

The flexibilities for the regulatory guidelines for the bio-similars in emerging markets

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Abstract

The Regulatory guidelines running parallel to the Intellectual Property Rights (IPR) are the keystones in establishing a well-set ruling system to be adhered to when developing bio-similars either during or after the expiry of the patents of the innovator drugs. As the biologic drugs are developed for most of the life saving drugs, it becomes mandatory that the set guidelines are well adhered to by the similar biologics for proper manifestation and to be on par with the biologics which are highly complex drugs. There is an ever growing health concern for some of the highly dreaded diseases, especially the infectious ones, which tend to progress to malignant stage, like in the case of Human Papilloma Virus, if left without proper diagnosis followed by treatment. As drugs, vaccines and antibodies are being developed or are already developed, the need of the hour is affordability, accessibility and awareness in the emerging markets like India. The operational hurdles for the development of the bio-similars in the emerging markets' needs, flexibilities and relaxation in the complexities involved in the manufacturing process. It also seeks the immediate attention for the global harmonization from the various international bodies of the highly regulated markets. The introduction of the bio-therapeutics for the betterment of the mankind through its flexibilities in the regulatory norms with special focus to the developing world would go a long way in combating many diseases.

Biography

Poongothai Ramaswamy is currently working as a Patent Associate with Hasan and Singh, Hyderabad, India. She carries over 14 years of professional experience, which includes both academia and industry. Her academic qualification includes, Master's in Human Genetics from Andhra University, Visakapatnam, India and Doctoral degree in Cancer Genetics, pertaining to hematological malignancies, with special emphasis to chronic myeloid leukemia. She is a recipient of UICC, ICRETT Fellowship to carry out part of her PhD work at Institute of Molecular Medicine, Sir John Radcliff Hospital, IMM, OXFORD, UK, under the mentorship of Dr Lyndal Kearney and also a recipient of CSIR and ICMR Fellowships for Post-doctoral Research at Osmania University and Centre for DNA Finger Printing and Diagnostics (CDFD). She also holds a PG diploma in Patent law from NALSAR, Hyderabad, India.