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India's biosimilars guidelines is an industry booster

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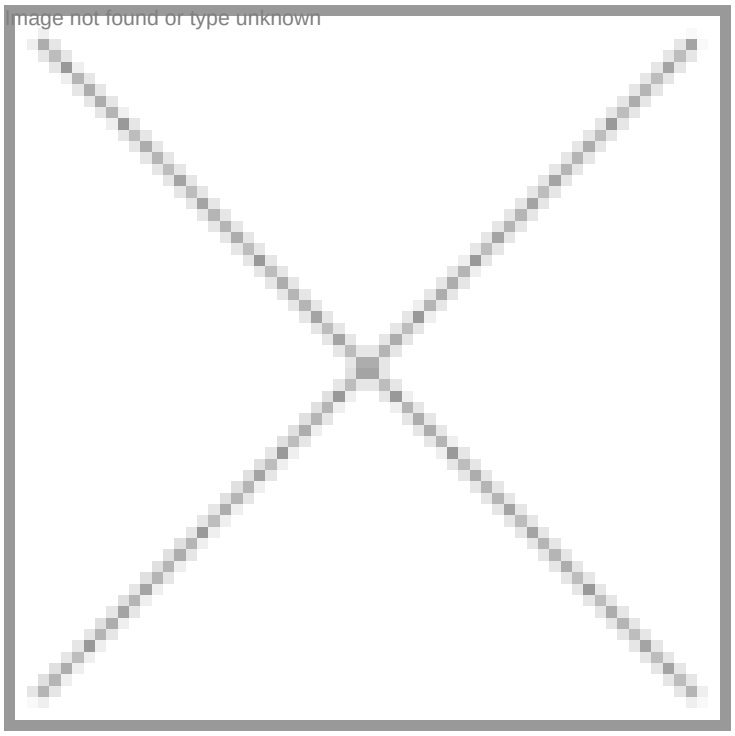

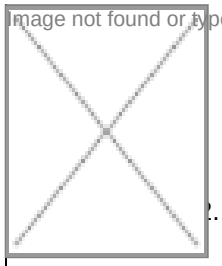

The much-awaited guidelines on which similar biologics, or what the rest of the world calls biosimilars, can be successfully manufactured and distributed in the country, has been made public. The Department of Biotechnology (DBT) secretary, Dr MK Bhan, made this a global event as he unveiled the guidelines in front of world media at the world's largest biotechnology event, BIO in Boston on .

Prepared jointly by scientists, regulators and industry representatives, the Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, the report is product of painstaking efforts by a committee co-chaired by the drug regulator, Dr G N Singh and eminent scientist, Dr V P Kamboj. Essentially, India's entrepreneurs can develop similar biologics against an authorized reference biologic that has been approved using a complete data package in India. More interestingly, the reference biologic should have been licensed and marketed for at least four years with significant safety and efficacy data. There is a also a clause that insists that the reference biologics should have been approved in one of the top developed countries. This is just to ensure that the product has already gone through an intensive regulatory process in one of the advanced nations. Also, the demonstration of similarity depends upon detailed and comprehensive product characterization, preclinical and clinical studies carried out in comparison with a reference biologic.

Though the guidelines were prepared in consultation with various biotech stakeholders, this will not be cast in stone, according to Dr Bhan. In fact, Dr Bhan has promised that a review of the guidelines will be done a year later from now incorporating the inputs from the entire biotech community. This is a commendable step and BioSpectrum will take the lead to organize wide ranging industry-wide consultations on the guidelines in the next few months and ensure that all the industry concerns are addressed during the next review process.

These guidelines have come at the right time as there is a strong realization with the industry and policy makers that a huge opportunity awaits India in the biomanufacturing space if the cards are played right. The global software icon turned healthcare evangelist, Mr Bill Gates of Microsoft fame has just gone back after praising the vaccine manufacturing capabilities of India's No. 1 biotech company, Serum Institute of India. Serum has demonstrated to the world that it can hold its head high in the highly sophisticated field of vaccine manufacturing.

A vaccine-like opportunity awaits the nation on making itself a global hub for biological manufacturing. India currently accounts for only an insignificant 1.4 percent share of the global annual similar biologics manufacturing market of $138 billion. With right policies, infrastructure and investments in innovation, Indian organizations can garner reasonable share of this segment, dominated by global companies. â€œHow can India become a global manufacturing hub for biopharmaceuticals?â€?, pg. 104, is a special report that highlights the ingredients required to make this happen fast.

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