The benefits of biosimilar medicines

Biosimilar medicines have demonstrated similarity with reference biologicals in terms of structure, function, safety and efficacy, but what are their benefits?
Europe is a pioneer of biosimilar medicines and continues to inspire the world

Since 2006, EU-approved biosimilar medicines have generated more than 400 million patient days of clinical experience worldwide\(^1\)

EU approved biosimilar medicines are available in over 60 countries around the world\(^1\)

European uptake accounts for 87% of the global biosimilar medicines market\(^3\)

Between 2006 and 2013, patient access rose by 44% following the launch of filgrastim\(^3\)

The first worldwide biosimilar medicine (somatropin) was approved in the EU in 2006\(^2\)

The first biosimilar monoclonal antibody (infliximab) was approved in the EU in 2013\(^2\)

European uptake accounts for 87% of the global biosimilar medicines market\(^3\)

There is more than 10 years’ worth of real-world evidence demonstrating the benefits that biosimilar medicines offer to patients and healthcare systems\(^1\)

Biosimilar medicines offer benefits to patients, healthcare professionals, and payers

**Patients**
- More patients gain access to biologic treatments, and at earlier stages of the therapy cycle
- Improved access drives better outcomes for patients

**Healthcare professionals**
- Access to a wider spectrum of treatment options
- Development of value-added services for patients via benefit-sharing models
- Reduced pressure on the prescribers’ budget

**Payers**
- Creation of a more competitive market with a broader range of cost-effective treatment options
- Generation of savings across healthcare systems, supporting their sustainability

References:
Availability of biosimilar medicines increases patient access to biologic therapies

- According to WHO, biosimilar medicines provide a good opportunity to **expand access** and to become a **game-changer** for access to medicines for certain complex conditions

- In countries with low initial usage or availability of biological products, the launch of biosimilar medicines appears to **lead to increased access**

<table>
<thead>
<tr>
<th>Product/Country</th>
<th>Treatment days per capita (Year before biosimilar entrance)</th>
<th>Volume change of treatment days following Introduction of biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HGH</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>0.02</td>
<td>152%</td>
</tr>
<tr>
<td>Czech Rep</td>
<td>0.08</td>
<td>68%</td>
</tr>
<tr>
<td>Poland</td>
<td>0.04</td>
<td>82%</td>
</tr>
<tr>
<td><strong>G-CSF</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>0.02</td>
<td>2542%</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.02</td>
<td>581%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.05</td>
<td>509%</td>
</tr>
<tr>
<td><strong>Anti-TNF</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.10</td>
<td>190%</td>
</tr>
<tr>
<td>Czech Rep</td>
<td>0.24</td>
<td>59%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.49</td>
<td>93%</td>
</tr>
</tbody>
</table>

Abbreviations: G-CSF, granulocyte-colony stimulating factor; HGH, human growth hormone; TNF, tissue necrosis factor; WHO, World Health Organisation.

Swedish launch of biosimilar filgrastim led to improved patient access

Initiation of treatment with filgrastim reference medicine required the formal approval of three physicians

Following the launch of biosimilar filgrastim:

- Treatment costs for granulocyte colony-stimulating factor (G-CSF) treatment of febrile neutropenia were reduced
- Regional authorities relaxed restrictions on the prescribing of G-CSF treatments
- Prescriptions do not need additional authorization

Driven by the use of biosimilar filgrastim, clinical use of G-CSF increased five fold in the Southern Healthcare region

Biosimilar medicines allow access for more patients, and at earlier stages in the treatment cycle

### Biosimilar medicines make biotherapeutics a cost-effective option, broadening treatment choice

- Biosimilar medicines are often able to reach an acceptable incremental cost-effectiveness ratio (ICER) in situations where reference products are not.
- In the UK, biosimilar medicines have introduced new treatment options for ankylosing spondylitis, and for treatment-induced anaemia in patients with cancer.

<table>
<thead>
<tr>
<th>Condition</th>
<th>2008 UK National Institute for Health and Clinical Excellence (NICE) guidelines</th>
<th>2015 NICE guidance recommendations use of infliximab biosimilar medicines in adults with non-radiographic axial spondyloarthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ankylosing spondylitis</strong></td>
<td>infliximab (originator) should not be used at all</td>
<td></td>
</tr>
<tr>
<td><strong>Cancer-treatment-induced anemia</strong></td>
<td>epoetin is clinically effective for cancer treatment-induced anaemia, but is not cost-effective</td>
<td>epoetin is both clinically effective and cost-effective</td>
</tr>
</tbody>
</table>

**Abbreviations:** NICE, The National Institute for Health and Care Excellence.

Globally, biosimilar medicines have the potential to offer healthcare systems huge savings for the same outcomes.

**Europe** – 16 billion USD
(15 billion Euros) between 2016 and 2020 in Europe
Based on a 30% price reduction across eight key reference products, driven by biosimilar competition1

**Japan** – 1.3 billion USD
(141.7 billion Yen) from biosimilars between 2015 and 20202

**USA** – 44–250 billion USD
over a ten-year period
Value dependent upon the policies adopted in the coming months and years5,6

**South Africa** – 6.4 million USD
(84.5 million Rand) per annum.
A 50% price reduction following the introduction of the biosimilar trastuzumab would translate into 670 more patients being treated (2016)4

**Australia** – 676 million USD
(880 million AUD) from biosimilars between 2015 and 20203

Biosimilar medicines represent a cost-effective alternative to the reference products.

Sharing the benefits of clinical use of biosimilar medicines

- In Germany, the medical association KV Westfalen-Lippe, and the statutory health insurance provider Barmer GEK, agreed a contract geared towards improving care of patients with inflammatory bowel disease
- Under the contract, patients with ulcerative colitis or Crohn’s disease will be primarily treated with infliximab biosimilars
- **Absolute savings** generated from prescribing infliximab biosimilar will be equally split between the treating physician and Barmer GEK

The use of biosimilar medicines has been **successfully implemented** within Europe for over a decade\(^1\)

**Benefit sharing models** involve all stakeholders and help to **demonstrate the cost benefits** associated with biosimilar medicine adoption\(^3\)

**Summary: The benefits of biosimilar medicines**

Biosimilar medicines improve the treatment options available to:\(^2\)–\(^4\)

**Patients**
Biosimilar medicines allow access for more patients, and at earlier stages in the treatment cycle

**Healthcare professionals**
Biosimilar medicines empower physicians, providing cost-effective treatment options

**Payers**
Globally, biosimilar medicines introduce competition by representing a cost-effective alternative to reference biologicals, and generate savings

**Biosimilar medicine policies are necessary to drive uptake and provide the benefits of biosimilar use**

**References:**