The Global Landscape on Interchangeability of Biosimilars

Anurag S. Rathore[1*], James G. Stevenson[2], **Hemlata Chhabra[1]**, Chinmoyee Maharana[1]

[1]Department of Chemical Engineering, Indian Institute of Technology, Delhi, India

[2]Department of Clinical Pharmacy, University of Michigan College of Pharmacy, Ann Arbor, USA

Abstract

Biosimilars hold the potential to be an integral healthcare component that can significantly improve affordability and thereby accessibility of the otherwise expensive biotherapeutic products. With the patents for most of the top selling biotherapeutics either recently expired or expiring in the near term, there is significant interest in development and commercialization of biosimilars. Regulators, payors, and policy makers, each have major roles to play in successful adoption of biosimilars. One of the issues that has been a point of frequent discussion is that of interchangeability of biosimilars. This is a contentious topic with diverse opinions across the various regulatory bodies. It is also expected to have a significant impact on the acceptance of biosimilars by prescribers, pharmacists and patients. This study aims to review the position that the major regulatory bodies have taken on interchangeability of biosimilars. Key issues that remain are also discussed. The need for gaining global harmonization on interchangeability is highlighted.