



ABU DHABI 2019
FIP WORLD CONGRESS
22-26 September



Pharmaceutical sciences:

Regulatory sciences

FIPSUB-1936

BIOSIMILARS: REGULATORY ASPECTS IN THE USA AND THE EU

Garba Mohammed Khalid¹, Paolo Rocco¹, Paola Minghetti¹

¹Department of Pharmaceutical Sciences, Università degli Studi di Milano, Milan, Italy

My preferred method of presentation is: Poster Presentation

Please fill in the presenting author's organization: Department of Pharmaceutical Sciences, Università degli Studi di Milano, Milan, Italy

Background: The high cost of biotechnological medicinal products and the increasing number of patent and data protection expirations is motivating manufacturers to develop biosimilar products and physicians to prescribe them, either spontaneously or due to payers' policies (non-medical switch or constrained prescription). Unlike generics, biosimilars approved by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) are similar, but not equivalent, to the originator in terms of quality, efficacy and safety. Therefore, biosimilarity does not necessarily implicate interchangeability and the possibility of automatic substitution.

Purpose: The purpose of this work is to assess the differences between the concepts of biosimilarity, interchangeability and substitution of biological medicinal products and their implications on the practice of health care professionals.

Methods: US Law and EU Law on biological medicinal products and biosimilars were analyzed, along with guidelines by the FDA and the EMA.

Results: The FDA and the EMA have already successfully addressed the issues related to the data required to obtain the Marketing Authorisation for biosimilar medicinal products. The FDA also explicitly addresses the issue of interchangeability between biological products. However, it considers difficult, from a scientific viewpoint, to establish interchangeability in a Marketing Application. The EMA, instead, leaves the decision about interchangeability to the individual member states.

Conclusion: The similarity of biosimilar medicinal products approved by the FDA or by the EMA is guaranteed. However, the issues of interchangeability and substitution remain open and will require further consideration.