Subsequent Entry Biologics

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  • Hoffmann-LaRoche
  • Janssen
  • AMGEN
Learning Objectives

• Provide working definitions of biologics and subsequent entry biologics

• Provide a summary of biologics & SEBs currently used in rheumatology

• Highlight some current attitudes of rheumatologists to the clinical introduction of SEBs

What are biologics?

**Biologics** are active pharmaceutical ingredients obtained from living organisms that are not amenable to large-scale chemical synthesis.
How do biologics compare to conventional small molecule drugs?

<table>
<thead>
<tr>
<th>Drug</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin (180)</td>
<td></td>
</tr>
<tr>
<td>Insulin (5,808)</td>
<td></td>
</tr>
<tr>
<td>Erythropoetin (30,400)</td>
<td></td>
</tr>
<tr>
<td>Monoclonal antibody</td>
<td>(150,000+)</td>
</tr>
</tbody>
</table>


Japanese clinical trials of biologic therapies for rheumatoid arthritis

What are SEBs?

**A Subsequent Entry Biologic** is a Canadian-approved, new version of an innovator biologic, following patent expiry; one that has undergone a rigorous comparability exercise.

## Biologics in rheumatology

<table>
<thead>
<tr>
<th>Reference biologic</th>
<th>RA</th>
<th>PsA</th>
<th>AS</th>
<th>Canadian patent expiry</th>
<th>Biosimilars</th>
<th>Approved in Canada</th>
<th>In development</th>
</tr>
</thead>
<tbody>
<tr>
<td>abatacept</td>
<td>Y</td>
<td>–</td>
<td>–</td>
<td>2012*</td>
<td></td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>tocilizumab</td>
<td>Y</td>
<td>–</td>
<td>–</td>
<td>2015</td>
<td></td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>adalimumab</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>2017</td>
<td>13</td>
<td>–</td>
<td>14†</td>
</tr>
<tr>
<td>infliximab</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>2017</td>
<td>2</td>
<td>–</td>
<td>14†</td>
</tr>
<tr>
<td>rituximab</td>
<td>Y</td>
<td>–</td>
<td>–</td>
<td>2020</td>
<td>–</td>
<td>–</td>
<td>35†</td>
</tr>
<tr>
<td>cetolizumab</td>
<td>Y</td>
<td>–</td>
<td>–</td>
<td>2021</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>golimumab</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>2021</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>etanercept</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>2023</td>
<td>–</td>
<td>–</td>
<td>27†</td>
</tr>
<tr>
<td>ustekinumab</td>
<td>–</td>
<td>Y</td>
<td>–</td>
<td>Infringement</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

* Data exclusivity until 2014
† Source: FirstView Biosimilar Index, March 2014


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**Survey Results** (Run from 15 February to 16 March, 2014)

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**Ontario Rheumatology Association (ORA)**

**Institute for Management & Innovation (IMI)**

**Canadian Rheumatology Association (CRA)**

**Société Canadienne de Rhumatologie (SCR)**
Where do you practice?

- **Alberta, 11, 14%**
- **British Columbia, 13, 16%**
- **Manitoba, 3, 4%**
- **Newfoundland & Labrador, 1, 1%**
- **Nova Scotia, 3, 4%**
- **Ontario, 36, 44%**
- **Saskatchewan, 2, 2%**

How familiar are you with SEBs?

- **Never heard of SEBs** 1, 1%
- **Unfamiliar** 23, 28%
- **Somewhat familiar** 32, 40%
- **Familiar** 10, 12%
- **Very familiar** 15, 19%
“I am generally comfortable prescribing biologic drugs to my patients.”

![Bar chart showing responses to the statement]

“SEBs will have a significant impact on rheumatology and how patients are treated.”

![Bar chart showing responses to the statement]
“If an SEB demonstrates that it is comparable to the brand-name drug, it is appropriate to offer it to a biologic-naïve patient instead of the brand-name drug.”

“If an SEB demonstrates that it is comparable to the brand-name drug, it is appropriate to switch a biologic treatment-stable patient to the SEB.”
“All things considered, I would feel comfortable prescribing SEBs to patients if approved today.”

Thank you

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