

BIOLOGICS AND BIOSIMILARS & BIOPHARMA & BIOTHERAPEUTICS

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Similar biologics in India: Navigating through regulations

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India is witnessing significant growth in Biologics as well as biosimilars. Biosimilars in India are referred to as similar biologics. They have become an integral part for the life science industry in India. Similar biologics has gained momentum in India over the past few years and many companies have started developing similar biologics. There is no specific law or regulation that govern similar biologics in India but various related and relevant regulations do play a major role. Many regulatory authorities are involved in overseeing the processes including granting approvals. CDSCO (apex authority in India for Pharma) and Department of Biotechnology have issued guidelines on similar biologics: Regulatory requirements for marketing authorization in India by is one of the most important regulations that provide guidance. Though these guidelines are not binding, companies do follow the same. Apart from guidelines, certain other regulations need to be complied with. India is also witnessing certain litigations in this space which may be avoided if the company navigates well through the regulatory requirements. India comes out as a strong collaborator in this space for other players to create the win-win situation. Many collaborations in this space have shown significant promise. The Indian government too has been providing incentives in this space to augment the growth of this sector.

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