

## Biologics and Biosimilars: Safety and Pharmacovigilance

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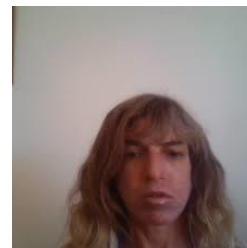
### Abstract

Biosimilars are biologics that are highly similar to approved biologics. According to European Medicines Agency, a biosimilar is a biological medicine that is similar to another biological medicine that has already been authorized for use. Thus, in contrast to generic drugs, biosimilars are similar but not identical to their reference products. Production of an identical copy of a biologic is quite difficult, due to a number of differences that exist between biologics and small molecules. Biologics are protein based drugs that can be thousands of times larger than small molecule drugs, are more complex and have higher immunogenic potential in comparison with small molecule drugs. Immune responses to biologics can lead to acute adverse reactions i.e severe hypotension, brochospasm, laryngospasm, laryngeal or pharyngeal oedema, wheezing, urticaria, anaphylactic shock, death, or can lead to chronic adverse reactions i.e. myalgias, arthralgias, skin manifestations. In addition, the manufacturing process for biologics is more complex and demanding in comparison with the manufacturing process for small molecule drugs. The whole complexity in the manufacturing process of biosimilars renders the evaluation of the safety profile of biosimilars rather difficult. A regulatory pathway has been developed for the approval of biosimilars and this pathway is constantly evolving. However, at the time of approval of a biosimilar agent, the knowledge on the safety profile of the agent is quite limited. Therefore extensive post-marketing surveillance is of paramount importance. Extrapolation of safety data from the reference product to the biosimilar is not straightforward. Pharmacovigilance plays a substantial role in the safety evaluation of biosimilars.



### Biography:

Eugenia Yiannakopoulou: Surgeon; Endocrine Surgeon; Breast Surgeon; Pharmacologist. Current position: Academic Teacher in the Department of Biomedical Sciences, Faculty of Health and Caring Professions, University of West Attica, Athens, Greece; Director of her own private medical practice. Titles: Ptychio of medicine; MSc Minimally Invasive Surgery; MSc Medical Biology; MSc Biostatistics; MSc in Digestive Oncology; PhD Pharmacology; University Diploma in Breast



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### Speaker Publications:

- 1 “Adherence to antihypertensive treatment: a critical factor for blood pressure control”; European Journal of Preventive Cardiology, 0000160601.41762.44
- 2.“ Virtual reality simulators and training in laparoscopic surgery”; International Journal of Surgery Volume 13, January 2015, Pages 60-64
- 3.“ Targeting epigenetic mechanisms and microRNAs by aspirin and other non steroidal anti-inflammatory agents - implications for cancer treatment and chemoprevention”, springer, 37, pages167–178(2014).

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