>
<td>Need?</td>
</tr>
<tr>
<td>Technique?</td>
<td>Budget affected?</td>
</tr>
<tr>
<td>What if reference product not reimbursed?</td>
<td>Consider volume evolution?</td>
</tr>
<tr>
<td>What if 2nd-generation products enter?</td>
<td>Consider price evolution?</td>
</tr>
<tr>
<td>Which comparator for 2nd-generation products?</td>
<td>Consider market entry of new products?</td>
</tr>
</tbody>
</table>

Process often delays market entry of biosimilar

Demand-side policies

Incentives for physicians

• **Quotas** on biosimilars:
  - Belgium: 20% biosimilars for treatment-naïve patients (Covenant)
  - Germany: Target agreements per region

• **Recommendations**:
  - Sweden: Use most cost-effective product (e.g., for etanercept)

• **Economic prescribing**:
  - Germany: Prescribing budgets
**Demand-side policies**

**Switching policies**
- Mostly at discretion of physician
- Some countries issued a position statement e.g., Norway, Sweden

Different approaches possible: discussion with patient, letter to inform patient

**Substitution policies**
- (Restricted) pharmacist substitution in Estonia, Latvia, Poland and Russia

France: Legislation introduced for treatment-naïve patients, not implemented

Germany: Groups of bio-identicals


**Demand-side policies**

**Education**
- Varies at country level, but tends to target physicians

- Initiatives of the European Commission and EMA


Website EMA. Biosimilar medicines
**Impact of policies?**

Important to create competition, not just uptake of biosimilars as originator might be the least expensive treatment option. However, biosimilars need to have market share to exert competitive pressure.

**Potential drivers for implementation:**
- Price difference between originator and biosimilar (Savings!)
- Attitude of key opinion leaders
- Local guidelines/recommendations/quota
- Gainsharing arrangements

→ Need for multi-stakeholder approach, communication on decisions, and education of stakeholders to make policy decision work!

**Conclusions**

Policies targeting price not sustainable in the long term

Focus on demand-side policies

Guidelines and recommendations

Quota

Gainsharing arrangements


Thank you!

Contact

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Step 2

Step 3  
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Go to your web browser and type in: https://myispor.cnf.io/ >> Select your session
Poll: To what extent is your healthcare system unlocking the biosimilar value proposition and fully utilizing biosimilars to enable broad access?