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10 year perspective: Science and commercial power- Battle of the giants in biosimilars

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Biosimilars uptake in Asia has been historically low. Recent evolutions in regional regulations are preparing the market for a step change. Countries like Japan and South Korea have developed their own regulatory pathways. India and China both recently finalized national biosimilar guidelines. Rapidly increasing research efforts in the region with more than 300 candidates in development indicate a huge potential for change. The Asia-Pacific Biosimilars market is expected to grow from $0.8 billion in 2016 to over $4 billion by 2021, India and China are estimated to grow the fastest. There is an opportunity to leverage local knowledge and learning's from experience to succeed in competition. The pioneering launches in Europe were the departure point for the fast moving industry. The early pathway in the development of biosimilars was based on advances in protein characterization with the ability to define and prove similarity. As biosimilar medicines are becoming common, success is built on efficient partnerships between specialists in development and companies with commercial power. Small molecule generic medicines manufacturers dominated success in the first phase of biosimilars. This pioneer phase was centered on the manufacture of 3 main products; EPO, GH and GCSF. Market leaders were highly capable in skills of protein characterization and invested in the iterative processes to achieve comparability. The early competitors worked with regulators to make biosimilars work. The first phase was built on capabilities in development including mastering the science of comparability. Recent events in the biosimilar global market place provide insights into drivers of future success. Major development players are pulling back on development of biosimilars; leading biosimilar commercial players are increasingly dominating the decisions in the global market. Core skills scarce in the early days of the industry are now common place and development skills are available from a great range of providers. Future success is built on market reach and commercial power. Competitors must be fast to market and able to deploy leading resources in commercializing their products. The blueprint for success is based on important factors including the capability to deploy global sales power along with access to efficient, smart, fast development in part secured with partnerships. Execution of development partnerships will be the key for future winners. It is not clear if the early runners from the first 10 years can match the giants. The markets in Asia will be key in the future to the global uptake of biosimilars, likely new approaches sensitive to local customer and patient needs will be key to success.

Biography

Richard Littlewood is the CEO Founder at appliedstrategic. He is a physician with clinical practice experience in hospital medicine, combined with excellent management consulting experience at Bain & Company and extensive senior pharmaceutical industry experience. Entrepreneurial success forming a medical device start-up company.

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