



Complex Biologics and Generic LMWH Consensus Conference

- February 18, 2010 •
- American College of Chest Physicians Headquarters •
Chicago, IL

Agenda

- 10:00 – 10:15 Welcome, Introductions, and Meeting Objective**
Jawed Fareed, PhD, DSC, FACB - Chairperson
Victor F. Tapson, MD, FCCP - Chairperson
Charles A. Carter, PharmD, MBA – Facilitator
Evi Kalodiki, MD, BA, DIC, PhD, FRCS – Recording Secretary
- 10:15 – 10:20 Update of Complex Biologics and LMWH Genericization**
Charles A. Carter, PharmD, MBA
- 10:20 – 10:30 Summary of Clinical and Safety Issues of Complex Biologics and LMWH Generics**
Victor F. Tapson, MD, FCCP
- 10:30 – 10:40 Potential Differences Between Generic and Innovator LMWH**
Walter P. Jeske, PhD
- 10:40 – 12:00 Organizational Position and Policy Statements**
Moderated by: Debra A. Hoppensteadt, PhD, DIC and Ilene Sussman, PhD
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| North American Thrombosis Forum..... | Ilene Sussman, PhD |
| International Union of Angiology..... | Evi Kalodiki, MD, BA, DIC, PhD, FRCS |
| American College of Chest Physicians..... | Sydney Parker, PhD |
| International Society on Thrombosis and Haemostasis..... | Job Harenberg, MD, PhD |
| South Asian Society on Atherosclerosis and Thrombosis | Jawed Fareed, PhD, DSC, FACB |
| Society of Hospital Medicine..... | David F. Lovinger, MD, FHM |
| American Pharmaceutical Association | L. Douglas Ried, PhD |
| European Perspective | Job Harenberg, MD, PhD
Ajay Kakkar, BSc, MBBS, PhD, FRCS
Evi Kalodiki, MD, BA, DIC, PhD, FRCS |
| Regulatory Perspective..... | Lilia Talarico, MD |
| Professional Practice | Henry I. Bussey, PharmD, FCCP, FAHA
John Fanikos, RPh, MBA
James B. Groce, III PharmD, CACP
Nancy Skinner, RN-BC, CCM |



- 12:00 – 1:00** **Lunch**
- 1:00 – 1:20** **Controversies and Agreement Relevant to Patient Safety Issues and LMWH Generics**
Ajay Kakkar, BSc, MBBS, PhD, FRCS and David Van Thiel, MD, PhD
- 1:20 – 2:30** **Consensus Development on Complex Biologics and Generic LMWH**
Facilitated by: Charles A. Carter, PharmD, MBA
- 1:20 – 1:40** **Presentation of Provisional Recommendation of Call to Action**
Craig M. Jackson, MD, PhD
- 1:40 – 2:10** **Discussion and Ratification of Provisional Call to Action**
Jawed Fareed, PhD, DSC, FACB
Victor F. Tapson, MD, FCCP
- 2:10 – 2:30** **Mobilization and Dissemination of Call to Action**
Moderated by: Debra A. Hoppensteadt, PhD, DIC
- 2:30 – 2:50** **Open Discussion on Future Steps to Assure Drug Safety and Efficacy Issues**
Moderated by: Ajay Kakkar, BSc, MBBS (Hons), PhD, FRCS, Charles Carter, PharmD, MBA
and Lilia Talarico, MD
- 2:50- 3:00** **Consensus Summary**
Jawed Fareed, PhD, DSC, FACB
Victor F. Tapson, MD, FCCP