Pre-congress satellite on Biosimilars

The science, regulation, practice and education of follow-on biologic pharmaceuticals

Saturday 1 September 2018, 08:30-17:30
Room A1sh

Chairs

Marianne Ivey (FIP Hospital Pharmacy Section, USA) and Michael Ward (FIP Board of Pharmaceutical Sciences, Australia)

Introduction

Biologic pharmaceuticals are very targeted medications that have made a major contribution to the clinical outcomes of patients with challenging diseases and conditions. These pharmaceuticals are very expensive and competition from products that are biologically similar has the potential of increasing patient access at a lower cost. The complexity of the science and practice of using these medications makes pharmacists' education of these agents critical to their appropriate use. This pre-congress satellite will address these areas with active learning opportunities for the audience.

Active learning components of this pre-congress satellite:

1. A pre-satellite survey of registrants to determine their learning expectations.
2. Within the programme conduct round-table attendee discussions:

a.) What are the structural and bioequivalence issues related to biosimilars?

b.) How does the approval and naming process effect the eventual marketing and use of biosimilars?

c.) What strategies have been used to overcome barriers to adding biosimilars to hospital and clinic medication formularies?

d.) How are colleges and schools of pharmacy educating pharmacists about biosimilars both for students and as continuing professional competence for practitioners?

For a separate certificate of attendance for this pre-congress satellite, please contact us: congress@fip.org with 'biosimilars' in the subject line.

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Programme:

08:30 – 09:00 Introduction by the chairs

The science of biosimilars

1. 09:00 – 09:40 What are biosimilars? How biosimilars differ structurally from generic pharmaceuticals – Drug product considerations for biosimilars
   Hanns-Christian Mahler (Lonza, Switzerland)
2. 09:40 – 10:20 Addressing variability data, dosing between and within an originator product and its biosimilar
   Michael Ward (FIP BPS, Australia)

10:20 – 10:40 Coffee/tea break (Hall 1)

3. 10:40 – 11:20 A manufacturer's responsibility in producing biologics
   Gay Gauvin (Amgen, USA)
4. 11:20 – 12:00 Incorporating biosimilars into practice: What pharmacists need to know
   James Stevenson (FIP HPS, USA)

12:00 – 12:30 Morning panel
12:30 – 13:40 Lunch break

The regulation of biosimilars

5. 13:40 – 14:45 How are biosimilars approved, named, patents protected?
   Philip Schneider (FIP, USA) and Raffaella Giovanna Balocco (World Health Organization)

Education of pharmacy students and practitioners

6. 14:45 – 15:50 Overcoming the gap between clinical use of biosimilars and education of pharmacists and other healthcare providers
   Arnold Vulto (Erasmus University, The Netherlands)

15:50 – 16:10 Coffee/tea break (Hall 1)

7. 16:10 – 16:30 Panel – Addressing addition to regulatory issues/clinical use and education
8. 16:30 – 17:30 Workshop