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India should now focus on biobetters and take the route of Europe to reach the US biosimilars market, said the speakers at a special session on "Biosimilar Guidelines for Development of Safe, Affordable and Efficacious biosimilars For The World" chaired by one of the main authors of India's Biosimilars Guidelines, Dr VP Kamboj, chairman, Biotech Consortium India Limited and former director, Central Drug Research Institute (CDRI), during Bangalore India Bio 2013 (BIB 2013).

The session moderated by Dr VP Kamboj comprised of Dr PM Murali, president, ABLE and managing director, Evolva Biotech; Dr Abhijit Barve, president, research and development, Biocon; Dr William Lee, head, regulatory strategy, strategic drug development, Asia Quintiles, Singapore; and Dr Subir Kumar Basak, president, Global Drug Discovery Services, Jubilant Life Sciences.

Dr VP Kamboj said, "Biosimilar guidelines in India was drafted in five intensive sessions by the regulators and academia along with the participation of companies and pater lawyers so as to make India as competitive as possible in the world. India has found a definite place in generics and is one of the leading nations to take generics to the global market particularly the US, Europe and Japan. Every company wants to reach the US and Japan markets as 40 percent of the world's total drug is consumed in the US and 19 percent in Japan, whereas only 14 percent of the total drugs are consumed by Africa, India and Asia together. There is 23-25 percent growth in Indian biopharmaceuticals and generics, which is the highest in the world. In 2011, US saved $192 million by using generics than other drugs. US is the goal for every biopharmaceutical company because of its major market."

According to Dr Murali there is a tremendous opportunity in biosimilars. "India can become the capital of biosimilars by capturing 25 percent share of the $3.4 billion market. The potential, hardworking and extraordinary talent that we have in India will fructify only by proper regulation and implementation by the government and later by companies. A bold initiative was taken by the government to frame which can be used as a model. Thus a commendable document from the panel was prepared. In 2009, 15 alliances were made globally out of which 12 percent was from Indian companies indicating that we are

on the right track. The investments made in the biosimilars are many times more than that in generics. Regulation is going to be the key for targeting and propelling a growth in the next two years .There is a criticism regarding the guidelines i.e. it is suited only for for semi-regulated markets and not for fully regulated markets like the US. For every company regulation must be an enabler and not disable its progress."

The biosimilar guidelines are evolving. The guidelines depend on how every country interprets it. Dr Abhijit Barve, added, "Europe is the front runner in the biosimilars, they regulated the tricky issue of how many clinical trials is important for the efficiency and clarity of the drug. The WHO guidelines are very similar to that of Europe's. The pyramid of biosimilars should have a robust foundation with many steps that make it up like the funding, studies, research, and availability. The Indian guidelines are quite similar in comparison with the WHO and European guidelines. The roadmap to Indian guidelines is mainly about the safety and the effectiveness of the product. To raise funds for a biopharmaceutical franchise there are two main important aspects namely the reference drug and the interchangeability law. The source of the reference drug and the materials used, since the laws in the US and the UK are very strict and they do not allow any reference drug from any other country. So, the FDI is helping the semi-regulatory markets in reference drug issue. The second being the interchangeability laws whether biosimilars can be used for conservative drugs. The product quality should meet the requirements of all the people around the globe. The prices of biosimilar will be huge so there should be a robust bottom of the pyramid and safety is paramount to all patients all over the world."

Dr William Lee, commenting on the global perception of India, said, "Biosimilars is a frontier in pharma. India plays an important role in pharma industry in providing cost effective drugs and if it continues so India will be the 'major player in the biosimilar space'. India has to converse all over the world to make its strong presence. India must focus on its positioning which is very important and it should be done quickly."

Highlighting the path to global stature, Dr Subir Kumar Basak, said, "The biopharmaceuticals companies in India now have many global partners and they have been developing many affordable and efficient drugs since the last 10 years though there was a lot of resistance initially from all the world for Indian drugs. For the development of high quality drugs the biologicals are very important along with huge investments, technology and other works. Eastern Europe, Latin America and South Korea have given access to Indian products."

The speakers agreed that India has a good ecosystem and it does not allow sub-standard medicines to be marketed so easily. Many innovative companies have moved out of biosimilar guidelines since everybody wants standard care for oncology and monoclonals. The UK and the US have the most expensive monoclonals and standard care. Many companies are now investing in the technology and scientific ability of biopharmaceuticals. The small hurdles faced in biosimilar guidelines have to be analyzed and prevented before it becomes a big issue for the government as well as the public. The game will shift from biosimilars to biobetters.

Dr Kamboj concluded the discussion summarizing that, "The patent laws in India respect the patents except during emergency and the innovators have tendency for evergreen innovations. The market expectancy of patent life is aimed in India not only for semi-regulated markets but also for non-regulated markets. The guidelines respect safety and ethnic variations in every country must be looked on. At least about five Indian drugs should enter the European market and also aim for the US market in the following year. The guidelines will be revised periodically as per the requirements."