+357 96 030922
info@marketpublishers.com

Biosimilars Regulatory Update: an Evolving Landscape

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Abstracts

They’re costly to develop, fraught with potential patient safety concerns and subject to regulations that have yet to be written.

Yet for the pharmaceutical industry, biosimilar monoclonal antibodies (mAbs) represent a potential treasure chest of new drugs—and bigger profits.

Yet while the industry is poised to move swiftly in developing new drugs that will plump weak pipelines, regulators have been cautious about instituting guidelines for what is a dynamic and evolving field.

All that is about to change, however, with the European Medicine Agency’s (EMA) recent release of draft guidelines for mAb development that make the prospect of lower cost, robustly-tested biosimilars a real possibility. Now full-fledged pioneers in the area, the EMA’s guidelines are expected to be finalized in May 2011, and may well forge a path for the United States to follow.

Although the Federal Drug Administration (FDA) has uncharacteristically trailed behind in the biosimilar race, it now has them firmly on the agenda. An approach to approving biosimilars through an abbreviated pathway is now being developed following a period of public consultation.

In Biosimilars Regulatory Update: an evolving landscape, FirstWord offers a timely and thorough analysis of Europe’s new biosimilar draft guidelines, cast against the FDA’s consideration of just how biosimilar approval should proceed in the US.

The fascinating report offers clear and critical insights into an otherwise complex topic,

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at a time when the industry must keep pace more than ever with developments. Containing a full breakdown of clinical and non-clinical requirements for Europe, immunogenicity assessments, a guide to the US position and a section on pharmacovigilance, the report is an accurate state-of-play on a dynamic and shifting environment.

The report offers:

A concise and timely overview of European and US developments

A comprehensive review of EMA and FDA consultations and guidelines

Key features

Analysis of the European regulations and potential moves by the US

Complete and concise review of guideline specifics including safety requirements

Examination of key issues facing biosimilar developments and how legislation may ease barriers

Analysis of immunogenicity assessments

Sections on pharmacovigilance and issues surrounding biosimilarity

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