Global Biosimilars Markets (Regulations, Pipelines and Major Players) | Biosimilars Advisory Service | US/EU5/Asia Pacific | 2014

The biosimilars market is not all about the United States, Europe, and Japan. Although these developed markets account for 80% of branded biologics sales, the rest-of-world segment includes many markets where treatment rates with branded biologics are currently low due to their high costs. Therefore, opportunity exists for biosimilars to expand the market and provide better access to biologic therapy. Regulators in more than 20 of the growth markets have adopted biosimilars guidelines and are eager to establish their own biosimilars industries. A wide range of companies are embarking on biosimilars development within their domestic markets and overseas. Understanding who the key competitors are in each region is critical to both biosimilar developers and branded biologic companies.

Questions Answered in This Report:

- The global biosimilars regulatory environment is rapidly evolving. What are the key regulatory characteristics of the G7 biosimilars markets? Is there likely to be a global process for the development of biosimilars? Are physicians and payers in the United States and Europe likely to be a barrier to establishment of a global development process for biosimilars? What is the status of biosimilars regulations outside the G7?

- There has been a 42% surge in the number of biosimilar development projects disclosed globally in the past 12 months. What are the most popular targets among developers of biosimilars? How will physicians choose between multiple biosimilars of the same reference product? Will region of biosimilar development impact U.S. and EU physician and payer trust?

- The introduction of biosimilars guidance and government initiatives to boost biotechnology in the growth markets are just two of the drivers that have led to many regional companies embarking on development of biosimilars. How is the well-developed South Korean biosimilars market evolving? Can MNCs compete with PDP-developed biosimilars in Brazil? Are domestically produced biologics a major threat to international biosimilars companies in Mexico?

- The size of the global biosimilars market is often inflated by other sources owing to misclassification of non-innovator biologics (those that were not required to demonstrate comparable safety and efficacy to a reference brand in robust clinical trials) as biosimilars.
How big is the true G7 biosimilars market and how will it evolve over the next ten years? Which biosimilars have been approved in the G7? Who are the major players in the global biosimilars market? How does the biosimilars opportunity compare in Brazil, India, Mexico, and South Korea?

Scope:
Markets covered: Global R&D pipeline of biosimilars and in-depth analysis of biosimilars competitive landscape in Europe, United States, Japan, India, South Korea, Brazil, and Mexico.

Primary research: Surveys with 560 specialist physicians across six different specialties in the United States and Europe. Surveys with an additional 60 U.S. managed care organization directors. Ten telephone interviews with key European payer advisors. Primary market research with key stakeholders to assess the following:
- Current opinions of biosimilars developed in emerging markets.
- How country of origin will affect biosimilar uptake.
- Perceptions of regulatory guidance.

Supportive primary market research with physicians in South Korea, Brazil, and Mexico to assess the following:
- Familiarity with biosimilars.
- Perception of similarity between biosimilars and their reference products.

Global Biosimilars Development Pipeline Deliverable: Includes more than 280 biosimilars development candidates across 14 drug classes and 43 different reference molecule targets.

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