EMEA/DIA Joint Workshop on: EMEA New Guidelines For Development and Approval of Biosimilars

DIA Drug Information Association

December 8-9, 2005, Hotel Le Meridien Paris Etoile, Paris, France

Programme Co-Chairpersons

Pekka Kurki, Chairman of the CHMP Similar Biological Medicinal Products Working Party, National Agency for Medicines, Finland

Marisa Papaluca-Amati, EMEA, EU

Nicolas Rossignol, EU Commission, Belgium

Jean-Hugues Trouvin, Chairman of the CHMP Biologics Working Party, Afssaps, France

Programme Committee

Eric Abadie, CHMP Vice-Chair, Afssaps, France

Iman Barilero, Co-Chairperson of the DIA Biotechnology SIAC, Johnson & Johnson PRD, UK

Daan J.A. Crommelin, Dean of the Faculty of Pharmaceutical Sciences, Utrecht University, The Netherlands

Sandy Eisen, EGA, Teva, UK

Christine-Lise Julou, EFPIA, Belgium

Suzette Kox, EGA, Belgium

Jacques Mascaro, Chair, DIA Advisory Committee for Europe, F. Hoffmann-La Roche, Switzerland

Michel Mikhail, EGA, Ranbaxy, UK

Anders Olauson, European Patient Forum, The Agrenska Foundation, Sweden

Tim Oldham, EGA, Mayne Pharma plc, UK

John Purves, EMEA, EU

Andrea Rappagliosi, EuropaBio, Serono International SA, Switzerland

Caroline Ruggieri, EBE, Belgium

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DIA Industry Non-Members EUR 1'280.00 + VAT

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Programme Overview

Patent and data protection for bio-pharmaceuticals have just expired or are about to expire in Europe, opening the way to new versions of these products, known as similar biological medicinal products ('biosimilars'). The Regulatory authorities have recognized that biosimilars differ from generic low molecular weight drugs in many important ways. These include the size and complexity of the active substance, which will affect the scientific requirement for testing; the nature of the starting materials (cell banks, tissues, and other biological products); the complexity of the manufacturing processes; and the limitations of state-of-the-art methods to characterize proteins and to detect all product variations that can affect side effects, clinical efficacy, or immunogenicity. Therefore, the established legal and regulatory principles of 'essential similarity' or 'bioequivalence' that are applied to standard generics cannot be readily applied to biosimilars.

A new legal basis for evaluating and approving similar biological medicinal products in Europe was established with Directive 2001/83/EC of 6 November 2001, as amended by Directive 2003/63/EC of 25 June, 2003, which entered into force on 1 July, 2003. Further developments were brought with the "Pharma Review" in particular Directive 2004/27/EC of 31 March, 2004, amending Directive 2001/83/EC, which is to be transposed by member states before 30 October, 2005.

The EMEA/CHMP issued further guidance documents in November 2004 as drafts for consultation: a guideline on similar biological medicinal products (CHMP/437/2004) and four concept papers on the development of similar biological medicinal products containing r-DNA granulocyte colony stimulating factors, insulin, growth hormones and erythropoietin. In March 2005, the CHMP released for consultation the guideline on the quality issues to be considered for the development of similar biological medicinal products (EMEA/CHMP/BWP/49348/2005) and in May 2005, the guideline on the non-clinical and clinical issues to be considered for the development of similar biological medicinal products (EMEA/CHMP/42832/2005) as well as guidelines for the development of similar biological medicinal products containing recombinant human insulin (EMEA/CHMP/32775/2005) and Somatropin (EMEA/CHMP/94528/2005). Further EMEA/CHMP guidelines for the development of similar biological medicinal products containing recombinant human granulocyte colony stimulating factor (EMEA/CHMP/31329/05) and recombinant human erythropoietin (EMEA/CHMP/94526/05), were released for consultation in June 2005.

Workshop Objectives

The contributions from the multidisciplinary faculty consisting of experts from regulatory agencies, industry (innovators and generics), academia, hospital pharmacists, hospital physicians and patient groups will offer the platform to:

- Provide an update on the EU regulatory framework and the recently released EMEA/CHMP guidelines on similar biological medicinal products: overarching guideline, quality and (non) clinical guidelines, guidelines for the development of similar biological medicinal products containing r-DNA granulocyte colony stimulating factors, insulin, erythropoietin and growth hormones
- Share the regulatory experience of the EMEA/CHMP Scientific Advice for review of Marketing Authorization Application for similar biological medicinal products
- Present the industry comments (innovators and generics) on the above mentioned guidelines
- Share the point of view of other stakeholders (academia, hospital pharmacists, hospital physicians and patient groups) on the challenges of the implementation of those guidelines
- Highlight prospective conclusions - how the future will look following the finalisation of the guidelines? Which tools do we have to ensure safe and effective use of similar biological medicinal products?
- Highlight the evolving scientific factors influencing the review, risk management and post-marketing surveillance of similar biological medicinal products

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Who should attend this conference?

Biotechnology Sector • Pharmaceutical R&D
Generic Industry • Regulatory Affairs • Pharmacovigilance • Health Care Professionals
Hospital Pharmacists • Patient Groups • Regulatory Authorities

Thursday, December 8, 2005

08:00 Registration & Welcome Coffee

09:00 PLENARY SESSION

Session Co-Chairpersons:
Nicolas Rossignol, EU Commission, Belgium
Eric Abadie, CHMP Vice-Chair, Afssaps, France

Welcome Notes
Marisa Papaluca Amati, EMEA, EU

EU Commission - The Legislation
Nicolas Rossignol, European Commission, Belgium

EMEA - Current and Future Direction (Rationale for Introducing the New EMEA Guidelines on Similar Biological Medicinal Products, Vision and Goals)
John Purves, EMEA, EU

Innovator Point of View
Aliza Eshkol, EBE/EuropaBio, Serono Intl. SA, Switzerland

Generic Point of View
Joerg Windisch, EGA, Sandoz Biopharmaceuticals, Austria

11:00 Coffee Break

11:30 Session 1
EMEA GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS - QUALITY ISSUES

Session Chairperson:
Jean-Hugues Trouvin, Chairman of the CHMP Biologics Working Party, Afssaps, France

Innovator Point of View
Stephan Fischer, EBE/EuropaBio, Roche Diagnostic GmbH, Germany

Generic Point of View
Cecil Nick, EGA, Parexel Consulting, UK

Round Table Questions and Answers
Pierrette Zorzi, Afssaps, France

Daan J. A. Crommelin, Dean of the Faculty of Pharmaceutical Sciences, Utrecht University, The Netherlands

and session speakers

Summary and Conclusions

13:00 Lunch Break

14:00 Session 2
EMEA GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS - (NON) CLINICAL ISSUES

Session Chairperson:
Frits Lekkerkerker, Medicines Evaluation Board, The Netherlands

Innovator Point of View
James Green, EBE/EuropaBio, Biogen Idec, USA

Generic Point of View - Non-clinical & Clinical
Non-clinical: Mike Parnham, EGA, Pliva Research Inst. Ltd., Croatia

Clinical: Yafit Stark, EGA, Teva Pharmaceuticals Ltd., Israel

Round Table Questions and Answers
Mette Due Theilade, Danish Medicines Agency, Denmark

Fritz Sörgel, Institute for Biomedical & Pharmaceutical Research (IBMP), Germany

and session speakers

Summary and Conclusions

15:30 Coffee Break

16:00 Session 3
IMMUNOGENICITY

Session Chairperson:
Pekka Kurki, Chairman of the CHMP Similar Biological Medicinal Products Working Party, National Agency for Medicines, Finland

Academia Point of View

- Clinical Aspects
Nicole Casadevall, Service d'Hérmatologie Biologique, HOTEL DIEU, France

- Analytical Methods Available: State of the Art
Robin Thorpe, National Institute for Biological Standards and Control (NIBSC), UK

Innovator Point of View
Adrian Thomas, EBE/EuropaBio, Johnson & Johnson PRD, USA

Generic Point of View
Sandy Eisen, EGA, Teva, UK

Summary and Conclusions

17:30 - 18:30 Reception

18:30 End of Day 1

Friday, December 9, 2005

08:30 **Session 4**
GUIDELINE FOR THE DEVELOPMENT OF SIMILAR BIOLOGICAL MEDICINAL PRODUCTS CONTAINING DNA-RECOMBINANT INSULIN

Session Chairperson:
Eric Abadie, CHMP Vice-Chair, Afssaps, France

Innovator Point of View
Inger Mollerup, EBE/EuropaBio, Novo Nordisk A/S, Denmark

Generic Point of View
Józef Drzewoski, EGA, University of Lodz, Poland

Round Table Questions and Answers
Gopalan Narayanan, MHRA, UK and session speakers

Summary and Conclusions

10:00 **Coffee Break**

10:30 **Session 5**
GUIDELINE FOR THE DEVELOPMENT OF SIMILAR BIOLOGICAL MEDICINAL PRODUCTS CONTAINING DNA-RECOMBINANT GRANULOCYTE COLONY STIMULATING FACTORS

Session Chairperson:
Christian Schneider, Paul-Ehrlich-Institut, Germany

Innovator Point of View
William Sheridan, EBE/EuropaBio, Amgen Inc., USA

Generic Point of View
Carey Bowker, EGA, C H Bowker Associates, UK

Round Table Questions and Answers
Barry Cookson, Health Protection Agency, UK
and session speakers

Summary and Conclusions

12:00 **Lunch Break**

13:00 **Session 6**
GUIDELINE FOR THE DEVELOPMENT OF SIMILAR BIOLOGICAL MEDICINAL PRODUCTS CONTAINING DNA-RECOMBINANT ERYTHROPOIETIN

Session Chairperson:
Mira Pavlovic, Afssaps, France

Innovator Point of View
Adrian Thomas, EBE/EuropaBio, Johnson & Johnson PRD, USA

Generic Point of View
Paul Chamberlain, EGA, MDS Pharma Services, UK

Round Table Questions and Answers
Gerald Haase, Parexel, UK and session speakers

Summary and Conclusions

14:30 **Coffee Break**

15:00 **Session 7**
GUIDELINE FOR THE DEVELOPMENT OF SIMILAR BIOLOGICAL MEDICINAL PRODUCTS CONTAINING DNA-RECOMBINANT GROWTH HORMONES

Session Chairperson:
Martina Weise, BfArM, Germany

Innovator Point of View
Raf Crabbe, EBE/EuropaBio, Serono Intl. SA, Switzerland

Generic Point of View
Robert Zeid, EGA, TLI Development, USA

Round Table Questions and Answers
Frits Lekkerkerker, Medicines Evaluation Board,
The Netherlands and session speakers

Summary and Conclusions

16:30 **Session 8**
THE WAY FORWARD

Session Chairperson:
Pekka Kurki, Chairman of the CHMP Similar Biological Medicinal Products Working Party, National Agency for Medicines, Finland

Panel Discussion with all Stakeholders
- How to build a collaborative approach with stakeholders to support effective and safe entry of biosimilars into the market in Europe
- Any further guidance is warranted?

Discussants:

Nicolas Rossignol, EU Commission, Belgium

Eric Abadie, CHMP Vice-Chair, Afssaps, France

Jean-Hugues Trouvin, Chairman of the CHMP Biologics Working Party, Afssaps, France

Pekka Kurki, Chairman of the CHMP Similar Biological Medicinal Products Working Party, National Agency for Medicines, Finland

Daan J. A. Crommelin, Dean of the Faculty of Pharmaceutical Sciences, Utrecht University, The Netherlands

Colin Brown, The Sheffield Kidney Institute, UK

Roger Tredree, Hospital Pharmacists section of International Pharmaceutical Federation, St. George's Hospital London, UK

Anders Olauson, European Patient Forum, The Agrenska Foundation, Sweden

Tim Oldham, EGA, Mayne Pharma plc, UK

Kenneth B. Seamon, EBE/EuropaBio, Amgen Inc., UK

18:00 **End of the Conference**

Hotel and Travel Information

The DIA has blocked a limited number of rooms at the:

Hotel Le Meridien Etoile
Reservation Department, 81 Boulevard Gouvion Saint-Cyr,
75848 Cedex 17, 75017 Paris, France
Tel: +33 1 40 55 67 89 Fax: +33 1 40 55 67 88
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Concorde, the Champs-Élysées and La Défense business district surround Le Meridien Etoile. The hotel is also located next to the Ring Road, providing easy access by car to numerous places around Paris. Roissy Charles de Gaulle Airport and Orly Airport are about 30 to 45 minutes away. The Air France shuttle bus stops across from the hotel and departs every 12 minutes to Charles de Gaulle Airport. The Gare du Nord, with the Eurostar terminal, is about 20 minutes from Le Meridien Etoile.

Attendees must make their own hotel reservation by telephone: +33 1 40 55 67 89, or by telefax: +33 1 40 55 67 88 referring to the EMEA/DIA Joint Workshop on: EMEA New Guidelines for Development and Approval of Biosimilars.

A deposit payment for one night must be made to secure the reservation by providing your name, number, expiry date of your credit card, and signature.

IMPORTANT: To be assured of accommodation in the Hotel Le Meridien Etoile, the registrants are recommended to complete their reservation, if possible, by November 15, 2005.

Workshop Cancellation Policy

On or before December 1, 2005
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Member/Nonmember = EUR 200.00
Government/Academia/Nonprofit (Member/Nonmember) = EUR 100.00
Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellations must be in writing. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants. Speakers and programme agenda are subject to change.

ACCOMMODATION BOOKING FORM

1 FORM PER RESERVATION

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EMEA/DIA Joint Workshop on:
EMEA New Guidelines for Development and Approval of Biosimilars
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by November 15, 2005
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Guest

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First Name & Middle Initial

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Job Title

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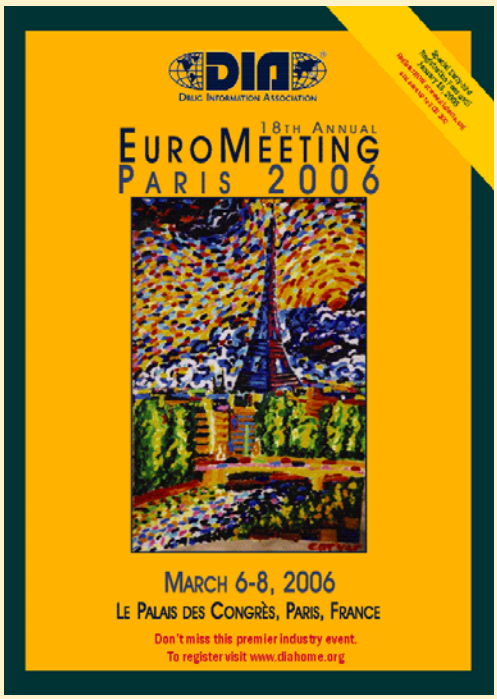

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Drug Information Association

EMEA New Guidelines for Development and Approval of Biosimilars
December 8-9, 2005, Hotel Le Meridien Paris Etoile, Paris, France

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Last Name: _____

First Name: _____

Company: _____

Job Title _____

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Postal Code: _____

City: _____

Country: _____

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Your name and company must be included on the transfer document to ensure payment to your account.

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Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation letter within five working days, please contact the DIA Basel Office.

Workshop Cancellation Policy: On or before December 1, 2005 an administrative fee will be deducted from the registration fee:
Member and Nonmember = EUR 200.00 / Government and Academia (Member/Nonmember) = EUR 100.00. Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellation must be in writing.

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