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info@marketpublishers.com

Biosimilars Update

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Abstracts

From Canada and the US to Japan, the EU and Australia, regulators around the world are establishing guidelines that will pave the way for competition between biosimilars and costly biologics.

For many, biosimilars represent a new and highly lucrative revenue stream for the pharmaceutical industry. This is increasingly important as many biologics—which are often 20 times the cost of traditional drugs—soon lose patent protection.

Promising as they may be, biosimilars face significant hurdles: a lack of stakeholder confidence, high manufacturing and distribution costs, a lengthy approvals process and more recently, the announcement next month of the European Medicine Agency's guidelines for biosimilar monoclonal antibodies (mAbs) development.

Are the hurdles for entry and development of biosimilars too high?

The answers in a special combination offer

For a limited time, FirstWord is offering a combination package of two top-selling reports: Biosimilars: Surveying the Market Landscape (Oct 2010) and Biosimilars Regulatory Update: An Evolving Landscape (Feb 2011). In the first report, FirstWord answers the most pressing questions facing the biosimilars industry. It reviews early entrants, current leaders and biosimilar production from manufacturing and marketing to the regulatory landscape across EU and American markets.

Our second dossier picks up where the first left off, by reviewing the EMA's new biosimilar mAb draft guidelines, cast against the FDA's consideration of just how biosimilar approval should proceed in the US. Containing a full breakdown of clinical and non-clinical requirements by the EMA, immunogenicity assessments, a guide to the

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FDA’s position and a section on pharmacovigilance, the report is an accurate state-of-play on a dynamic and shifting industry.

The reports offer:

Complete overviews of the current issues facing biosimilars and their regulation

Concise and timely insight into European and American developments

Scope

The reports

Examine the regulatory environment in the EU and how it may impact US regulations

Review target biopharmaceutical products

Identify biosimilar leaders, innovators and emerging companies

Review EMA guidelines specifics, including safety requirements

Examine key issues facing biosimilar developments and how legislation may ease barriers

Review immunogenicity assessments and include sections on pharmacovigilance and biosimilarity

Key issues examined

With biosimilar mAbs already available in less-regulated pharmaceutical markets, the real challenge for manufacturers now lies in successfully meeting the more stringent regulatory requirements of developed markets.

Despite the breadth of topics presented for discussion at the FDA’s 2-day public consultation concerning a biosimilars approval pathway, there was considerable consensus.

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The regulatory system needs to ensure that biosimilars are as safe and effective as the reference product. But is this even possible for such complex molecules? Economically, there is a need to balance the incentive to innovate with the need for lower prices and greater access.

Who are the successful biosimilar manufacturers likely to be? Since biosimilars are very different from traditional generics, it’s an open question. Brand development is important and direct marketing to small numbers of specialists is required. These are not the skills traditional generics manufacturers have.

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Contents

BIOSIMILARS ARE NOT GENERICS

Manufacturing
Safety and immunogenicity
Development Marketing
Market acceptance
Patents

REGULATORY PICTURE

EU
- Guidelines
- Substitution
- Data exclusivity
- Pre-approval trials
- Post-marketing surveillance (pharmacovigilance)
- Extrapolation
- Europe on the way to biosimilar monoclonal antibodies
  - Non-clinical and clinical requirements
  - Immunogenicity assessment
  - A risk-based approach to developing biosimilar mAbs

USA
- US takes first step towards a biosimilars approval pathway
  - Guidance documents
  - User fees
  - Exclusivity
    - Data versus market exclusivity
    - Potential for evergreening
    - Comments from consultation
  - Biosimilarity
    - Is a demonstration of biosimilarity currently feasible?
    - How should biosimilarity be evaluated?
    - To what degree are clinical trials required?
    - Extrapolation of data to other disease indications
    - Interchangeability
  - Pharmacovigilance
  - Unique international non-proprietary names for biosimilars?

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Biosimilar drug labeling
Pharmacovigilance
Biosimilars approval in the US likely to be guidance-driven
Patent information exchange
Biological products approved as drugs
Other markets

TARGET BIOPHARMACEUTICAL PRODUCTS

BIOSIMILARS COMPANIES

FUTURE PROSPECTS

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