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- The Antitrust policy is available on the ISPOR website, under “Policies & Legal.”
• **Purpose:**
  – To present an overview of the goals, barriers and facilitators of biosimilar adoption in countries with limited resources, from HTA and policy perspective

• **We are interested in your view:**
  – Interactive session after presentation through poll questions - be prepared with your mobile

• **Moderator:**
  – Vera Pataki, MD, MBA,
    • Head of International Market Access, Egis, Budapest, Hungary
    • Chair of CEE Network, Medicines for Europe, Brussels, Belgium

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### Speakers

- **András Inotai**
  - Associate Professor, Semmelweis University, Budapest, Hungary

- **Evelien Moorkens**
  - PhD Researcher KU Leuven, Leuven, Belgium

- **Iga Lipska**
  - Project Manager, Strategic research grant, NHF HQ, Warsaw, Poland

- **Dalia Dawoud**
  - Scientific Adviser, Science Policy and Research, NICE, London, UK
Access to biological medicines
- big differences across Europe

Compared with Western Europe, Central and Eastern Europe have experienced reduced access to biological medicines\(^1,2\)

<table>
<thead>
<tr>
<th>Percentage of patients with rheumatoid arthritis (RA) treated with a biological medicine:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Europe*</td>
</tr>
<tr>
<td>11–12%</td>
</tr>
</tbody>
</table>

Footnotes: *Based on values from 2009; **Based on values from 2011.


This difference in access to biological medicines is largely due to general economic conditions\(^2\)

Increased patient access to biologicals
– thanks to biosimilar medicines

Accordking 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\(^1\)

<table>
<thead>
<tr>
<th>Product/Country</th>
<th>Treatment days per capita(^2) (Year before biosimilar entrance)</th>
<th>Volume change of treatment days following introduction of biosimilar(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</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>G-CSF</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>Anti-TNF</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.

CEE – still huge gap

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### Biosimilar penetration - differences among molecules and countries

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Infliximab</th>
<th>Insulin Glargine</th>
<th>Etanercept</th>
<th>Rituximab</th>
<th>Trastuzumab</th>
<th>Adalimumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>92.2</td>
<td>9.0</td>
<td>82.0</td>
<td>91.5</td>
<td>60.7</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>51.3</td>
<td>13.3</td>
<td>56.8</td>
<td>60.9</td>
<td>28.3</td>
<td>1.4</td>
</tr>
<tr>
<td>France</td>
<td>59.1</td>
<td>14.6</td>
<td>17.9</td>
<td>63.6</td>
<td>27.5</td>
<td>0.08</td>
</tr>
<tr>
<td>Italy</td>
<td>78.5</td>
<td>19.2</td>
<td>45.6</td>
<td>74.5</td>
<td>9.2</td>
<td>0.01</td>
</tr>
<tr>
<td>Spain</td>
<td>55.8</td>
<td>12.0</td>
<td>30.2</td>
<td>27.8</td>
<td>10.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Denmark</td>
<td>98.5</td>
<td>9.3</td>
<td>90.6</td>
<td>67.2</td>
<td>99.3</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>17.8</td>
<td>6.0</td>
<td>6.1</td>
<td>6.2</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>76.1</td>
<td>10.8</td>
<td>24.1</td>
<td>93.4</td>
<td>95.0</td>
<td>3.2</td>
</tr>
<tr>
<td>Norway</td>
<td>97.6</td>
<td>5.8</td>
<td>90.1</td>
<td>0.0</td>
<td>81.2</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>95.2</td>
<td>35.6</td>
<td>36.6</td>
<td>34.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: Trastuzumab and Rituximab subcutaneous form excluded from calculations

Source: IQVIA MIDAS Restricted MTH October 2018
Good biosimilar uptake - does not guarantee better patient access without further actions

Line shows average volume (TD) 1 year before BS entry per capita, across all countries in scope
Sustainability for Biosimilars in Europe - Policies evaluation report; Sustainability Score 1 = low; Score 5 = high

Anti-TNFs: Adalimumab, Certolizumab pegol, Etanercept, Golimumab, Infliximab

Source: IQVIA MIDAS Restricted MTH October 2018

Biosimilars’ uptake from a CEE perspective – theory vs. Practice

András Inotai PhD, DrHabil$^{1,2,3}$

1 Associate Professor, Semmelweis University, Budapest, Hungary;
2 Co-chair, ISPOR SIG on Biosimilars Key Project;
3 Principal Researcher, Syreon Research Institute, Budapest, Hungary
Policy objectives of biosimilar medicines

- Biologicals at Western European price level are usually not cost effective in CEE
- Off-patent biologicals with price erosion after patent expiry provides more affordable treatment alternatives
- The policy objective of off-patent pharmaceuticals can be approached in two different ways:
  - Disinvestment aspect: Reduce health care expenditure without compromising health outcomes
  - Investment aspect: Increase population health gain by improved patient access without increasing health expenditure


C/E plan for biologicals before and after patient expiry

C/E plan for biologicals before and after patient expiry

$\quad$

Original biological (before patent expiry)

Off-patent biological (same INN, after patent expiry)

Western Europe

Health gain

Before patent expiry | After patent expiry
---|---
**Western Europe:**
All eligible patients have access to the original biological prior patent expiry

![Smiley faces]

Research on hidden access barriers

Methods

• Volume restrictions are implemented by payers to ensure financial sustainability of reimbursing high-cost pharmaceuticals
• Aim: to reveal these transparent and hidden access barriers in CEE
• Methods:
  – Disease: RA
  – Scope: TNFa inhibitor bDMARDs
  – 3-3 interviews with 4 stakeholder groups (payers, patients, rheumatologists, industry) in each country
  – Participating countries: CZ, HU, PL, RO, SK
  – 3x4x5=60 interviews
  – Results aggregated at country level

Results

• TNFa bDMARDs are on the reimbursed list in CEE, but...
• ...the following barriers were reported the most frequently:

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Number of reporting countries (out of 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>limited number of RA centers with prescribing rights</td>
<td>5</td>
</tr>
<tr>
<td>uneven budget allocation among RA centers</td>
<td>3</td>
</tr>
<tr>
<td>maximised patient number on reimbursed biologics / RA center</td>
<td>3</td>
</tr>
<tr>
<td>insufficient human resource capacities to administer IV bDMARDs</td>
<td>4</td>
</tr>
<tr>
<td>more restrictive financial protocols compared to EULAR guidelines in prescribing bDMARDs</td>
<td>4</td>
</tr>
<tr>
<td>significant administrative burden of prescribing biologics</td>
<td>3</td>
</tr>
<tr>
<td>significant travelling time and cost for patients to RA centers</td>
<td>5</td>
</tr>
</tbody>
</table>

• Altogether 33 different types of access barriers were reported

Consequence: Not all eligible patient may have access to bDMARDs in RA in CEE
<table>
<thead>
<tr>
<th>Before patent expiry</th>
<th>After patent expiry</th>
<th>$</th>
<th>$/</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Western Europe:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All eligible patients have access to the original biological prior patent expiry</td>
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<td>🌻🌻🌻</td>
<td>🌻🌻</td>
<td></td>
</tr>
<tr>
<td><strong>Central Eastern Europe:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume restrictions to the original biological prior patent expiry</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>🌻🌻🌻🌻</td>
<td>🌻🌻</td>
<td></td>
</tr>
</tbody>
</table>

Before patent expiry | After patent expiry
---|---
**Western Europe:**
All eligible patients have access to the original biological prior patent expiry

**Central Eastern Europe:**
Volume restrictions to the original biological prior patent expiry


---

C/E plan for biologicals for low income countries

C/E plan for biologicals for low income countries

Before patent expiry

Western Europe:
All eligible patients have access to the original biological prior patent expiry

Central Eastern Europe:
Volume restrictions to the original biological prior patent expiry

Eastern European non-EU countries:
Original biological is not cost effective prior patent expiry

After patent expiry

$ 

$ / (CMA)

N/C

Before patent expiry

After patent expiry

$✔$/ (CMA)

**Western Europe:**

*All eligible patients have access to the original biological prior patent expiry*

Before: 4/5
After: 4/5

**Central Eastern Europe:**

*Volume restrictions to the original biological prior patent expiry*

Before: 2/5
After: 4/5

**Eastern European non-EU countries:**

*Original biological is not cost effective prior patent expiry*

Before: 2/5
After: 2/5


---

**How to select first line treatment of compounds with no or limited differential value?**

Original biologicals (before patent expiry, no major difference)
How to select first line treatment of compounds with no or limited differential value?

How to select first line treatment of compounds with no or limited differential value?

Original biologicals

Off-patent biological (same INN, after patent expiry)

$\leftarrow$ Health gain

Original biological

Off-patent biologicals (after patent expiry)
<table>
<thead>
<tr>
<th>Before patent expiry</th>
<th>After patent expiry</th>
<th>$</th>
<th>$/😊</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Western Europe:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All eligible patients have access to the original biological medicine prior patent expiry</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Before patent expiry</th>
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<tr>
<td>All eligible patients have access to the original biological medicine prior patent expiry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Region</td>
<td>Before patent expiry</td>
<td>After patent expiry</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Western Europe</strong></td>
<td>All eligible patients have access to the original biological medicine prior patent expiry</td>
<td>$</td>
<td></td>
</tr>
<tr>
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<td>✔ (CMA)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Region</th>
<th>Before patent expiry</th>
<th>After patent expiry</th>
</tr>
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<tr>
<td><strong>Western Europe</strong></td>
<td>All eligible patients have access to the original biological medicine prior patent expiry</td>
<td>$</td>
</tr>
<tr>
<td><strong>Central Eastern Europe</strong></td>
<td>Volume restrictions to the original biological medicine prior patent expiry</td>
<td>✔ (CMA)</td>
</tr>
</tbody>
</table>
New patients should start on more affordable off patent biologicals

Using other patented biologicals w/o added benefit if off patent biologicals are available has opportunity cost

Western Europe: All eligible patients have access to the original biological medicine prior patent expiry

Central Eastern Europe: Opportunity cost: reduced opportunity for savings

Volume restrictions to the original biological medicine prior patent expiry

Opportunity cost: reduced opportunity to treat additional patients

The case of infliximab in Hungary

Increasing utilisation of biologicals implicitly confirms hidden barriers

The case of infliximab in Hungary

- Increasing utilisation of biologicals implicitly confirms hidden barriers
- After patent expiry the market share of off-patent infliximab showed a decrease

Utilisation pattern of treatment naive patients after patent expiry

<table>
<thead>
<tr>
<th>Indication</th>
<th>Originator infliximab</th>
<th>Biosimilar infliximab</th>
<th>Other patent protected biological(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative Colitis</td>
<td>13.5%</td>
<td>50.3%</td>
<td>36.3%</td>
</tr>
<tr>
<td>Adult Crohn’s Disease</td>
<td>14.3%</td>
<td>37.0%</td>
<td>48.7%</td>
</tr>
<tr>
<td>Paediatric Crohn’s Disease</td>
<td>17.1%</td>
<td>18.4%</td>
<td>64.6%</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>0.4%</td>
<td>1.2%</td>
<td>98.4%</td>
</tr>
<tr>
<td>Ankylosing Spondylitis</td>
<td>1.1%</td>
<td>4.1%</td>
<td>94.8%</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>1.4%</td>
<td>1.6%</td>
<td>97.0%</td>
</tr>
<tr>
<td>Psoriatic Arthritis</td>
<td>1.5%</td>
<td>5.4%</td>
<td>93.1%</td>
</tr>
</tbody>
</table>

Despite of the economic rationale, in many indications physicians did not even try the more affordable off patent biologicals for new patients


Conclusion

- Using patented biologicals with no added value if off-patent biologicals are also available has opportunity cost:
  - In case of disinvestment: reduced opportunity for savings
  - In case of investment (e.g. volume restriction): reduced opportunity to treat additional patients

In case of limited access, if naive patients start on original bDMARDs when off patent biologicals are available, some patients will be denied treatment

Are lower income countries rich enough not to use off patent biologicals as first line treatments?
Policies on biosimilars: What can we learn from the European experience?

Evelien Moorkens
PhD researcher, KU Leuven, Leuven, Belgium
Supply-side policies

**List prices**

- **Pricing of biosimilars:**
  - Often different pricing mechanisms
  - % below price of originator
  - Maximum price
  - …

- **Pricing of off-patent biologicals:**
  - Price cuts for originators

**Tenders**

- Often by INN → no difference between treatment-naïve patients and on treatment
- National – regional – hospital level
- Multiple winners – single winner

Reimbursement

- Approximately half of European countries use internal reference pricing

---

Demand-side policies

- Policies tend to target physicians, …
- rather than pharmacists and patients

- Quotas
- Recommendations
- Economic prescribing
- Switching
- Education

---

**Case study in Sweden**

- Study local/regional level: 21 counties in Sweden
- Focus on infliximab and etanercept

**Infliximab (Hospital setting)**
- Biosimilar market shares: 18-96% (2017)
- Regression analysis: 59% of variability explained by relative difference in discounted price between originator and biosimilar
- Uptake influenced by regional tender contracts

**Etanercept (Outpatient setting)**
- Biosimilar market shares: 40-82% (2017)
- Small differences in actual costs between products for regions after MEA on national level and gainsharing arrangements
- Prescription provided for a year: Active pull-back or wait?
- Uptake influenced by KOLs, guidelines, gainsharing

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**Moorkens et al. (2019).** Different policy measures and practices between Swedish counties influence market dynamics. *BioDrugs*

---

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**Impact of policies on market dynamics?**

**Case study in Sweden: Rate of volume growth accelerates (AND cost savings)**

---

**Moorkens et al. (2019).** Different policy measures and practices between Swedish counties influence market dynamics. *BioDrugs*
Case study in UK

- Study local/regional level: England (10 historical regions), Scotland (14 health boards), Wales (7 health boards)
- Focus on infliximab and etanercept: *Early and late adopters* of biosimilars can be seen

**UK biosimilar uptake is positively influenced by:**

a) **A price difference** between biosimilar and originator product making it worth to switch patients
b) **A good relationship** between commissioner and provider in England resulting in gainsharing agreements
c) **Leadership** on biosimilars in regional NHS offices in England or Scottish and Welsh health boards
d) **Key opinion leaders** or leading hospitals that start using biosimilars early and gain experience

⚠️ High biosimilar market shares can be reached even without gainsharing! (Scotland, Wales)

---

Case study in UK: *Example of biosimilar adalimumab in Scotland*

**Before patent expiry:**

- Groups on efficient use of high cost medicines were tasked to come up with a **strategy** for biosimilar use
- Health Boards were encouraged to put in place a **switching plan**
- A **case study** on the biosimilar switch for etanercept was made available
- Some Health Boards invested in **additional staffing** (‘invest to save principle’)

**After patent expiry:**

- **Statistics** on biosimilar market shares were shared monthly for benchmarking purposes
- Also, for anti-TNFs a national biological medicines **treatment cost comparator** was developed
Case study in Germany: Constant rate of volume growth (but cost savings)

- Access to TNF-alpha inhibitors seems to increase at the same rate after introduction of biosimilars

Impact of policies on market dynamics?

Before biosimilars  After biosimilars

Conclusions

- Policies targeting price may not be sustainable in the long term
- Focus on demand-side policies
- Guidelines and recommendations
- Target agreements
- Gainsharing arrangements
- Create an open environment with multi-stakeholder involvement
Policy objectives of biosimilar medicines

- **Biologics** are usually not cost effective in CEE
  - Price levels at Western European countries at launch
  - International Reference Pricing
- Creates a financial barrier for patients to have access to effective treatments
- **Biosimilars** create new cost saving opportunities
  - The same clinical effectiveness (patient outcomes)
  - Less costly – better cost – effectiveness
- The policy objective of off-patent pharmaceuticals can be approached in two different ways*:
  - Disinvestment aspect: Reduce health care expenditure without compromising health outcomes
  - Investment aspect: Increase population health gain by improved patient access without increasing health expenditure

Public payer perspective

- Public payer priority:
  - To provide appropriate health care to the population covered
  - Poland – population of 38 mln
  - Within limited budget / financial resources

- What’s specific about CEE countries?
  - Worse health status of the population
  - Less money invested in health care (5% GDP in Poland, EU average 9%)
    - eg. OECD/European Commission report „Health at glance”
  - Patients are less satisfied with health care services
    - European Health Consumer Index EHCI 2018 (32/35 with 585/1000 points)

- The ongoing discussion about:
  - Value-based health care (VBHC)
  - Michael Porter Redefining health care 2006 & What is value in healthcare? NEJM 2010

Medicines Policy for 2018-2022

- Governmental document approved in Sept 2018
- Currently in the implementation phase

- Authors:
  - M. Czech – Vice Minister responsible for Drug Policy 2017-2019 (chair)
  - J.Adamski, A. Falek, A. Lech, I. Lipska, I. Skrzekowska-Baran, R. Zyśk

- The document addresses also:
  - „Special categories of medicinal products: biological medicines and biosimilars"
• The market for biological medicines in Poland reached the value of PLN 3.5bn*  
• Three groups of medicines accounted for more than 50% of the market: monoclonal antibodies, human insulin and its analogues and heparins  
• Monoclonal antibodies and human insulin and its analogues are also the main areas of development of biosimilars  
• In view of the expiry of patent protection of key biological drugs, the biosimilars segment has experienced rapid growth in recent years  
• The main biosimilars in Poland were immunomodulating agents (non-interferon) and the highest sales were generated by the biosimilar filgrastim (2016)  

• Challenges in pricing negotiations on biosimilars
  • Pricing negotiations by the Economic Commission MoH
    – 5 representatives of National Health Fund
  • Price reduction
    – by definition 25% when generic or biosimilar enters a market
    – The Act of Law on Drug Reimbursement
  • In practice much bigger price reduction has been expected in pricing negotiations
  • Sometimes we were successful with substantial price reduction
  • BUT
  • Risk sharing mechanisms were implemented
  • Clear financial mechanisms:
    – discounts, payback, price volume agreements
    – to ensure financial sustainability of health care budget (public payer)

• Education around biosimilars highly needed
• For different stakeholders
  – Clinicians, patients, decision-makers
  – Perhaps also media? Journalists?
• Clinicians need to be informed on the entry and use of biosimilars
  – In order to create trust
• There is a framework in place in Poland
  – Top-down approach
  – Including incentives for health care providers by a public payer
• Still the uptake of biosimilars is very low
• Bottom-up approach would be helpful
  – Including education
Conclusions

- Extensive use of biosimilars creates cost-saving opportunity for health care systems
  - Everywhere but in particular in CEE countries

- But more importantly provides more value (health gain) for patients
  - Creates potential to cover patients in need
  - More patients can be treated as compared to very expensive biologics

- By investing in biosimilars public payers are able to provide clinically-effective and cost-effective treatments for patients in need
  - Incentives for health care providers

- Education around biosimilars is needed
Disclaimer

- The views expressed in this presentation are those of the author not the Institute

Why Biosimilars?

New cost-saving opportunities without adversely affecting patient outcomes
Opportunities

“As the biosimilar market develops, increased competition between biological medicines has the potential to deliver significant savings of at least £200m to £300m per year by 2020/21 through increased uptake of the best value biologic medicine, including biosimilars.” [NHS England, Commissioning framework for biological medicines (including biosimilar medicines), 2017]

Source: Rx-InfoDefine (Infliximab is used to treat rheumatology conditions and inflammatory bowel disease; etanercept is used for rheumatology conditions. These biosimilars came onto the UK market in March 2015 and April 2016 respectively)

Opportunities

• Improved patient access

• Increased choice for patients and clinicians,

• Enhanced value propositions for individual medicines

• Releasing valuable resources to be invested elsewhere in the healthcare system
Challenges

- Lack of clear guidance around how to assess their actual value
- Uncertainty around data extrapolation from one indication to another
- Uncertainty around immunogenicity and long-term safety
- Slow uptake
- Switching back

How to address these challenges?

- Education around biosimilars (clinicians, patients, decision makers)
- Transparent and clear evaluation and decision-making frameworks
- Establishing sustainable and appropriate procurement mechanisms
- Experience and use
NICE’s position statement

a. Published Appraisals

2. NICE has decided that normally all relevant published guidance that includes the originator molecule will apply to the biosimilar medicinal product at the time it is made available for use in the NHS. A funding direction will apply to a new biosimilar if the active drug substance has already been recommended by NICE.

5. NICE will consider appraising the evidence for any new relevant biosimilar product(s) when a published Technology Appraisal is considered for review; the introduction of a biosimilar would not automatically trigger an earlier consideration for review or an automatic decision to update the guidance.

a. Published appraisals

**TA323**

Epoetins in treatment of chemotherapy induced anaemia - new clinical data supporting enhanced efficacy when combining epoetin with IV iron (2014)

[https://www.nice.org.uk/guidance/ta323/chapter/1-Guidance](https://www.nice.org.uk/guidance/ta323/chapter/1-Guidance)

**TA383**

Infliximab for treatment of severe ankylosing spondylitis and severe non-radiographic axial spondyloarthritis. Previously the originator was not supported due to high price (whereas other originator TNFs were supported). (2016)

[https://www.nice.org.uk/guidance/ta383](https://www.nice.org.uk/guidance/ta383)
b. Future appraisal topics (before invitation to participate or scoping)

- Intervention
- Comparator

10. Biosimilar medicines will be considered to differ from the originator product only in terms of price.

**TA569**

Pertuzumab combined with biosimilar trastuzumab for the treatment of HER-2 positive, node positive, early breast cancer patients (2019) [https://www.nice.org.uk/guidance/TA569/chapter/1-Recommendations](https://www.nice.org.uk/guidance/TA569/chapter/1-Recommendations)
Best Value Biologic Medicine (BVBM)

- Ambition 90% of new patients prescribed a BVBM within 3 months of product launch
- 80% of existing patients switched to BVBM within 12 months, or sooner if possible

Latest success story

- Adalimumab (Humira; AbbVie) came off patent in October 2018 and was projected to achieve savings of £300m by 2021
- The rate of uptake of best-value adalimumab has varied across different regions across England, ranging from around 20% to approximately 90%
- The switch program will achieve the projected savings by the beginning of 2020
ISPOR Biosimilars SIG

**Mission**
To identify and discuss emerging issues of biosimilars, as related to their originator biologics, focusing on health economics and outcomes research (HEOR) and reimbursement policy.

**Goal**
- Discuss the current state of biosimilars as a unique category of therapeutics
- Highlight the gaps in understanding and evaluating biosimilars from an HEOR lens
- Propose solutions to issues pertaining to biosimilar accessibility, adoption, utilization, value, and impact

**Member engagement**
- NOLA 2019 workshop
- Updating ISPOR book of terms
- Copenhagen 2019 joint forum with CEE network
- Webinar on existing Biosimilars access policies

**Key project**
- Manuscript for Value in Health
- Gaps and challenges in value assessment of biosimilars
ISPOR Biosimilars SIG

Key Project Co-Chairs
- Steven Simoens
- Andras Inotai
- Evelien Moorkens

Leadership
- Dalia Dawoud
  - Chair
- Jackie Vanderpuye-Orgle
  - Chair-elect

Member Engagement Co-Chairs
- Catarina Lopes Pereira
- Liese Barbier

ISPOR Leads
- Amy Pavlock
  - Associate Director, Scientific and Health Policy Initiatives
- Theresa Tesoro
  - Associate Director, Scientific and Health Policy Initiatives

How to JOIN our Special Interest Group

- Sign up now
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  - Provide a business card

- Go to the Website
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BIOSIMILARS: AN OPPORTUNITY FOR COUNTRIES WITH RESTRICTED RESOURCES TO IMPROVE PATIENT ACCESS?

DISCUSSION
In case of volume restrictions (i.e. not all eligible patients can have access to biologicals), what do you consider more important:

Options:

• Promote mandatory switch of patients treated with original biological medicine to lower priced biosimilars with the same active compound to release funds to treat additional patients (i.e. maximise access)

• Allow patients staying on the original biological medicine after patient expiry even if lower priced biosimilars are available (i.e. maximise patient preference)
How would you incentivise increased uptake of off-patent biologicals?

Options:

• Via top-down approach, mainly driven by regulation of payers

• Via bottom-up approach, mainly driven by incentivising and educating physicians
BIOSIMILARS: AN OPPORTUNITY FOR COUNTRIES WITH RESTRICTED RESOURCES TO IMPROVE PATIENT ACCESS?

DISCUSSION

THANK YOU

- Please come to the front to leave your business card and/or use the sign-up sheet to provide your information if you are interested in joining and/or participating in our SIG!

- Questions? Please email biosimilarsig@ispor.org.