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Can India Dominate the biosimilar market?

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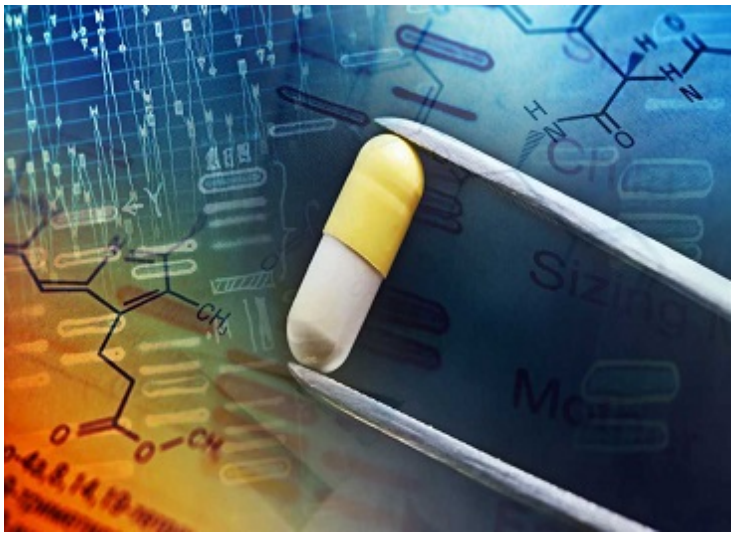

Why India is not on the Biosimilars' Radar?

Over the last 15 years, Indian Pharmaceutical Industry from having less than 5 percent market share in the US generic market, now has more than 25 percent. But we are yet to see the same advancements in biosimilars.

The major bottle-neck for developing biosimilar molecules in India lies in the regulatory challenges, says Dr Sunit Maity, AVP, product development, Theramyt Novobiologics.

He added, "Currently BioPharma companies which are developing biosimilars, must receive approval from multiple government agencies, significantly increasing the overall time it will take to bring the product to market. A single-window agency and streamlined approval process will reduce the complexity and encourage the players to develop the biosimilar molecule."

Cost and complexity of developing biosimilars poses another challenge. "Biosimilars are large and complex molecules compared to generic pharmaceuticals. Therefore, development and manufacturing of biosimilars is capital intensive and the overall commercialization timelines are 5-7 years, even for launch in domestic market, said Mr KV Subramaniam, president, Reliance Life Sciences.

He further added, "Very few generic pharmaceutical companies have capabilities and competencies in R&D and manufacturing of biosimilars."

Dr Murtaza Khorakiwala, managing director, Wockhardt provides another view, "The Biosimilar Industry even in the regulated markets is still in a nascent infancy stage and accounts for less than 5% of total Biotechnology Market. However, there are at least 8-10 corporates from India that have significant progress in developing and launching biosimilars in India and emerging markets."

Challenges in the manufacturing and development of Biosimilars
Biosimilars manufacturing is capital intensive. The development of biosimilars require extensive preclinical and clinical trials. Thus, the investments required for development and commercialization of these products is quite high.

"The investments in biogenerics are very high when compared to conventional generics. The development is itself lengthy and expensive; a successful biosimilar manufacturer has to have good science and manufacturing technology, and the capability to deal with complex regulations," said Mr Rajiv Malik, president, Mylan.
The development of biosimilars is also much more challenging due to the greater complexity of biological drugs and the complex manufacturing process.

"The major challenges would be significantly higher barriers to entry in terms of - capital investments in scientific / clinical development and manufacturing capacities, evolving regulatory process and still to mature market development strategies and also availability and accessibility of people capability and depth," said Dr Khorakiwala.

Another big challenge is on the competency front says Mr Subramaniam.
He added, "Very few companies today possess the competencies and capabilities required for development and manufacturing of biosimilars."

Dr Maity pointed out that an in-depth understanding of the product and manufacturing process, as well as highly specialized analytical tool are required for development of biosimilar molecule.

Cost and Complexity deterrent for Indian companies?
The development of biosimilars is much more challenging due to the greater complexity of biological drugs and the high cost of development. Could these be a deterrent for Indian companies?

"This is partially true. Small generic pharmaceutical companies may not have wherewithal to develop biosimilars given the capital outlay for commercialization of these molecules. For large companies, it largely depends on their overall strategy and capital allocation for these new class of molecules," said Mr Subramaniam.

Cost of conducting clinical trial for biosimilar is a huge burden on the developers.
"It has also been deliberated that may be it is better to develop biobetters or novel biologics than biosimilar. It is possible then to launch a product with improved efficacy and immunogenicity profile which can get branded product pricing and it can potentially replace the previous product and will get a major market share," said Dr Maity.

Lack of Biotech Boom a barrier?
Part of the problem that India has not made significant mark in biosimilar is said to be that, biotechnology is not as well developed in India as chemistry.

"It is partially true that capabilities in applied research in biology limited India's growth with regard to biological drug development," said Mr Subramaniam.
He continues, "The other key issue was that the generic pharmaceutical industry was 'behind the curve' on this front, as it was always focused on generic pharmaceuticals development, which did not require large capital and had shorter commercialization timelines."

However, Dr Maity absolutely disagree with this view. He said, "Indian biotech industry is very well developed otherwise we could not become world leader in vaccine industry."

Does India have the expertise to dominate biosmilars industry?
"India does have the expertise in biogenerics and recognises the potentials with biosimilars, as was done in the generics industry, and make bio-generic manufacturing an important part of the Make in India movement," Mr Rajiv Malik, president, Mylan.

Biotechnology requires specialization and is not as job intensive as compared to pharmaceuticals.

"State-of-the-art production facility dedicated to manufacturing of only biotech products are now available with many Indian companies focusing on biosimilars. Indian biotechnology industry is thriving resulting in launch of more than 50 biosimilars till

the date," said Dr Khorakiwala.

One of the major advantage we have is the significant success and experience in pharmaceutical manufacturing that has been achieved over the last 2 decades. That has brought in rich experience in topics such as GMP manufacturing, documentation practices, scale up, technology transfer and validation.
"Indian biopharma industry today has all of the essential pre-requisites that are essential for it to emerge as a global manufacturer of economical, safe and efficacious biotech therapeutic products," said Dr Maity.

Can India dominate global biosimilars market?
"Yes absolutely, if we can become world leader in generics and vaccines then why not in Biosimilar. We need to make a concentrated effort in every level to achieve this," said Dr Maity.

Dr Khorakiwala counterfeits the view, "India has immense potential to become one of the key players in the development and manufacture of biosimilar drugs."
"There have been many Indian companies who are developing this portfolio & have sold biosimilars in emerging markets. Identifying portfolio with well-laid strategy to develop, manufacture and commercialization of the products in key markets is very essential. The key is investing in research & development," he added.

However, Indian companies would have to overcome the challenges mentioned to manufacture high-quality, cost-competitive products.

"The companies also would need to invest significantly in talent development specifically in the area of molecular biology, process development and manufacturing of biosimilars," said Mr Subramaniam.

"Biosimilars are going to be the next big growth driver in India, playing a major role in offering quality and affordable solutions for disease management," said Mr Malik.

New 'Biosimilar Guidelines' of India provides similarity in approach with those in the US and Europe, certainly a step in the right direction. In addition, DBT has launched schemes to promote the development of biosimilars. Given this scenario, India is set to make its mark in the biosimilars market.

Some of the Indian companies in biosimilar space
Biocon's Insulin Glargine Receives Regulatory Approval in Japan and is also gearing up for the US launch.
Intas Pharmaceuticals launched INTACEPT, the First Etanercept Biosimilar. It is also expecting US approval of their Neulasta biosimilar soon.
Wockhardt is said to be the first in India to launch recombinant human Insulin "Wosulin, recombinant Insulin Glargine "Glaritus" and recombinant human Erythropoietin "Wepox".
Hetero launched biosimilar 'Rituximab' under the brand name 'MABALL'.
Dr Reddy's launched the first biosimilar filgrastim (G-CSF) in India, first biosimilar MAb (Rituximab) and biosmilar darbepoetin alfa- Cresp.
Reliance Life Sciences markets, ReliFeron® (Recombinant Interferon Î±), ReliPoietin™ (Recombinant Erythropoietin), ReliGrast® (Recombinant Granulocyte colony stimulating factor) and MIRel™ (Recombinant Reteplase - tissue plasminogen activator), among others biosimilars in India and overseas market.