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Biosimilars: Important in overall advancement of Indian Pharmaceutical Market

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Biosimilars for the Indian Market:

In our view biosimilars are going to play a vital role in advancing the overall Indian Pharmaceutical Market. There is still a significant unmet need for biologics with only about 10-30% of Oncology patients in India being treated with biologics. Additionally, biologics are increasingly receiving more traction in multiple therapeutic areas and are considered an integral part of therapy in nephrology, immunology, gastrointestinal diseases and so on. All these factors call for the need of affordable, high quality biosimilars that will drive future growth. As one of the pioneers in this field, we at Dr. Reddy's have

seen a significant growth in the number of patients served year on year, through our biosimilar portfolio. While this opens up a great opportunity for Indian companies to further expand and grow the market, one should never forget that high quality biosimilars are an absolute necessity and this requires a highly focused approach, and a long term view of the market.

Regulatory challenges for Biosimilars:

In the Indian context, there are no specific legal or operational challenges. However, biosimilars are inherently more complex molecules and therefore the underlying challenges are of development and manufacturing and of the associated regulatory pathways. There has recently been significant progress in clarifying the regulatory expectations in India. The CDSCO has issued guidelines on Similar Biologics which provide granular clarity on the requirements at different stages of development as well as bringing in procedural simplifications.

In most other Emerging Markets, on the contrary, limited regulatory maturity has meant that the emergence of biosimilars has been delayed significantly with each country attempting to strike a balance between the high bar being set by the EU and US (which would mean long expensive programs, limited competition and minimal price reductions). There is also the pressing need to accelerate access to biosimilars against a backdrop of widespread unmet need.

In Developed Markets (DM) there are well defined regulatory and established precedents which mandate comprehensive clinical programs. This in turn has necessitated very high upfront investments. Coupled with significant commercial uncertainty, this has resulted in a DM biosimilar competitive landscape that is now dominated by big pharma.

Major challenges in manufacturing Biosimilars:

Biosimilars are highly complex molecules manufactured by living cells. Their manufacturing needs to be managed through a highly controlled processes and manufacturing environments because of the risk of even minor variations introducing unacceptable changes to product quality. This entails a high focus on quality across the entire manufacturing process and raw materials, equipment used as well as the people who undertake the process. The process involved in Biosimilars is much advanced from what is typically expected for chemical processes and therefore it’s a significant learning curve for companies that are new to the field. Also, significant investments are required in setting up these facilities as well as increasing capacities, so it is imperative to ensure facilities are fully utilized in order to keep costs under control.