Pharmaceutical Sector

20 August 2019

Sector Update

Key takeaways from our meeting with a biosimilar industry expert

At an investor conference held by us we hosted an expert in the biosimilar space – Mr. Hareesh Parandhaman. Mr. Parandhaman has been associated with the biosimilar space for more than a decade and has worked with the key players. The takeaways from the meeting are as under.

Potential impact of interchangeability guidelines: Unlike small molecule generics, which are interchangeable for innovator brands, biosimilars that are approved by the USFDA need to be promoted under brands and are not interchangeable for innovators' brand prescriptions. A couple of months back, the USFDA issued guidelines for companies that intend to develop interchangeable copies of biosimilars of innovators' biologics. According to Mr. Parandhaman, the guidelines on interchangeability have raised the entry barrier for biosimilar players. Only In case of few select biosimilar drugs (already approved), the guidelines may provide an advantage to incumbents, as they can leverage on post marketing evidence collated either through post marketing surveillance or post marketing study on their drug to apply for interchangeability. The scope of evidence that would be required to demonstrate interchangeability would depend on the extent of analytical characterization, product complexity (structural and receptor activity) and potential impact of immunogenicity on clinical outcome. These interchangeability studies would address Pharmacokinetic and Pharmacodynamic endpoints (if possible) and would be incremental to the evidence required for the demonstration of similarity. These incremental requirements would escalate the total cost of developing biosimilars (interchangeable) while the overall developmental timelines may also get stretched. A case in point is Boehringer Ingelheim, which has initiated interchangeability studies on BI 605501 or Cyltezo (biosimilar of Humira) will enroll 340 patients and trial duration will be 58 weeks.

Developed Market versus Emerging Markets: Emerging Market (EM) is about enhancing volumes through unlocking access / affordability, while the Developed Market (DM) strategy has to focus around an early mover advantage so as to reap the advantage of premium pricing. Upfront investments required in case of EM are much lower than DMs. Success in EM's require an ability to discount biosimilar version to the point of affordability for enhancing access.

Quality of analytical data would determine the size and scope of clinical trials that a biosimilar needs to undergo. A way to reduce expense on clinical studies is to develop the best set of analytical data that is able to demonstrate the closest resemblance to the innovator compound.

Can biosimilar drug substance facility be used as multipurpose sites? Drug substance facilities for biologics just like manufacturing facilities for small molecule API's can be used as multipurpose facilities but there are limitations to what can be manufactured.

Quality of the sourced cell line remains critical to success of biosimilar players in the long term. Over the medium to long term, the biosimilar space is expected to get commoditized and players which have worked on cell lines that offer best yields will deliver for perpetuity. Due diligence while sourcing these cell lines is critical and would determine the success of biosimilar on regulatory and commercial aspects.

Optimal sizing and scaling of manufacturing facilities: To ensure market competitiveness in the long term when prices are commoditized the initial strategy around developing biosimilars has also to focus on optimal sizing of its facilities. If at all there is a change in the batch scale during a future capacity expansion, there is a chance that the regulators might seek evidence around the batches by way of analytical evidence or bridging studies. Biosimilar production quality is highly susceptible to variations in manufacturing scale. It is also believed there are variations even within two separate batches manufactured in the same plant. During the process of development of a biosimilar, it is also imperative that the innovator reference standard that is sourced is obtained from different batches.

Competition from Biobetters: Unless biosimilar are interchangeable, they remain prone to competition from biobetters. The biosimilar strategy has to pursue interchangeability, or else biobetters are poised to do better. A case in point is Celtrion is looking to develop subcutaneious copies of Remicade which may put non interchangeable biosimilar players at a disadvantage.

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