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Acceptance of biosimilar products in the treatment of rheumatoid arthritis

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A biosimilar is a bio-therapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference bio-therapeutic product. At present, India is one of the leading contributors in the world to the biosimilar market. India has demonstrated the greatest acceptance of biosimilars, which is reflected from over 50 biopharmaceutical brands getting marketing approval. Currently, several products labeled as biosimilars are approved for treatment of rheumatoid arthritis in a number of countries that, at the time of approval, did not have stringent regulatory processes in place to ensure comparability The role of biosimilars in rheumatic diseases will be determined by the confidence placed in them by rheumatologists; stringent regulatory approval processes are designed to provide this. If a biosimilar is deemed to be interchangeable with the reference drug, pharmacists would be able to make substitutions without the authorization of the prescribing physician. Repeated interchanges between biosimilars and reference drugs might bring about an immune response to the biological agent that could compromise the efficacy and safety of both drugs, with the risk that the patient could never again take either the biosimilar or the reference product. Acceptance of biosimilars among rheumatologists requires an understanding of the regulatory processes governing their approval. Biosimilar clinical development program must demonstrate equivalence to a reference product already licensed.

Biography

Narendra Kumar Vemulapalli is a 4th year student of PharmD, JSS College of Pharmacy, India.

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