Biosimilars Market Access in the US

Description: The route to a formal US regulatory pathway for biosimilar approval was established with the creation of the Biologics Price Competition and Innovation Act of 2010. However, it has taken five more years for the first biosimilar to be launched in the US through this pathway. Despite the presence of this regulatory pathway a number of regulatory uncertainties exist that require clarification in order for the US biosimilars market to be fully realized. These uncertainties include the naming of biosimilars, as well as questions on labeling, substitution, and interchangeability. In addition to the regulatory questions there are also a number of legal issues that are yet to be resolved and which may have a significant impact on the future approval and launch of biosimilars in the US.

Once these regulatory and legal hurdles are overcome, it is anticipated that there will be few, if any, major obstacles to market access, with access expected to be relatively straightforward due to the cost benefits that biosimilars offer. Physician reluctance to use biosimilars interchangeably with the original product may prove to be an issue, albeit one that can be overcome with education efforts.

This report addresses the following questions:

- What are the regulatory approval requirements in the US and how do they differ from Europe?
- What are the current biosimilars naming and substitution rules and how will they impact access to biosimilars?
- What precedents have been set by ongoing legal dispute and how will they impact the timing of market entry of biosimilars?
- How do payers view biosimilars and what measures do they intend to use to stimulate biosimilars uptake?
- Which stakeholders to biosimilars and branded biologics manufacturers need to target in their biosimilars education efforts and with what information?

Contents:

EXECUTIVE SUMMARY

- Regulatory pathway
- Legal considerations
- Pricing, reimbursement, and access
- Education needs

THE NEED FOR BIOSIMILARS

- What are biosimilars
- The US has lagged behind the EU in developing a regulatory process for biosimilars
- Biosimilars are expected to deliver considerable cost savings for the US healthcare system.
- There are several questions around biosimilars that need to be addressed
- Bibliography

REGULATORY PATHWAY

- Omnitrope was a "copy" biologic that was approved prior to 2
- via the 505(b)(2) process
- The BPCI Act established a dedicated biosimilar approval pathway in the US
- FDA released guidance on biosimilar approval requirements
- There are still several uncertainties around the regulatory pathway in the US
- Indication extrapolation poses the greatest regulatory uncertainty for manufacturers
- There are several key differences in US and EU approval processes
- Zarxio was the first biosimilar to be approved through the BPCI Act pathway
- Bibliography
SUBSTITUTION AND NAMING POLICY
- Biosimilars naming is a contentious issue yet to be resolved
- Biosimilar labeling is also a key issue
- Substitution policies are likely to vary across states
- Bibliography

LEGAL ISSUES
- The innovative industry lobby secured a long period of exclusivity for biologics.
- Biologics currently have four years of data exclusivity followed by eight years of market Exclusivity
- Patent litigation is being pursued by many originator companies
- Bibliography

PRICING, REIMBURSEMENT, AND ACCESS
- Different tools are used to control spending on biologics. 27.Biosimilars are expected to offer at least
discounts relative to the brand
- Biosimilar use will be driven by a number of measures
- Payers' drive to promote biosimilar use depends on the indication
- Payers will treat biosimilars as brands
- Accountable care organizations and group purchasing organizations will have an interest in using
biosimilars.
- Bibliography

EDUCATION AND COMMUNICATION NEEDS
- There are still residual uncertainties regarding biosimilars in the eyes of many stakeholders
- A large proportion of physicians have concerns about biosimilars
- Patients likely to accept biosimilars
- Education around biosimilars is critical for access and uptake in the US
- Concerted education efforts are required in order to boost biosimilar acceptance and use,
- Bibliography

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