

## "We need a stonger Pharmacovigilance program" says deputy DCGI

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At the recently organized 3rd Biosimilar Congregation 2013, the challenges involved in the development of biosimilars were brought to center stage, allowing industry professionals, regulators and legal experts to share their views.

Dr. V.G Somani, Deputy Drugs Controller India was positive about the scope of biosimilars in India. He said, "India has a good capability in the field of biosimilars as well as a good market, since most innovative molecules are out of reach for the common man. The real challenge in giving approvals for biosimilars is that there is no data from innovator companies available in the country for reference molecules . This makes things very difficult, from a regulatory point of view. Whether we compare it with the actual reference molecule or the Indian reference, things like these present difficulties."

When asked what he expects from the drug industry he replied," What we need today is a strong and focused Pharmacovigilance program. This is extremely important from a patient perspective. We are not active about Pharmacovigilance and doctors have been passive about this issue as well. Those you develop a product could take the onus of gathering information about it as well."

One of the leading companies in the biosimilar space has been the biopharmaceutical firm, Reliance Life Sciences. About the market for biosimilars, Bobby George, assistant vice president and head, Regulatory Affairs, Reliance Life Sciences said, "RLS currently has 7 biosimilars in the market with few others in clinical development. Overall, the biosimilar sector has shown a healthy growth. there are approximately 55 players in this market, overall. However there are very few manufacturers in this space, a lot of them import the products."

The conferences featured a number of experienced professionals in the biosimilars space, talk about different aspects related to the development and marketing of biosimilars in not just Indian markets but also the US and EU ones. The talk on Indian biosimilar regulations featured Yasmin Shenoy, director, Regulatory Affairs, Sanofi Aventis as well who said, "Even though Sanofi is known worldwide as an innovator company, we are open to biosimilars as well, Shantha Biotechnics is a perfect example of that."

