Sustainable biosimilar policies

Panel discussion -
Joint 22nd Medicines for Europe and 19th IGBA Annual Conference in Dubrovnik

June 9, 2016
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Agenda

- Project overview
  - Sustainability in the biosimilar market
  - Principles for a sustainable biosimilar market
Project overview

Preliminary results
Sustainability of country-specific biosimilar P&MA policies

Geographical scope

<table>
<thead>
<tr>
<th>Country</th>
<th>Flag</th>
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<tbody>
<tr>
<td>France</td>
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<td>Germany</td>
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Stakeholder focus

<table>
<thead>
<tr>
<th>Focus of this project</th>
<th>Indirectly considered</th>
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<tr>
<td><strong>Biosimilar manufacturers</strong></td>
<td><strong>Patients</strong></td>
</tr>
<tr>
<td><strong>Payers</strong></td>
<td><strong>Physicians</strong></td>
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<tr>
<td><strong>Policy makers</strong></td>
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Source: Simon-Kucher & Partners
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- Project overview
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- Principles for a sustainable biosimilar market

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How do the different stakeholders draw their ideal picture of a sustainable biosimilar market?

Biosimilar manufacturers

“A sustainable biosimilar market is a predictable market allowing for co-existence of biosimilar manufacturers and a price-volume combination that enables continuous investment in further innovation.”

Payer

“A sustainable biosimilar market is a situation in which biosimilars create financial savings without jeopardizing the current treatment standards.”

Criteria for a sustainable biosimilar market need to be defined that find acceptance among both stakeholder groups, payers and manufacturers

Overview of sustainability criteria, designed to allow reflecting both perspectives - payers’ and manufacturers’

Which criteria best describe a sustainable biosimilar market?

1) High biosimilar penetration
2) Payer guidance on biosimilars vs. originators
3) Fair price level for biosimilars
4) Commercial attractiveness
5) Acknowledgement of high complexity of biosimilars within P&MA process
6) Maintain healthy competition in the long-term
7) Low effort needed to monitor & enforce policy
8) Parallel sourcing from multiple manufacturers (short-term perspective)
9) Earlier and broader use of biosimilars in additional patient segments
A high biosimilar penetration as well as a payer guidance on biosimilars vs. originators are perceived as important sustainability criteria from both, payers and manufacturers.

### Importance of sustainability criteria from a payer and biosimilar industry point of view

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Payer Average across Countries</th>
<th>Industry Average across Manufacturers</th>
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<tbody>
<tr>
<td>1. High biosimilar penetration</td>
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<td>2. Payer guidance on biosimilars vs. originators</td>
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**Source:** Simon-Kucher & Partners

### Qualitative insights on selective sustainability criterion: High biosimilar share

**Stakeholder incentive behind sustainability criterion**

- **Biosimilar industry:** Additional sales
- **Payer:** Budget savings

**Stakeholder reaction towards sustainability criterion**

- **Aligned:** Importance of high biosimilar share
- **Not aligned:** Distribution of biosimilar share
  - Biosimilar industry: Shared business potential (multiple manufacturers)
  - Payer: Source of supply often not in focus

"Only if the biosimilar share is high, multiple manufacturers will be able to participate in the market."

"I favor the highest share for the least expensive alternative and this is mostly a biosimilar."
### Qualitative insights on selective sustainability criterion: Payer guidance on biosimilars vs. originators

<table>
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<tr>
<th>2 Payer guidance on biosimilars vs. originators</th>
<th>Stakeholder incentive behind sustainability criterion</th>
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<tr>
<td></td>
<td><strong>Biosimilar industry</strong>: Additional sales</td>
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**“Payers and their national healthcare systems have to feel responsible to encourage biosimilar uptake.”**

**“If the market works well, there is no strong need to put further payer guidance in place.”**

### Stakeholder reaction towards sustainability criterion

**Aligned**: Importance of payer guidance on biosimilars vs. originators

**Not aligned**: Extent of payer guidance required to drive uptake appropriately

- Biosimilar industry: Expect payers to more intensively drive biosimilar uptake via guidances
- Payer: Only few payers admit that current biosimilar guidances need to be improved

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### Qualitative insights on selective sustainability criterion: Fair price level

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<th>3 Fair price level</th>
<th>Stakeholder incentive behind sustainability criterion</th>
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<tbody>
<tr>
<td></td>
<td><strong>Biosimilar industry</strong>: Appropriate sales/income</td>
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<tr>
<td></td>
<td><strong>Payer</strong>: Budget savings</td>
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**“Several markets have P&MA policies in place, implicitly requiring biosimilar manufacturers to immediately offer high discounts in order to stay in the market (e.g. single-winner tenders).”**

**“It’s not always the payers asking for high discounts. Often, it’s the biosimilar industry itself, offering voluntary price concessions of 50% or higher.”**

### Stakeholder reaction towards sustainability criterion

**Aligned**: Both parties must benefit from biosimilar price

**Not aligned**: Exact level that is then considered to be fair

- Biosimilar industry: Higher prices and reasonable price erosion over time
- Payer: High price expectation & influenced by price concessions of manufacturers
### Qualitative insights on selective sustainability criterion: Commercial attractiveness

#### Stakeholder incentive behind sustainability criterion
- **Biosimilar industry**: Coverage of substantial investments
- **Payer**: Maintained competition for future biosimilars

#### Commercial attractiveness

**"We need to sustain long-term profits in order to be able to further invest in future biosimilar research and development. Every price discount should be compensated with an appropriate uptake in volume."**

**"I agree that investments have to be balanced by income, but can’t judge if e.g. a 10% ROI is sufficient for manufacturers. But they will never provide us with their real cost structure. And if so, would we believe them?"**

#### Stakeholder reaction towards sustainability criterion

**Aligned**: Fair return on investment

**Not aligned**: Which return on investment would be considered fair
- Biosimilar industry: Upfront expenditures have to be balanced by income, allowing for continuous investments
- Payer: No trust in manufacturers’ argumentation of commercial business case

### Qualitative insights on selective sustainability criterion: Acknowledgement of biosimilar complexity

#### Stakeholder incentive behind sustainability criterion
- **Biosimilar industry**: Appropriate compensation for higher upfront investment
- **Payer**: Maintain attractiveness of market for manufacturers

#### Acknowledge high complexity of biosimilars within P&MA policy

**"It is crucial to acknowledge that biosimilars are complex in many ways: development, production, transportation, supply and storage."**

**"Higher complexity of biosimilars vs. generics is already being considered throughout our P&MA policies – for generics we are expecting much higher discounts."**

#### Stakeholder reaction towards sustainability criterion

**Aligned**: Biosimilar complexity to be considered throughout P&MA policies

**Not aligned**: Magnitude of influence on P&MA policies
- Biosimilar industry: P&MA policy to stronger appreciate biosimilar complexity
- Payer: Current P&MA policies already take into account biosimilar complexity
‘Area of misalignment’ between biosimilar industry and payers should be addressed by targeted principles

On certain sustainability aspects, payers and biosimilar industry show differences in terms of the perceived level of importance or in the way they interpret their exact meaning.

Principles for a more sustainable biosimilar market

- High biosimilar share
- Fair price level for biosimilars
- Commercial attractiveness

**Principle 1**

**Principle 2**

**Principle 3 & 4**

Source: Simon-Kuchner + Partners

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Principle 1

P&MA policies and payer decisions should ensure that the significant investments for biosimilar manufacturers are balanced by a reasonable income

Characteristics of biosimilars demonstrate the need for high investments:

1. More than 250 manufacturing quality tests
2. Marketing approval requires large clinical trials in patients
3. May take 8-9 years of clinical development time
4. Significant upfront investment; can be in the range of €150m to €250m
5. Potential for high adverse immune reaction for biologics in general → high pharmacovigilance cost

Source: Simon-Kucher & Partners and manufacturer discussions
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Principle 2

P&MA policies should ensure a continuous market participation of several biosimilar manufacturers in order to maintain healthy competition

‘Win-wins’ due to continuous market participation of multiple biosimilar manufacturers

- Short-term supply guarantee
- Budget savings due to competition triggering price decreases
- Maintain interest of manufacturers to keep market participation
- Better predictability of business
- Healthy co-existence of several suppliers

Example: Pharmadialog (agreement between industry and payers/policy makers)
- Increased risk of supply guarantee has been observed with current procurement measures (e.g. rebate contracts)
- As a consequence industry and payers/policy makers have agreed that future procurement measures need to enable parallel supply from multiple manufacturers

Source: Simon-Kucher & Partners
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**Principle 3**

P&MA policies enforcing lower biosimilar prices compared to their originators have to be accompanied by specific guidance on biosimilar use and prescribing incentives. A lower price for biosimilars on its own will prevent generation of return on investments for biosimilar manufacturers.

**Balanced relationship between price discount and added volume via prescribing incentives**

**Unbalanced relationship between price discount and added volume via prescribing incentives**

Source: Simon-Kucher & Partners analysis based on IMS data

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**Principle 4**

A P&MA policy that does not allow for commercial attractiveness for biosimilar manufacturers will reduce competition in the long run and thus negatively impact the likelihood for payers to generate savings.

1. Aggressive biosimilar P&MA policy demanding high price discounts w/o encouraging uptake
   1.1 Limited savings potential for payers
   1.2 Limited biosimilar awareness & acceptance of relevant stakeholders
   1.3 Limited negotiation dynamics for payers

2. Limitation of commercial attractiveness
   2.1 Lack of acceptance & buy-in of essential stakeholder groups (e.g. patients & physicians)
   2.2 Lack of competition

3. Constraining ability to earn back future investments
   3.1 Limited means to provide physician education on biosimilars & to invest in data generation & similar activities
   3.2 Individual manufacturers refraining from market participation

Source: Simon-Kucher & Partners

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Principle 5

Gain sharing has proven to be a successful driver of biosimilar uptake across multiple markets, with benefits for both prescribers / decision makers and payers.

<table>
<thead>
<tr>
<th>Non-cash gain sharing at hospital level</th>
<th>Gain sharing at hospital level</th>
<th>Gain sharing at level of physician (association)</th>
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</table>
| Fix drug program / hospital budgets    | Hospitals entitled to keep generated savings (difference between DRG and spendings) | Agreement between physicians’ association (KV Westfalen-Lippe) and statutory health insurance (Barmer GEK) to improve quality of care of patients with IBD*:
| Generated savings (e.g., via lower drug acquisition cost) allow for more patients to be treated within existing budget | Hospitals incentivized to purchase T2A products at low prices: difference between the reimbursement and price paid are split (hospitals, payers) | – Part of this agreement:
|                                                                                       |                                                                                       | Absolute savings generated from prescribing infliximab biosimilar will be split equally between the treating physician and the health insurance |
| No ‘cash-based’ savings, but release of budget constraints                             | Savings can ‘get lost’ in hospital overhead, leading to no tangible benefits for treating physicians | Treating physicians directly benefit from generated savings |

Gain sharing is most effective in case the healthcare provider sees tangible benefits from generated savings (additional services for patients, improved working conditions, monetary benefits, etc.)

How should the biosimilar market ideally be shaped in order to be sustainable for both, payers and the biosimilar industry?

A sustainable biosimilar market from the perspective of both payers and the biosimilar industry should deliver the following:

1. Long-term savings for the health care system due to a fair erosion of prices at an adequate volume of prescribed biosimilars
2. Viable business through healthy competition of several manufacturers:
   - Limited changes to the P&MA policies over time reduce payers’ efforts and increase predictability for the industry
   - Procurement practices that allow for simultaneous business potential for several manufacturers in the same market, e.g. by regional differentiation or multiple tender lots
   - Prescribing incentivization of less expensive biosimilars vs. their reference products
3. Physician education and incentivization to ensure appropriate but cost-conscious prescribing

Source: Simon-Kucher & Partners
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Thank You!