PRICING AND REIMBURSEMENT CONSIDERATIONS FOR BIOSIMILAR S的成功

Paul Craddy
Managing Director, Remap Consulting
Remap Consulting is a specialist Pricing, Reimbursement and Market Access Consultancy focusing on three core areas:

- **Launch**
- **Training**
- **Pricing**
We partnered with a biosimilar company to secure pricing and reimbursement of a biosimilar in 31 EU countries

**Project scope**

Development and submission of payer communication materials and pricing and reimbursement dossiers for a biosimilar across 31 EU markets

**Our overall approach**

- Identified country specific P&R requirements
- Identified and mitigated gaps in products evidence base
- Prepared payer communication materials
- Executed country specific P&R dossier submissions

**Outcome**

"You guys are awesome. Your expertise and responsiveness are second to none. Without your support we could never have achieved an EU launch."

Senior Director, Marketing

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Agenda

P&R considerations for biosimilars

Biosimilar market access strategies

Development of sustainable biosimilar markets

Considerations for the US biosimilar market

Summary
Biosimilars have the potential to improve sustainability of healthcare systems

- The annual growth of the biologic market is >8%
- 30% of pharmaceutical sales in Europe are for biologics
- €1.5BN in savings in the EU5 alone with the introduction of biosimilars
Despite the opportunity presented by biosimilars uptake, pricing and market share has varied substantially across markets

The biosimilar market in Europe is significantly more established compared to the US

- **Europe**: 29 approvals since 2006
- **US**: 5 approvals since 2015

However, even within Europe, approaches to biosimilars vary significantly;

- **Biosimilars typically achieve substantial market share vs. originator (68 – 96%) in countries such as Norway and Poland**
- **Greatest price reductions (>60%) are common in countries such as Denmark and Norway**
- **Germany has one of the most competitive biosimilar markets in Europe**

Overall, there is no ‘one size fits all’ strategy for biosimilars
National payers recognise the value of biosimilars and have facilitated pricing and reimbursement processes to gain access

<table>
<thead>
<tr>
<th>Full P&amp;R submission required</th>
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<tbody>
<tr>
<td><img src="flag.png" alt="France" /> <img src="flag.png" alt="Spain" /> <img src="flag.png" alt="Sweden" /> <img src="flag.png" alt="Greece" /></td>
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<table>
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<tr>
<th>Abbreviated biosimilar process</th>
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<td><img src="flag.png" alt="Austria" /> <img src="flag.png" alt="Poland" /> <img src="flag.png" alt="Netherlands" /> <img src="flag.png" alt="Italy" /></td>
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<th>No national consideration</th>
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<tr>
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Note, reimbursement through these processes is only achieved for indications within which the originator has already gained approval. In the case of new indications, additional HTA submissions will be required.

Approval pathways impact evidence base requirements and launch sequencing

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However, regional/local payers can pose a major challenge in securing patient access for biosimilars.

Most biosimilar companies struggle to gain effective local market access.
Stakeholder support and influence varies depending on the biosimilar product indication

<table>
<thead>
<tr>
<th>“Specialist” indications</th>
<th>Broader indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>‣ Infertility, anaemia and growth hormone deficiency</td>
<td>‣ Rheumatoid arthritis, autoimmune diseases</td>
</tr>
<tr>
<td>‣ E.g. epoitein alfa, filgrastim and somatropin biosimilars</td>
<td>‣ Anti-TNFs (associated with greater costs than “specialist” biosimilars)</td>
</tr>
<tr>
<td>‣ Less payer focus, due to limited budget impact and smaller patient populations</td>
<td>‣ Higher payer focus due to greater patient numbers, chronic and lifelong therapy, plus high cost</td>
</tr>
<tr>
<td>‣ High existing knowledge base (patient registries etc.) and strong existing links</td>
<td>‣ Significantly less physician / KOL engagement and input</td>
</tr>
<tr>
<td>between specialist KOLs and manufacturers</td>
<td></td>
</tr>
<tr>
<td>‣ Physicians are unlikely to switch mid-treatment, limiting uptake to new patients</td>
<td>‣ Biosimilar may enable treatment of more patients</td>
</tr>
</tbody>
</table>
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The biosimilar competitive environment can significantly impact your pricing and patient access strategy

<table>
<thead>
<tr>
<th>Big Pharma</th>
<th>Traditional generic companies</th>
<th>“Disrupter” biotechs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer, Roche, Amgen</td>
<td>Teva, Sandoz, Hospira</td>
<td>Samsung, Finox</td>
</tr>
<tr>
<td>Use in-house capabilities to focus biosimilar pipeline on development of monoclonal antibodies</td>
<td>Focus on commercializing biosimilar hormones, cytokines and enzymes (e.g. insulin)</td>
<td>Develop innovative biologics but typically limited experience</td>
</tr>
<tr>
<td>Strategy is focused on generating and selling for “value”</td>
<td>Less complex manufacturing process allows products to be sold at “generic-like” prices</td>
<td>Have capabilities to produce biosimilars at very little additional cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disrupter strategy focused on gaining significant market share, usually by price reduction</td>
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Strategies employed by biosimilar manufacturers are often unaligned to expectations of payers

There are key discrepancies between payers and industry views on biosimilar guidelines and on pricing of biosimilars

**Guidelines**

- Biosimilar manufacturers expect greater guidance on biosimilars in local markets* to aid market access strategy
- However, in general, payers believe current guidelines are sufficient to aid biosimilar entry

**Pricing**

- Ideally, biosimilar manufacturers aim for moderate rebates at launch, followed by gradual price erosion
- Payers have expectations of high price reductions at launch and are influenced by price concessions of manufacturers

*Germany and the UK are exceptions to this and are considered to have pricing and market access policies in place which effectively support a sustainable biosimilar market
Payers and physicians must work together to achieve cost savings; however physician support can be lacking.

Physicians are key decision-makers in determining the treatment patients receive. It is important that they be educated on the:
- Clinical benefits of biosimilars
- Health system benefits of using biosimilars

Germany has been more successful in implanting physician education programs than other markets:
- 50% of Germany HCPs report they are extremely familiar with biosimilars (versus 32% of HCPs in France and 34% in the US)

<table>
<thead>
<tr>
<th>Issue</th>
<th>Task</th>
<th>Countries with effective biosimilar education processes in place</th>
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<tbody>
<tr>
<td>Manufacturers are not always trusted by HCPs for education</td>
<td>Build trust with key stakeholders</td>
<td>Denmark, Germany, Italy, Norway, Spain</td>
</tr>
<tr>
<td>Lack of education processes by regional / local payer</td>
<td>Implement education strategies (e.g. German GKV system)</td>
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In Norway, the NOR-SWITCH study helped gain physician support for biosimilars by comparing to the originator.

NOR-SWITCH

Randomised, double-blind study designed to evaluate the effects of a single switch from the original biologic (Remicade) to the biosimilar (Remsima) across six inflammatory diseases for which infliximab is approved.

Used by Norwegian payers as an additional argument in favour of switching practice.

500 patients enrolled

Studies such as these have the potential to influence policies that govern biological medicines and impact how biosimilars are approached by physicians around the world.

Commissioned by the Norwegian Government.
Automatic substitution has the potential to drive biosimilar market share, but clearer guidance for physicians is needed

- Payers employ varying approaches to interchangeability across markets
- Inconsistencies mean HCPs are often unsure about switching
  - E.g. France – automatic substitution is permissible but rarely occurs in practice
- Automatic substitution can often be seen as an “extreme measure” (with concerns of safety and efficacy mainly from patients and physicians)
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In the longer term, payers and manufacturers need to work together to develop a sustainable biosimilar market

**Ideal sustainable biosimilar market characteristics**

- High biosimilar share
- Parallel sourcing from multiple manufacturers
- Acknowledge high complexity of biologics
- Payer guidance on biosimilar use
- Fair price level for biosimilars
- Early and broader use of biosimilars

**Sustainable biosimilar market?**

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
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<tbody>
<tr>
<td>Denmark</td>
<td>✗</td>
</tr>
<tr>
<td>Italy</td>
<td>✗</td>
</tr>
<tr>
<td>Norway</td>
<td>✗</td>
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<tr>
<td>Russia</td>
<td>✗</td>
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<tr>
<td>Spain</td>
<td>✗</td>
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<tr>
<td>France</td>
<td>✗</td>
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<tr>
<td>Germany</td>
<td>✓</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>✓</td>
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Payers agree that a competitive biosimilar market is beneficial for supply guarantee and sustainable growth.

Benefits to manufactures:
- Predictable market
- Sustainable price-volume combination

Benefits to payers:
- Reduced budget impact
- Continuing patient care

Increasing number of biosimilar manufacturers

Commercial attractiveness per individual manufacturer

Supply guarantee and bargaining power of payer

High biosimilar uptake
In Norway, the use of national single-winner tender grants is leading to significant price reductions and increased uptake

- National single-winner tenders drive high voluntary price concessions
- Remsima (infliximab; Remicade biosimilar, launched December 2013):
  - Å 69% discount
  - Å 30-months post-launch: 95% of market share
- Payers in many Central and Eastern European countries are using the example of Norway to demand similar discounts:
  - Å Denmark: Remicade biosimilar gained 96% market share after >70% price reduction
Extreme pricing discounts such as these lead to rapid increases in biosimilar market share

Within 12 months of employing a 69% discount, Remsima® became market leader in Norway (gaining 51% market share)

However, although significant discounts allow short term savings, this strategy is unsustainable in the long term.

Payers in Norway have not been able to achieve the same level of discount with recent biosimilar launches, e.g. etanercept biosimilars launched with a 47% discount in 2016.
The aggressive pricing and lack of competition will pose challenges for the sustainability of the Norwegian market.
Overall, a number of key steps need to be taken to improve the future sustainability of the biosimilar market in Europe.

**Investigator-led studies**
- E.g. further studies such as NOR-SWITCH to increase physician support

**Multi-tender rather than single-tender systems**
- Maintain competition within the biosimilar market to ensure future sustainable growth

**Future outlook for payers and manufacturers**

**Physician education programs**
- Both payers and manufacturers will play a role in educating HCPs on the use of biosimilars

**Gradual price erosion favoured over extreme discounts at launch**
- Greater alignment between payers and industry on biosimilar pricing strategies will allow long-term benefits and ensure patient access
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In contrast, the future of the US biosimilar market is highly uncertain, with a number of potential opportunities and challenges.

**Potential opportunities**

- Use of patient incentives by PBMs
- Categorization of biosimilars as “single-source” drugs on Medicaid
- Unrestricted distribution models

**Potential challenges**

- Rebate concerns
- Extensive interchangeability requirements
- Patent litigation (the “patent dance”)

Uptake of biosimilars in the US could lead to Medicare savings of $4 billion / 10 years.
Biosimilars launching in the US can face significant barriers from originators, as demonstrated by Pfizer’s Inflectra

<table>
<thead>
<tr>
<th>Biosimilar: Inflectra, Pfizer</th>
<th>Originator (Remicade) defense strategy</th>
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<tbody>
<tr>
<td>Biosimilar of Remicade (J&amp;J)</td>
<td>Segmentated stakeholders into three groups; payers, hospitals and independent infusion centers and targeted each;</td>
</tr>
<tr>
<td>Launch date: October 2016</td>
<td>Payers: exclusive contracts and volume-dependent discounts</td>
</tr>
<tr>
<td>Pricing strategy: 15% discount (vs. Remicade) at launch; since increased to 35% with further discounting expected</td>
<td>Hospitals: bundling deals of several drugs and medical devices</td>
</tr>
<tr>
<td>Launch strategy: HCP education initiatives; patient assistance program offering financial support</td>
<td>Independent infusion centers: deeper discounts</td>
</tr>
</tbody>
</table>

**Outcome (2017 sales):** $2.24 billion for Remicade vs. $40 million for Inflectra

**Current situation:** Pfizer has filed suit accusing J&J of using “anti-competitive” measures (September 2017)
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Summary
In summary, payers are becoming more accepting of biosimilars and broadly facilitating market access

**Reimbursement**
- Payers are facilitating biosimilar pricing and reimbursement processes at the national level.
- Greater challenges at the regional/local levels, due to budget issues.
- Pricing remains controversial, with payers demanding high discounts.

**Strategies**
- Manufacturers either sell on value, sell at a generic-like price or use other "disruptor strategies".
- These strategies often depend on if the biosimilar is indicated for a specialist or broader therapy area.

**Sustainability**
- Sustainable biosimilar environment is needed.
- Requirements for sustainable biosimilar markets include fair pricing discounts and stakeholder education.
- Progress has been made in Europe, although uncertainties remain in the US.
THANK YOU

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