Building on the experience and success of biosimilar medicines

Biosimilar medicines are increasingly becoming an integral part of modern healthcare systems, so what does the future hold?
Biosimilar medicines are internationally recognized for expanding access to life-changing treatments

“Biosimilars could be game-changers for access to medicines for certain complex conditions.”

Dr Suzanne Hill, Director Essential Medicines and Health Products, World Health Organisation (WHO)

“Biosimilars can provide more treatment options for patients, and possibly lower treatment costs, enabling greater access for more patients.”

Dr Janet Woodcock, Director, Centre for Drug Evaluation and Research, Food and Drug Administration (FDA)

“Whether it's in the public or the private sector, we need to provide sustainable healthcare and biosimilars are clearly a good way to improve affordability.”

Professor Josep Tabernero, President-elect, European Society of Medical Oncology (ESMO)

Biosimilar medicines are cost-effective therapeutic alternatives to reference biological products

Globally, there is a huge opportunity for biosimilar medicines to provide competition to existing biological medicines.

**Percentage of global biological medicine sales by region**

- US: 59%
- Europe: 22%
- Japan: 6%
- Other: 13%

**Percentage of global biosimilar medicine sales by region**

- US: 2%
- Europe: 87%
- Japan: 7%
- Other: 4%

Experience of biosimilar medicines in Europe is expected to support faster uptake in other regions.

Uptake of biosimilar medicines is supported by an increasing number of biosimilar medicine approvals*

<table>
<thead>
<tr>
<th>Active Substance</th>
<th>Europe¹</th>
<th>Australia²</th>
<th>Japan³</th>
<th>Canada⁴</th>
<th>USA⁵</th>
<th>South Africa⁶</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enoxaparin sodium**</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epoetin (alfa/kappa/lambda/omega)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Etanercept</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Filgrastim</td>
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<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Follitropin</td>
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<td>✓</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Insulin glargine§</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
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<tr>
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<td>✓</td>
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<tr>
<td>Teriparatide</td>
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</tr>
</tbody>
</table>

Often, for each active substance, more than one biosimilar medicine has been approved¹–⁶

Footnotes: *Data compiled April 2017; **Approval of enoxaparin sodium in Japan and in the US was not under the biosimilar medicines pathway; §Approval of insulin glargine in the USA was not via the biosimilar medicines pathway; ¶Approval of somatropin in the USA and Australia was not via the biosimilar medicines pathway.

Switching biological medicines is considered safe\textsuperscript{1,2}

- **Switching is a physician-led decision** to exchange one medicine for another medicine with the same therapeutic intent\textsuperscript{1}

- **Europe is leading the way** in switching from the reference to a corresponding biosimilar medicine\textsuperscript{3}

- EPARs, available on the EMA website, provide **substantial evidence** for the safety of a switch\textsuperscript{3}

- In Japan, a switching study from reference product filgrastim to the biosimilar demonstrated the same clinical efficacy and safety, but at a **reduced cost**\textsuperscript{4}

- **Large clinical experience** in Europe supports switching not only between new versions of the same product, but also between a reference and its biosimilar medicine\textsuperscript{3}

- **EU data from thousands of patients** consistently shows that safety, efficacy, and immunogenicity is not affected when the switch is made\textsuperscript{3}

- The lack of safety signals in Europe **provides further reassurance** of the safety of switching between the reference and the biosimilar medicine\textsuperscript{3}

**Abbreviations:** EMA, European Medicines Agency; EPAR, European Public Assessment Report.


Under the supervision of the treating physician, patients can be safely switched from the reference product to the biosimilar medicine and vice versa\textsuperscript{3}
Increasing experience with biosimilar medicines is supporting faster uptake of new biosimilar medicines

- Infliximab was the first biosimilar monoclonal antibody (mAb) to be launched in Europe
- Uptake of a subsequent complex biosimilar, etanercept, was generally similar or improved compared with that of infliximab

Comparison of post-launch market share of biosimilar infliximab with that of etanercept for the same time period

The launch and uptake of multiple biosimilar medicines provides a competitive biologics marketplace

*Denmark data from MIDAS monthly restricted database

Biosimilar medicine development focuses on autoimmune diseases and oncology

Global biosimilar pipeline by therapy area 2016:
Phase III to registration

Number of biosimilar medicines in development

45% of biosimilar medicines candidates

40% of biosimilar medicines candidates

In a competitive market, physicians, payers and patients are able to benefit from the improved choice on offer

Data not exhaustive, contains only publically announced biosimilar medicines

A rich pipeline supports the long-term availability of biosimilar medicines

- Introduction of biosimilar medicines has increased **competition**\(^1\)
- At the end of 2015, **41 biosimilar medicines candidates** were in the pipeline for four key reference biological products\(^2\)

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**A stable supply chain helps to ensure patients have access to these important treatments**

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Availability of biosimilar medicines improves the security of the supply chain

- The FDA and EMA have identified manufacturing problems, delays in supply, and lack of available active ingredients as the most frequent causes of drug shortages\(^1\)

- Drug shortages can compromise patient safety and clinical outcomes, and increased healthcare costs, due to delays or changes in treatment regimens\(^1\)

- Biosimilar medicines help prevent future biologic shortages and ensure access to effective and safe treatment options\(^1\)

“[...] the biosimilar market will see a more diverse range of companies, greater competition, and improved supply chain security.”\(^2\)

Alex Kudrin, Biopharmaceutical Consultant, United Kingdom

Biosimilar medicines offer improved access to more cost-effective healthcare, today and in the future

EMA, European Medicines Agency; FDA, Food and Drug Administration.

Summary: Building on the experience and success of biosimilar medicines

The benefits offered by biosimilar medicines are internationally recognized

Switching from a reference product to a biosimilar medicine is considered safe

Experience with biosimilar medicines improves uptake

A strong pipeline supports the continuous introduction of new biosimilar medicines

Availability of biosimilar medicines safeguards the supply chain, ensuring patient access to key therapeutics