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Biosimilars: Global Acceptance, Importance of Regulatory Consistency and current trends

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Editorial Note: Biosimilars are authorized via a regulatory pathway separate from that used for generic drugs; they are also regulated separately from novel biologics. Biosimilar approval pathways in many major regulatory regions worldwide are, to a broad degree, scientifically aligned. However, owing to regional differences in health care priorities, policies, and resources, some important regulatory inconsistencies are evident. Acceptance of biosimilars by health care systems, health care professionals, and patients will be a key factor in the uptake of these therapies, and such regulatory variations could contribute to confusion and diminished confidence regarding the quality, efficacy, and reliability of these agents. Furthermore, the need for manufacturers to account for regulatory inconsistencies introduces inefficiencies and delays into biosimilar development programs. These issues should be addressed if biosimilars are to attain their maximal global potential

Keywords: Biosimilar; FDA requires for biosimilar; biosimilar or interchangeable product; Biosimilar approval pathway

Conclusion: FDA requires biosimilar and interchangeable biological