European Biosimilars Group
EGA sector group

17 March 2016
15:00-16:30
EAHP CONGRESS
Austria Center Vienna
Hall K

EBG Biosimilars Satellite Symposium

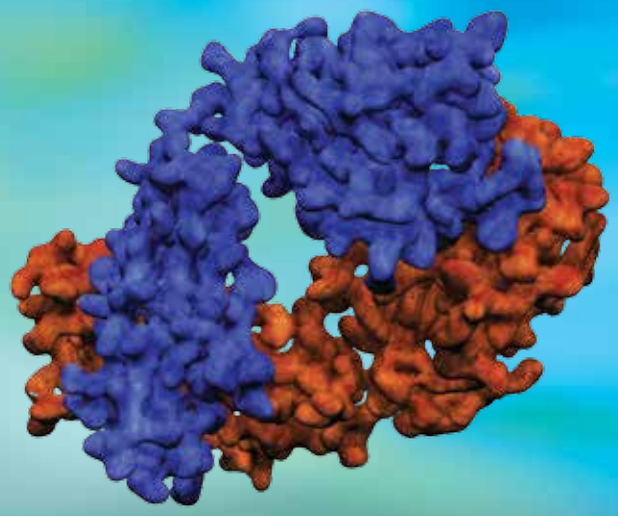
> "The Facts about Biosimilars"

SPEAKERS

Dr. Niklas EKMAN
Quality Assessor; Finnish Medicines Agency (FIMEA), Member of Biosimilar Medicines Working Party (BMWP) at the European Medicines Agency (EMA)

Dr. Paul CORNES
Oncologist, Bristol, UK

Prof. Arnold VULTO
Professor of Hospital Pharmacy & Practical Therapeutics; Erasmus University Medical Center Rotterdam



The European Biosimilars Group (EBG), a sector group of the EGA, represents the leading companies in the biosimilar medicines space. The EBG members bring competition to the biologicals market, thereby increasing access to highly innovative medical treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.

The EGA represents the European generic, biosimilar and value-added medicines industries, which provide high-quality cost-competitive medicines to millions of European patients. The European generic, biosimilar and value-added medicines industries' vision is to provide sustainable access to high quality medicines for all European patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

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EBG[1] Biosimilars satellite symposium: "The Facts about Biosimilars"

Chair: EBG Chairperson

Presentations:

- "What is a biosimilar? – explained by a regulator" – Dr Niklas Ekman
- "Biosimilars, the Physician's Learning Curve" – Dr. Paul Cornes
- "How to address the misconceptions regarding biosimilars: the role of the hospital pharmacist" – Professor Arnold Vulto

Abstract:

A clear understanding of the scientific principles of the biosimilar medicines concept and access to unbiased information on licensed biosimilar medicines are important for healthcare professionals to make informed and appropriate treatment choices for their patients. This is especially key for pharmacists as they are the experts on medicines and are the first port of call for medicine-related queries. They play a pivotal role in providing physicians and patients with reliable information on medicines, and in the creation and implementation of cost-effective formularies.

The role of pharmacists will become increasingly important as more biological medicines lose their market exclusivity and biosimilar medicines enter markets. The high cost of biological medicines, coupled with reduced pharmaceutical budgets due to austerity measures, means that they are not accessible by all patients and create financial challenges for healthcare systems. Biosimilar medicines can ease this situation as they increase access to patients through competition - biosimilar filgrastim ensured 44% more patients gaining access to gold standard medicines earlier in Europe.

Biosimilar medicines have the same quality, safety and efficacy as the comparator biological product. This is ensured through an established European legal pathway in existence since 2005, and detailed regulatory guidance on data requirements for their development and licensing. Concerns however remain regarding interchangeability under the supervision of a physician and around traceability. Pharmacists must therefore be highly knowledgeable in biosimilar medicines.

By providing physicians and other stakeholders with unbiased information on biosimilar medicines, pharmacists will ensure that patients receive the high quality, safe and effective biological treatments they need, while guaranteeing the efficient allocation of already constrained resources.

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The EGA represents the European generic, biosimilar and value-added medicines industries, which provide high-quality cost-competitive medicines to millions of European patients. Companies represented within the EGA provide over 160,000 skilled, high value direct jobs in Europe. Without generic medicines, payers in Europe would have had to pay €100 BN more in 2014. Generic medicines account for 56% of all dispensed medicines but for only 22% of the pharmaceutical expenditure in Europe. The European generic, biosimilar and value-added medicines industries' vision is to provide sustainable access to high quality medicines for all European patients, based on 5 important pillars: patients, quality, value, sustainability and partnership. For more information please visit: www.egagenerics.com and follow EGA and EBG on Twitter at: @egagenerics and @ebgbiosimilars.

In this session, hospital pharmacists will learn:

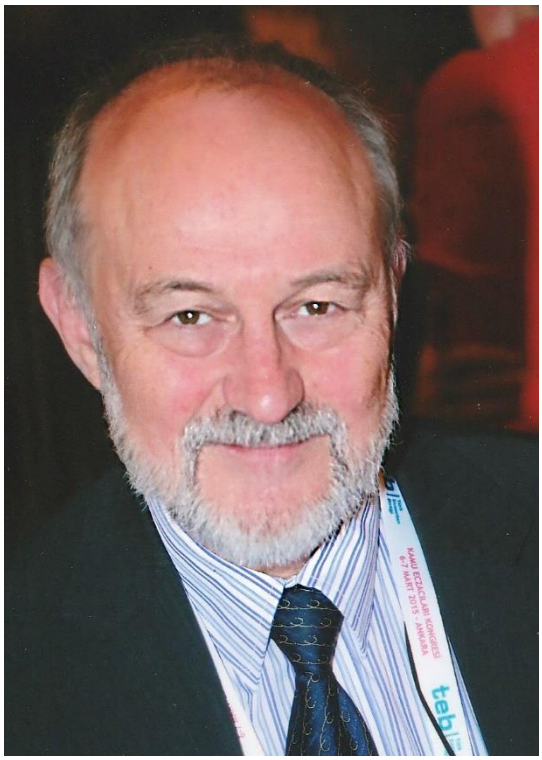
- The scientific concept of biosimilar medicines, the development process and how therapeutic equivalence to the originator biological product is achieved
- How to address the topics of interchangeability under the supervision of a physician and traceability in daily practice
- How biosimilar medicines improve patient access and increase cost-effectiveness in treatments.

Speakers Bio:

Dr Niklas Ekman

Dr Niklas Ekman has a background in molecular cell and cancer biology. Before joining the Finnish Medicines Agency in late 2006, he worked as a post-doc researcher in the Cell Cycle and Cancer Cell Circuitry Laboratory at the University of Helsinki, Finland. Currently, Dr Ekman holds a position as a Senior Researcher and quality assessor for biological medicinal products at the Finnish Medicines Agency. His main activities and responsibilities include assessment of European Medicines Agency (EMA) centralised marketing authorisation applications, scientific advices, as well as national clinical trial applications. At EMA, Dr Ekman is a nominated member of the Biosimilar Medicinal Products Working Party (BMWP) and the Finnish alternate member of the Biologics Working Party (BWP).

Professor Arnold G. Vulto



Arnold G. Vulto (1952) obtained his pharmacy-degree from Groningen University (The Netherlands) in 1981, with undergraduate studies in Cambridge (UK). He was trained as a pharmacologist at the Rudolf Magnus Institute at the University of Utrecht and at the Karolinska Institute (Stockholm, Sweden). He specialised in hospital pharmacy at the University Hospital Maastricht and obtained his PhD from Utrecht University.

In 1988 he was appointed Head of the Hospital Pharmacy of the Veterinary Faculty, University of Utrecht and in 1995 as Deputy Head / Research director of the Hospital Pharmacy of the ErasmusMC in Rotterdam, where he became in 2004 professor of Hospital Pharmacy & Practical Therapeutics.

Professor Vulto is the (co)author of more than 120 international peer reviewed papers and has been supervising 15 PhD-projects. He was member of the Board of Directors of the EAHP and was Chairman of its Scientific Committee. He was a member of the Steering Committee and chair of the Program Committee of the First Global Conference on the Future of Hospital Pharmacy (Basel). He received different awards: “Visionary guidance and leadership” in hospital pharmacy (EAHP) and the Jan Glerum Lifetime Achievement Award for his contribution to the training of hospital pharmacists. Professor Vulto was almost 10 years Editor in Chief of the European Journal of Hospital Pharmacy Practice.

Dr Paul Cornes

Paul Cornes is an Oncologist from the Bristol, UK. Oncologists have had access to biosimilar drugs in Europe since 2008. Oncologists have therefore already addressed the same issues of biosimilar safety; immunogenicity; extrapolation and switching that may concern gastroenterologists, dermatologists and rheumatologists in 2016.

Biologic disease modifying drugs are transforming Gastroenterology, Dermatology and Rheumatology much as they have done in oncology. However the costly technology and development of these agents have limited access to treatment in even Europe's richest countries. The NHS, as with many EU health systems, faces funding cuts over the next five years that threaten our opportunities to bring innovation to patients. Paul has looked at this dilemma as part of the steering group for the recent European School of Oncology Working Party on the Access to Innovation in Cancer Treatment.

Paul has been a NHS cancer clinical trial lead, and for more than a decade has lectured on the biennial London TPI course on clinical trial designs and on improving the effectiveness of clinical trials. He is part of the Wolfson Institute Cochrane Group at Bath and the Clinical Outcomes Group. He helped to organise the Cambridge Blue-Sky Future Cancer meeting with the Centre for the Study of Financial Innovation; this looked at the institutions and culture that would be required to deliver cancer care 100 years ahead. He was fortunate to be invited as part of the team presenting to the FDA ODAC meeting for the successful first approval hearings of a biosimilar in the USA in January 2015.

Paul has taught cost-effectiveness in countries as different as the USA, Russia, China and Japan. He reminds us the "*The only effective treatment is one that a patient can afford!*"