Value proposition of biosimilars in countries with resource constraints

András Inotai PhD, DrHabil
Assistant Professor,
Head of Pharmaceutical Policy Research

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Off-patent medicines: objectives of pharmaceutical policies

- Disinvestment aspect: Reduce health care expenditure without compromising health outcomes → sustainability of health care financing
- Investment aspect: Increase population health gain by improved patient access without increasing health expenditure → health improvement

Opportunity for the investment aspect of biosimilars in Eastern European countries

In lower income countries the accessibility of patients to high cost biological medicines may be limited, because sustainability of health care financing is facilitated by implementing volume limits, influencing

1. prescribers:
   - financing protocols to allow prescriptions only for subgroup of patients
   - volume limit for individual prescribers or health care institutions
   - second-line reimbursement only after the first-line therapy fails
   - prescription is limited to selected centers

2. patients:
   - waiting lists
   - limited treatment duration
   - significant copayment for biological medicines or related services
   - significant travel time and costs to prescribing centers

3. manufacturers:
   - delayed reimbursement
   - price-volume agreement

Biosimilars at lower price can improve patient access


Evidence from access restrictions related to biologics in 10 CEE countries

## Value proposition of biosimilar medicines

<table>
<thead>
<tr>
<th>Decision context</th>
<th>Originator is reimbursed without access limits to patients</th>
<th>Originator is reimbursed with access limits to patients</th>
<th>Originator is not reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value proposition</td>
<td>• savings in drug budget</td>
<td>• no increase in drug budget</td>
<td>• potential increase in drug budget</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• improved patient access</td>
<td>• health gain</td>
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<tr>
<td></td>
<td></td>
<td>• health gain</td>
<td></td>
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<tr>
<td></td>
<td>Disinvestment</td>
<td>Re-investment of savings</td>
<td>Investment</td>
</tr>
</tbody>
</table>


### Treatment arms

<table>
<thead>
<tr>
<th>Drug price:</th>
<th>Non-biologic medicine</th>
<th>Biosimilar medicine</th>
<th>Original biologic medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1000 €</td>
<td>3000 €</td>
<td>5000 €</td>
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<table>
<thead>
<tr>
<th>Number of patients</th>
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<tr>
<td>Before patent expiry</td>
</tr>
<tr>
<td>After patent expiry</td>
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</tbody>
</table>

- **Improved population health with neutral budget impact**

Not really, because ....

- ... for treatment naive patients, physicians prefer prescribing therapies with no biosimilar alternative due to hypothetical concerns related to indication extrapolation.
  - to avoid risk of (being forced to) switching patients to biosimilars.
  - as biosimilars and other patented biologicals are in the same treatment line in financing protocols (i.e. first line therapy).

- ... in maintenance therapy, physicians prefer continuing the original therapy due to hypothetical risks of immunogeneicity related to switching to biosimilars.

Suboptimal biosimilar medicines policy in access-restricted environment

Social Q&A

Poll: What are the key barriers for biosimilar utilization in your healthcare system?
Poll: What is the balance in your healthcare system between maximising short term gains of biosimilars versus creating a sustainable biosimilar market for sustained benefit?