

## Bangalore Bio: Regulation must enable progress

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**Bangalore:** Day two of India's premier biotech event, Bangalore India Bio 2013, saw several eminent individuals discuss on the topic of 'Biosimilar guidelines for development of safe, affordable and efficacious biosimilars for the world'.

The session was chaired and moderated by Dr VP Kamboj, chairman, Biotech Consortium India Limited (BCIL), and former director, Central Drug Research Institute (CDRI). The panelists at the discussion were Dr PM Murali, president, ABLE and MD, Evolva Biotech, India; Dr Abhijit Barve, president, R&D, Biocon, India; Dr William Lee, head, strategic drug development Asia, Quintiles East Asia, Singapore; and Dr Subir Kumar Basak, president, global drug discovery services, Jubilant Life Sciences, India.

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 law makers, 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 countries to take generics to the global market particularly in the US, Europe and Japan. Every company wants to reach the US and Japanese markets because about 40 percent of world's total drug are consumed in the US and 19 percent in Japan, whereas only 14 percent of the is consumed by Africa, India and Asia together. There is 23-to-25 percent growth in Indian biopharmaceuticals and generics, which is the highest in the world. In 2011, US saved \$192 million by using generics. In India about 50 percent of the drugs that is produced are consumed."

Dr PM Murali said that, "There is a tremendous opportunity in biosimilars. India is the capital in biosimilars as it has by captured 25 percent of the \$3.4 billion market, which is a big task. The potential, hard-working 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 heading towards the right track. The investments made in 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 that it is suited only 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."

Dr Abhijit Barve, said, "There's been a evolution in biosimilar guidelines. The guidelines depend on how every country interprets it. 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, availability etc. The Indian guidelines grafted is quite similar in comparison with the WHO and European guidelines."

He also said, "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, 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 biosimilar space. India has taken on with lots of guts in the space of biosimilars. 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."

Dr Subir Kumar Basak, said, "The biopharmaceuticals companies in India now have many global partners and now finally we have biosimilar guidelines which are the combined efforts of companies and academia. Indian biotech companies have been developing many affordable and efficient drugs from the past ten years though there was 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 market to Indian products. The tremendous talent, hard work and resources in Indian companies have helped us to produce safe medicines."

He further said, "The main challenges faced by these companies are the number clinical trials, fulfilling government regulations and figuring out how the drug works. We have a good ecosystem and we should maintain it since Indian ecosystem 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. UK and 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 analysed 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 session by saying, "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."