

3rd International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Biosimilars: Globalization of biosimilars

Ravi R Ghanghas
Govt. Medical College, India

Biologic medicines, though expensive, are in growing demand as they target variety of diseases. With biosimilars hitting the markets in 2005 the sector has grown at a fare rate. Once the 'patent-cliff' is crossed, this sector is expected to be a multi-billion one. The biosimilars are segmented (proteins, peptides, glycoslation) and the sector is globally fragmented. Wide variations in regulations on biosimilars are one likely contributor. US-FDA is likely to finalize its draft on biosimilar policy regulation which may help the United States overtake Asia as leader in sales of biosimilars in future. Biosimiars are expected to reduce cost, improve affordability but complex structure and manufacturing issues are key challenges, as expected. The surprising scenario that has emerged is of sluggishness in acceptance of the biosimilars due to non-availability of manufacturing details which make innovator companies continue to gain success post-patent expiry. The innovator companies are likely to retain stranglehold over biologics and biosimilars alike, on account of the fact this sector requires huge investments in research and development. Joint ventures are likely to perform extensive research and development (R&D) to overcome the problem of adverse risk-reward ratio associated with biosimilars. Government sectors can be effective pace setters -besides bringing clarity in policy regulations-in R&D and Taiwan has already taken bold steps in this matter. Health-care professional form another important stake-holders but lack of awareness as well as interest among them hinder adoption of biosimilars.

Biography

Ravi R Ghanghas has completed his MD in Pharmacology at the age of 28 years from Maharashtra University. He is Assistant Professor in Pharmacology, at Govt. Medical College, Miraj. He has published four scientific papers and contributed to a chapter in book on endocrinology.

ravighanghas@gmail.com