Biologics Market Dynamics: Setting the Stage for Biosimilars

FDA/FTC Workshop on a Competitive Marketplace for Biosimilars

MARCH 9, 2020

Murray Aitken, Executive Director
Biologics Market Dynamics

- Biologics are a growing share of the pharmaceutical market with significant growth over the past five years relative to small molecules.
- The R&D pipeline suggests this growth dynamic will continue and be broad-based across most disease areas.
- Biologics reach the market through multiple channels and paytypes, each with its own characteristics and payment dynamics.
- The largest biologic originator brands have achieved significant cumulative sales since their launch.
- Market exclusivity dynamics for small molecules are generally consistent and a steady share of the market is subject to competition from generics, which dominate volume share.
- Market exclusivity dynamics for large molecules have begun to shift over the past three years in terms of exposure to biosimilar competition and shares.
Biologics now represent 42% of the total medicines market, up from 30% in 2014

Source: IQVIA, National Sales Perspectives, IQVIA Institute, Jan 2019; U.S. Census Bureau; U.S. Bureau of Economic Analysis (BEA), Dec 2018
Small molecules have declined 12% since 2014 on a real net per capita basis, while biologics have increased by 50%.

*Real Net per Capita Medicine Spending and Growth by Product Type US*

Source: IQVIA, National Sales Perspectives, IQVIA Institute, Jan 2019; U.S. Census Bureau; U.S. Bureau of Economic Analysis (BEA), Dec 2018
Biologics are in development in most therapy areas, including those traditionally based on small molecules

*Share of late-stage R&D pipeline activity by molecule type*

Source: IQVIA Pipeline Intelligence, Dec 2019
Biologics reach the market through multiple channels and paytypes, each which distinct payment characteristics

Medicare is 35% overall; Medicaid 22%; Commercial 42%, Cash 1%

Source: IQVIA Institute for Human Data Science, Feb 2020
The top 10 biologics each has cumulative sales of more than $40 billion since launch and been on the market more than 17 years.

Cumulative invoice sales from launch to Sep 2019

<table>
<thead>
<tr>
<th>Biologic</th>
<th>Cumulative Sales</th>
<th>Years since launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMIRA</td>
<td>112</td>
<td>17</td>
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<tr>
<td>EPOGEN</td>
<td>97</td>
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<tr>
<td>ENBREL</td>
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<td>NOVOLOG</td>
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<td>19</td>
</tr>
<tr>
<td>HUMALOG</td>
<td>40</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: IQVIA National Sales Perspectives, Launch Edition Sep 2019
About 40% of small molecule market sales are accessible to generics, and generic efficiency remains flat at 97%

Percent of Small Molecule Sales Accessible to Generics and Generic Efficiency, 2014–2019

Chart notes: “Generic efficiency” measures share of market where generics are approved and launched

Source: IQVIA National Sales Perspectives, Dec 2019
By year-end 2019, 17% of the biologics market is accessible to biosimilars, and biosimilars have achieved 20% share

Percent of Biologics Sales Accessible to Biosimilars and Biosimilar Efficiency, 2013–2019

Chart notes: Chart includes ‘biosimilars’ as non-original molecules for medicines even if approved outside the 351(k) biosimilar pathway; “Biosimilar efficiency” measures share of market where biosimilars are approved and launched

Source: IQVIA National Sales Perspectives, Dec 2019
Including approved but not yet launched biosimilars, 50% of biologic market sales could face biosimilar competition

Percent of Biologics Sales Accessible to Approved and Launched Biosimilars and Biosimilar Efficiency, 2013–2019

Including approved but not yet launched biosimilars, 50% of biologic market sales could face biosimilar competition.

Biologics Market Accessible to Biosimilar, Launched (US$)
Biologics Market Accessible to Biosimilar, Approved (US$)

Biosimilar Efficiency (Volume)

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