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
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