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Brexit and biosimilars

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The UK decided to leave the European Union on 23 June 2016, but will Brexit change biosimilar market? One group believes that Brexit UK will have a significant impact on biosimilar market in UK because UK currently doesn't have a regulatory pathway to approve biosimilars. The approval process for biosimilars is currently carried out through a centralized procedure with the EMA. Additionally, none of the seven biosimilars available in UK are manufactured locally. Brexit could result in disruption of supply chain, additional importation testing, additional recertification requirements after importing, new import/export charges and uncertainty regarding regulatory strategy. Others optimistic group pinpoints that the EMA is currently headquartered in London and relocation of the headquarters to other EU country will not happen soon. Furthermore, UK may not want drug manufacturers to follow two separate regulatory pathways for biosimilars. It is beneficial for both UK and EU to remain part of same regulatory scheme. How Brexit will impact regulatory pathway and approval of biosimilars, is yet to be determined. In this presentation, author will present the impact of Brexit on Biosimilar market.

Biography

Dipti Gulati has completed her PhD from Allahabad University and Post-doctoral studies from Indian Institute of Sciences, India and Albert Einstein College of Medicine on Protein-Carbohydrate Interactions, USA. Currently, she is the President of PJI Biotech, a Consulting Services Organization. Previously, she held various Management Positions at Amgen, BioMerieux, Emergent Bio Solutions, Diosynth and SmithKline Beecham Pharmaceuticals. She has published more than 25 papers in reputed journals and is a member of PDA Regulatory and Quality Advisory Board.

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