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Similar biologics in India – Legal and regulatory perspective

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Biologics sector in India has seen significant growth in last few years with many players entering this sector aggressively to meet the global demands. The similar biologics are regulated in India through various acts and guidelines. The Department of Biotechnology (DBT) that comes under the Ministry of Science and Technology is the main regulatory body that is responsible for approval of 'similar biologics' in India. DBT operates through its Review Committee on Genetic Manipulation (RCGM) and the Central Drugs Standard Control Organization that comes under the Ministry of Health and Family Welfare. Though there are regulations that govern similar biologics, there is a need to have more robust legislation that is conducive for the industry players. The talk will explain existing legal and regulatory landscape for similar biologics in India and way to navigate through the same.

Biography

Milind Antani is Partner in-charge of Pharma and Life Sciences Practice at the multi-skilled, research-based international law firm, Nishith Desai Associates. He represents clients in corporate, IP and regulatory matters including corporate mergers and acquisitions, investments, regulatory and transactional matters, intellectual property prosecution and litigation, joint ventures and formation of new companies. He practiced as an ENT surgeon for 14 years prior to joining Nishith Desai Associates. He has authored and co-authored many articles, publications including two books. He has been speaking regularly at various national and international forums. He has been a visiting faculty at various institutions. He has been nominated as one of the world's leading practitioners in 'Who's Who Legal' for Life Sciences 2013 and 2014 in the 'Regulatory' section as only lawyer from India. He is also the member of the Committee of Telemedicine Society of India.

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