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From brand vs. generic to biologic vs. biosimilar: The regulatory challenge and the search for a holistic solution

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There is a fundamental difference between Generics and Biosimilars. "A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." About a Biosimilar, small differences in structure or chemistry due to the processes and chemicals used in the culture, purification, storage, etc., may result in differences in efficacy, safety and immunological outcomes as compared to a Biologic. As such, Biosimilars, are in many ways analogous to generics, but are not generic drugs. The question is, "Can the need for preclinical and clinical studies be eliminated in case of Biosimilars before they are put to therapeutic use"? The issue is intricate attracting different viewpoints and it is currently not clear if separate evidence for each indication will be required. The approach so far adopted in the USA and Europe has been heterogeneous and the matter needs to be studied in-depth. In this paper, I examine the issue from multiple perspectives i.e., the academic, industry, regulatory agencies, patients and clinicians in an attempt to search a holistic solution.

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