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Strategic trends, current and future competitive landscape in biologics and biosimilars (follow-on biologics) drug development in USA and emerging markets-a brief snapshot from 2012 through 2022

A presence in biologics and biosimilars has become a strategic priority for nearly all the world's leading and emerging pharmaceutical companies. Below is an approximate snapshot of biologic drug sales for top 10 pharmaceutical companies during last five years and future five years will be discussed. Biosimilars or follow-on biologics are similar terms used to describe officially approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. The following topics during this presentation will be briefly discussed; Historical growth of the biologics market, Leading players, Changes to the competitive landscape 2017-2022 and Outlook for the biologics market, Leading players in 2016 vs 2022. Subsequently; Some examples of biosimilars and how it may affect the biologics will be briefly explained. While the FDA designates interchangeability, states control drug substitution laws. Once an interchangeability designation is acquired, a biosimilar may be substituted for the reference product by the pharmacist at the retail or specialty pharmacy without the intervention of the prescriber in states that have approved legislation or regulation establishing state standards for biosimilar substitution. As of January 2017, there are no interchangeable biologics approved in the U S. Biologics generally exhibit high molecular complexity, and may be quite sensitive to manufacturing process changes, unlike the more common small-molecule drugs. The follow-on manufacturer may not have access to the originator's molecular clone and original cell bank, nor to the exact fermentation and purification process, nor to the active drug substance. They do have access to the commercialized innovator product. Differences in impurities and/or breakdown products may have serious health implications. This has created a concern that copies of biologics might perform differently than the original branded version of the product. While summarizing above dynamics, the status and most recent developments in biologics and biosimilar (follow-on) drug development in United States of America and global trends will be explained.

Biography

Dr. Silay serving as the Chairman of Labiopharma, LLC in US, providing clinical trial administration, market access, medical writing, patient recruitment, retention, regulatory and medical affairs support, drug repositioning for hospitals, academic institutions and pharmaceutical companies from preclinical to post marketing stages for several years. Dr. Silay is also providing comprehensive and strategic consulting services for the approval of Drugs and Medical Devices and attended several meetings with FDA, EMA, Health Canada and Turkish Health authorities and social security institute. Dr. Silay in US, most recently worked as the Vice President, Medical Affairs, and head of Medical Affairs Neurology in the US headquarters Basking Ridge, New Jersey reporting to the President and CEO of Ipsen North America where he was key in building a Neurology Franchise by hiring many employees. He has Proven ability to build high performing teams and productive organizations, turn around brands, and build revenue in diverse markets. As the former director, Market Access & Health Policy for AIFD(Research Based Pharmaceutical Companies) which the 40 members represent all major global pharmaceutical companies, 650 billion dollars of 1 billion dollar Global Pharmaceutical market. He represented pharmaceutical companies and was in discussion with all ministerial levels, including ministry of health, finance, labor, development and science& technology in Turkey.

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