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3rd International Conference and Exhibition on
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Biosimilars-destination in India

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According to the World Bank (2012), 1.237 billion people reside in India, accounting for about 17.5% of the world's population. India is fast growing from the 15 largest pharmaceutical market in 2007 to 12 in 2011 and is expected to become the 8 largest by 2015. In fact, India's pharmaceutical market is guided by Increased accessibility and affordability of prescription drugs; An increase in the diagnosis and treatment of chronic diseases.; Mergers, acquisitions and partnerships with big pharmacy ; High growth in the hospital sector. In view of the Biosimilars patents expiry, there is an anticipated surge in the manufacture and serve the people of the country at affordable prices. Biologics are an important component of the pharmaceutical industry and have grown exponentially in the last decade. In recent years, the pharmaceutical industry has placed greater and greater emphasis on developing biopharmaceutical-based drugs (biologics). As a result, the global biologics market is expected to reach $220 billion by 2019. By 2020, patents on several biological products with global sales of more than US$67 billion will expire. Biopharmaceuticals are particularly complex molecules, and biosimilar insulins present special challenges, which is perhaps the most needed by India in the years to come. In part this reflects their structure and chemical modification after synthesis to attain a biologically active form. The manufacturing process for a similar biologic should be highly consistent and robust. If the host cell line used to produce the reference biologic is known, it is preferable to use the same cell line to manufacture the similar biologic. If such a host cell line is not available, any cell line that is adequately characterized and appropriate for intended use can be used to develop the similar biologic. The applicant will need to describe the steps taken to minimize the potential for significant changes in critical quality attributes of the product and to avoid introduction of process related impurities that could impact clinical outcomes and cause immunogenicity issues.

The intricacies regarding the vaccine and non-Vaccine products would be reviewed keeping in view of the disease demographic pattern peculiar to India.

Biograp hy

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