Steps to Reducing Barriers to Biosimilars in the United States

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Overview

• Biosimilars Landscape
• Barriers to Biosimilars by Category
  1. Reference Product Manufacturers
  2. Biosimilar Manufacturers
  3. Policy
  4. Stakeholder Education and Awareness
• Tipping Points for Biosimilars
• Strategies for Overcoming Barriers
Landscape: U.S. Sales of Reference Biologics

$119.2 Billion

37%

U.S. BIOLOGICS SALES

BIOLOGICS SALES AS SHARE OF TOTAL U.S. DRUG MARKET

Source: IQVIA Institute for Human Data Science.
Landscape: U.S. Biosimilars Approved

- Zarxio 2015
- Renflexis 2016
- Cyltezo, Mvasi, Ogivri, Ixifi
- Inflectra, Erelzi, Amjevita 2017
- Retacrit, Fulphila, Nivestym 2018
Landscape: U.S. Biosimilars in Development

Source: FDA.
# Barriers to Biosimilars by Category

#1: Reference Product Manufacturers
- Rebate practices
- Lifecycle management (e.g., late-stage patents)

#2: Biosimilar Manufacturers
- Market uncertainty
- Limited discounting and low volume
#3: Policy
- Patent thickets
- FDA guidance

#4: Stakeholder Education and Awareness
- Lack of education and awareness
- Limited prescribing experience
Tipping Points for Biosimilars

Market, regulatory, legal, perception, and reimbursement issues are reduced so biosimilars can enter the market with ease

Sufficient competition to a reference biologic exists to achieve meaningful savings
Strategies to Overcome Barriers, by Category

#1: Reference Product Manufacturers

Brand biologics manufacturers use contracting practices and lifecycle management strategies to protect market share, including penalties for customers who move patients to a biosimilar and additional patents late in a reference product’s life.

**Strategies**

- **Payors:** Adopt longer-term perspective in contracts/formularies
- **Employers:** Identify cost-saving opportunities
- **Policymakers:** Ensure fair market access for biosimilars
Strategies to Overcome Barriers, by Category

#2: Biosimilar Manufacturers

Biosimilars are expensive to develop, the market is uncertain, and biosimilars’ price discounts at launch have not been steep enough to capture market share.

**Strategies**

- **Payors:** Institute policies to drive biosimilar utilization
- **Biosimilar manufacturers:** Offer competitive contracting terms
- **Employers:** Require biosimilar coverage in contracts
#3: Policy

The threat of patent litigation can deter biosimilar development; lack of guidance on interchangeability and state restrictions on substitution will limit development.

**Strategies**

- **Congress**: Limit frivolous late-stage patents
- **FDA**: Continue to support and clarify interchangeability
#4: Stakeholder Education and Awareness

Physicians, patients, and employers lack awareness about the safety of and savings opportunity from biosimilars

**Strategies**

- **Biosimilar manufacturers**: Provide patient and physician education
- **Payors**: Incentivize stakeholders to gain experience
- **Employers**: Share biosimilar savings with employees
- **Policymakers**: Promote biosimilars as safe and effective
Thank you.

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