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Challenges, development and future role of follow on biologics in the US, EU and India

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"Biologics", considered one of the fastest growing sectors of the pharmaceutical industry, has introduced many new treatments to life-threatening and rare illnesses. The first generation of biopharmaceutical products manufactured using recombinant technologies was launched in the 1980s, and they are now on the way to patent expiration. As a result, research based and generic pharmaceutical companies alike are pursuing the opportunity to develop "generic" substitutes for original biologics, herein referred to as biosimilars. However, the process of introducing a biosimilar to an innovator product is far more complex than the straightforward process of introducing a generic equivalent to an innovator product based on a new chemical entity. Biologics are produced by cells in culture or whole organisms, which are inherently more variable than chemical synthesis methods. Therefore, unlike generic pharmaceuticals, it is impossible to generate the same or identical copy of an innovator product.

In this way, biosimilars are "similar but not the same" or in other words biosimilars are "the twin but not the clone" to the original biologic innovator product. Therefore the field of biosimilars presents several important challenges, including i) verification of the similarity, ii) the interchangeability of biosimilars and innovator products, iii) the possible need for unique naming to differentiate the various biopharmaceutical products, iv) regulatory framework, v) commercial opportunities as well as guidelines to assist manufacturers in product development, vi) intellectual property rights, and vii) public safety.

The lower cost of biosimilars/follow-on products will undoubtedly play an integral role in the future development of this market. Because of this, a number of large, established generic drug manufacturers, and more recently, several major pharmaceutical companies, have been positioning themselves to compete in the biosimilars/follow-on biologics markets. The actual size of the biosimilar/follow-on market remains to be determined. However, contrary to early assertions, it is highly unlikely that smaller, under-financed generic manufacturers will have the resources to enter the biosimilars/follow-on marketplace. "They simply won't be able to compete with the large generic and pharmaceutical companies who have the money, marketing, and distribution capabilities to dominate the market,"

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