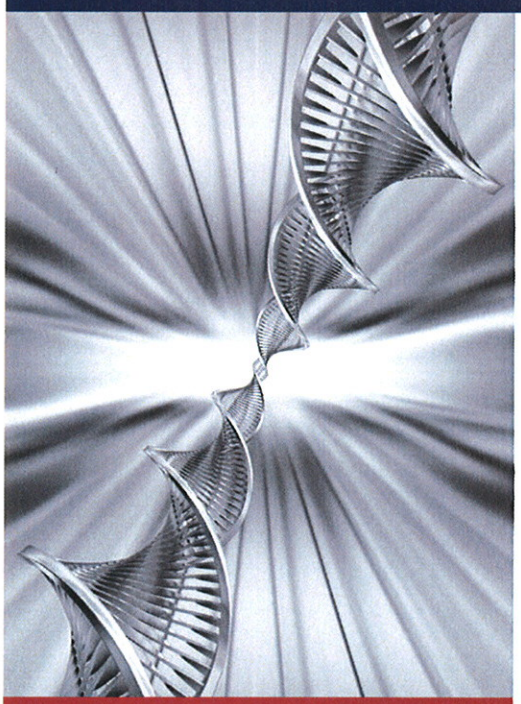
DRUG INFORMATION ASSOCIATION

INNOVATION FORUM

September, 29-30, 2008 – London Marriott Regents Park, UK



Objectives

- Provide an update on the initiatives in Europe to support innovation in research and development
- Share the FDA experience with the implementation of the Critical Path Initiative and coordination with the EU initiatives
- Provide a platform to discuss the implementation of the European Parliament and Council Regulation on Advanced Therapy and the EMEA draft technical guidelines.

The conference will involve all stakeholders including regulators, industry, academia and patient groups.

The conference is organised over two days. The first day will address the progress with the implementation of the Innovative Medicines Initiative and the EMEA initiatives in relation to innovation including the qualification of biomarkers and new methodologies. The second day will focus on the practical aspects to implement the Regulation on Advanced Therapy.

Conference Co-Chairs

Georgette Lalis
Director of the Directorate for Consumer Goods, European Commission, DG Enterprise and Industry, EU
Thomas Lönngren
Executive Director, EMEA, EU

Programme Co-Chairs

Iman Barilero
Divisional Director Regulatory Development Strategy, H. Lundbeck A/S, Denmark
Patrick Le Courtois
Head of Unit Pre-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Programme Committee

Day 1:
Eric Abadie, Chairman, CHMP, EMEA, EU, General Directorate, AFSSAPS, France
Hans-Georg Eichler, Senior Medical Officer, EMEA, EU
Bruno Flamion, Chair, Scientific Advice Working Party, EMEA, University of Namur, Belgium
Kerstin Franzen, Senior Director Worldwide Regulatory Policy & Intelligence, Pfizer AB, Sweden
Hilary Malone, Senior Vice President and Head of Global Regulatory Affairs, Wyeth, USA, EFPIA RDG
Marisa Papaluca-Amati, Deputy Head of Sector, Safety & Efficacy of Medicines, EMEA, EU
Spiros Vamvakas, Acting Deputy Head of Sector, Scientific Advice & Orphan Drugs, EMEA, EU

Day 2:
Eric Abadie, Chairman, CHMP, EMEA, EU, General Directorate, AFSSAPS, France
Arnd Hoeveler, Head of Unit Biotechnology for Health, European Commission - Research Directorate General, EU
Wills Hughes-Wilson, Director, Health Policy Europe, Genzyme, Belgium, EuropaBio, EBE and Eucomed
Detlef Niese, Head, External Affairs, Clinical Development & Medical Affairs, Novartis Pharma AG, Switzerland, EuropaBio, EBE and Eucomed
Dario Pirovano, Consultant, Regulatory & Technical Affairs, Belgium, EuropaBio, EBE and Eucomed
John Purves, Head of Sector, Quality of Medicines, EMEA EU
Irene Sacristán Sánchez, Deputy Head of Unit - Pharmaceuticals DG Enterprise and Industry, European Commission, EU
Martin Terberger, Head of Pharmaceuticals Unit, DG Enterprise & Industry, European Commission, EU

Who Should Attend?

- Regulatory Representatives
- Industry Representatives
- Academia Representatives
- Patient Groups

REGISTER ONLINE! VISIT OUR WEBSITE WWW.DIAHOME.ORG

MONDAY, SEPTEMBER 29, 2008

Day 1
Update on Initiatives to Support Innovation in Europe

08:00 - 09:00 **Registration and Welcome Coffee**

09:00 **Session 1**

Innovation in Europe – What are the Challenges of the Future?

Session Co-Chairpersons:
Thomas Lönngren, Executive Director, EMEA, EU
Martin Terberger, Head of Pharmaceuticals Unit, DG Enterprise & Industry, European Commission, EU

Update from EU Commission DG Enterprise
Martin Terberger, Head of Pharmaceuticals Unit, DG Enterprise & Industry, European Commission, EU

Update from EMEA
Thomas Lönngren, Executive Director, EMEA, EU

Update from EFPIA
Brian Ager, General Director, EFPIA, Belgium

Patient Point of View
Nikos Dedes, Chairman of the Board of Directors European AIDS Treatment Group, Belgium

10:30 **Coffee Break**

11:00 **Session 2**

Innovative Medicines - Implementation

Session Co-Chairpersons:
Jackie Hunter, Senior Vice President and Head of Neurology and GastroIntestinal Centre of Excellence in Drug Discovery (N&GI CEDD), GlaxoSmithKline, UK, EFPIA RDG, member of IMI Board
Alain Vanvossel, Interim Executive Director, IMI JU, European Commission, EU

The Development of the Innovative Medicines Initiative
David Roblin, Vice President, Pfizer Global R&D, UK and member of the EFPIA Research Directors Group

Experience from Academia in PPP: InnoMed
Wolfgang Dekant, Professor, University of Würzburg, Germany

IMI Governance and Interaction with Stakeholders
Alain Vanvossel, Interim Executive Director IMI JU, European Commission, EU

FDA Critical Path and Potential for Synergies with IMI
Federico Goodsaid, Associate Director for Operations in Genomics Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, FDA, USA

13:00 **Lunch**

14:15 **Session 3**

Qualification of Biomarkers and Novel Methodologies

Session Co-Chairpersons:
Hans-Georg Eichler, Senior Medical Officer, EMEA, EU
Federico Goodsaid, Associate Director for Operations in Genomics, Office of Clinical Pharmacology, Office of Translational Science,Center for Drug Evaluation and Research, FDA, USA

EU Consortium – Predictive Toxicology
David Laurie, Regulatory Policy Expert, DRA Management, Novartis Pharma AG, Switzerland, EFPIA RDG

AddNeuroMed - Alzheimer's Disease Biomarker Discovery
Simon Lovestone, Director NIHR Biomedical Research Centre for Mental Health, South London and Maudsley NHS Foundation Trust and King's College London, UK

Identify Potential Biomarker – PSTC Experience
Federico Goodsaid, Associate Director for Operations in Genomics Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, FDA, USA

EMEA Qualification Process and Global Perspective
Bruno Flamion, Chair, Scientific Advice Working Party, EMEA, University of Namur, Belgium

15:45 **Coffee Break**

16:15 **Session 4**

Role of EMEA in Relation to Innovation – Think Tank Report Implementation

Session Co-Chairpersons:
Eric Abadie, Chairman, CHMP, EMEA, General Directorate, AFSSAPS, France
Iman Barilero, Divisional Director Regulatory Development Strategy, H. Lundbeck A/S, Denmark

Introduction: Think Tank Report Recommendations and CHMP Programme
Eric Abadie, Chairman, CHMP, EMEA, EU, General Directorate, AFSSAPS, France

Plan for Think Tank Report Implementation and other various Initiatives
Marisa Papaluca-Amati, Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU

Update on new EMEA Scientific Advice
Spiros Vamvakas, Acting Deputy Head of Sector, Scientific Advice and Orphan Drugs, EMEA, EU

Panel Discussion and Q&A with session speakers

17:45 **Reception**

18:30 **End of Day 1**

TUESDAY, SEPTEMBER 30, 2008

Day 2
Advanced Therapy
Implementation of the New Regulation

08:30 **Session 1**

EU Commission and EMEA Implementation

Session Co-Chairpersons:
Patrick Le Courtois, Head of Unit Pre-Authorisation Evaluation of Medicines for Human Use, EMEA, EU
Irene Sacristán Sánchez, Deputy Head of Unit - Pharmaceuticals DG Enterprise and Industry, European Commission, EU

Update from EU DG Enterprise – Vision and Implementation Plan
Irene Sacristán Sánchez, Deputy Head of Unit - Pharmaceuticals DG Enterprise and Industry, European Commission, EU

Update from EU DG Research – Vision and Implementation Plan
Arnd Hoeveler, Head of Unit Biotechnology for Health European Commission - Research Directorate General, EU

Update from EMEA – Overview of Procedures and Guidelines and Establishment of the Committee for Advanced Therapies
John Purves, Head of Sector, Quality of Medicines, EMEA, EU

Industry Point of View
Wills Hughes-Wilson, Director, Health Policy Europe, Genzyme, Belgium, EuropaBio, EBE and Eucomed

Patient Point of View
Fabrizia Bignami, Director of Therapeutic Development, EURORDIS, France

TUESDAY, SEPTEMBER 30, 2008

10:30 **Coffee Break**

11:00 **Session 2**

EU Commission and EMEA Implementing Technical Requirements
Session Co-Chairpersons:
Detlef Niese, Head, External Affairs, Clinical Development & Medical Affairs, Novartis Pharma AG, Switzerland, EuropaBio, EBE and Eucomed
Irene Sacristán Sánchez, Deputy Head of Unit - Pharmaceuticals DG Enterprise and Industry, European Commission, EU

Update on Annex I and Certification
Irene Sacristán Sánchez, Deputy Head of Unit - Pharmaceuticals DG Enterprise and Industry, European Commission, EU

Specific EMEA Guidelines
Patrick Celis, Scientific Administrator, EMEA, EU

Point of View from Industry
Winfried Dalemans, Vice President Regulatory Affairs and Corporate Quality, TiGenix, Belgium, EuropaBio, EBE and Eucomed

Point of View from Academia
Philippe Menasché, Department of Cardiovascular Surgery, Hôpital Européen Georges Pompidou, France

13:00 **Lunch**

14:15 **Session 3**

Risk Management, Pharmacovigilance and Traceability
Session Co-Chairpersons:
Dario Pirovano, Consultant, Regulatory & Technical Affairs, Belgium, EuropaBio, EBE and Eucomed
Jan Petracek, Risk Management Team, Sector Pharmacovigilance and Post Authorisation, Safety and Efficacy of Human Medicines, EMEA, EU

Risk Assessment and Pharmacovigilance
Jan Petracek, Risk Management Team, Sector Pharmacovigilance and Post Authorisation, Safety and Efficacy of Human Medicines, EMEA, EU

Traceability: EU Commission DG Enterprise
European Commission Representative invited

Industry Point of View
Eric Klasen, Vice President, Regulatory Affairs & Quality, Medtronic International Trading Sàrl, Switzerland, EuropaBio, EBE and Eucomed

15:45 **Coffee Break**

16:15 **Session 4**

GMP and GCP Issues
Session Co-Chairpersons:
Christine Abouzeid, Regulatory Affairs Manager, BioIndustry Association, UK, EuropaBio, EBE and Eucomed
European Commission Representative invited

GMP Guidelines
Ian Rees, Expert Inspector, GMP/GDP, MHRA, UK

Industry Point of View – The Way Forward
Ian Harris, Director, Cell Therapy Company, a division of Centocor R&D inc., USA, EuropaBio, EBE and Eucomed

Academic Point of View – The Way Forward
Michael Whitaker, Dean of Development, Institute for Cell and Molecular Biosciences Medical School University of Newcastle upon Tyne, UK

17:45 **End of Conference**

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

London Marriott Regents Park
128 King Henrys Road
Swiss Cottage
London NW3 3ST
United Kingdom

Tel: +44 207 722 7711
Fax: +44 207 586 5822
www.londonmarriottregentspark.co.uk

at a special rate of:
£ 129.14 + 17.5 % VAT (including Breakfast)

To make a booking please contact Marriott reservations on +44 800 221 222 and mention the special rate code: diadiaa
or book online at:
http://www.marriott.com/hotels/travel/lonrp-london-marriott-hotel-regents-park/?groupCode=diadiaa&app=resvlink

Important: To be assured of accommodation at the London Marriott Regents Park, registrants are recommended to complete their reservation by **August 15, 2008.**

In case of cancellation:
Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

WORKSHOP CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 17:00 CET on September 22, 2008.

Cancellations received in writing by the date above are subject to an administrative fee:

Member/Non-member = EUR 200.00
Government/Academia/Non-profit (Member/Non-member) = 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. DIA Europe reserves the right to alter the venue if necessary.

Transfer Policy
You may transfer your registration to a colleague prior to the meeting start but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify DIA Europe office of any such substitutions as soon as possible.

If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.
Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe.
If you have not received your confirmation letter via fax within five working days, please contact DIA Europe.

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Disclosure Policy It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the programme audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

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The DIA Europe Customer Services Team will be pleased to assist you with your registration.
Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET, or email diaeurope@diaeurope.org

REGISTRATION FORM - I.D. CODE # 08108

INNOVATION FORUM

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If DIA Europe cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration includes conference material and refreshment breaks for the value of € 250.00.

DRUG INFORMATION ASSOCIATION

Registration will be accepted by mail, fax, email or online at www.diahome.org

Join DIA now to qualify for the early-bird member rate!
Please mark the box indicated below if you wish to take this option.
To qualify for the early-bird discount, registration form and accompanying payment must be received by the date below.
The early-bird rate does not apply to government or academia/nonprofit attendees.

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❑ **€ 130.00**

EARLY-BIRD DEADLINE On or before AUGUST 18, 2008	MEMBER Fee	MEMBER TOTAL	NON-MEMBER (with optional membership) Fee	NON-MEMBER (with optional membership) Membership	NON-MEMBER (with optional membership) TOTAL	NON-MEMBER (without optional membership) Fee	NON-MEMBER (without optional membership) TOTAL
Early-bird Industry	**€ 1'100.00**	€1'100.00 ❑	NOT AVAILABLE			NOT AVAILABLE	
Industry	**€ 1'300.00**	€1'300.00 ❑	**€ 1'300.00**	€ 130.00	€ 1'430.00 ❑	**€ 1'430.00**	€ 1'430.00 ❑
Charitable Non-profit/ Academia (Full-Time)	**€ 975.00**	€ 975.00 ❑	**€ 975.00**	€ 130.00	€ 1'105.00 ❑	**€ 1'105.00**	€ 1'105.00 ❑
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❑ **TOTAL AMOUNT DUE:** € _____ **NOTE:** Payment of registration fees must be received before commencement of the meeting.

❑ I WISH TO REGISTER FOR DAY 1 ONLY	MEMBER Fee	MEMBER TOTAL	NON-MEMBER (with optional membership) Fee	NON-MEMBER (with optional membership) Membership	NON-MEMBER (with optional membership) TOTAL	NON-MEMBER (without optional membership) Fee	NON-MEMBER (without optional membership) TOTAL
Industry	**€ 780.00**	€ 780.00 ❑	**€ 780.00**	€ 130.00	€ 910.00 ❑	**€ 910.00**	€ 910.00 ❑
Charitable Non-profit/ Academia (Full-Time)	**€ 468.00**	€ 468.00 ❑	**€ 468.00**	€ 130.00	€ 598.00 ❑	**€ 598.00**	€ 598.00 ❑
Government (Full-Time)	**€ 390.00**	€ 390.00 ❑	**€ 390.00**	€ 130.00	€ 520.00 ❑	**€ 520.00**	€ 520.00 ❑

❑ **TOTAL AMOUNT DUE:** € _____ **NOTE:** Payment of registration fees must be received before commencement of the meeting.

❑ I WISH TO REGISTER FOR DAY 2 ONLY	MEMBER Fee	MEMBER TOTAL	NON-MEMBER (with optional membership) Fee	NON-MEMBER (with optional membership) Membership	NON-MEMBER (with optional membership) TOTAL	NON-MEMBER (without optional membership) Fee	NON-MEMBER (without optional membership) TOTAL
Industry	**€ 780.00**	€ 780.00 ❑	**€ 780.00**	€ 130.00	€ 910.00 ❑	**€ 910.00**	€ 910.00 ❑
Charitable Nonprofit/ Academia (Full-Time)	**€ 468.00**	€ 468.00 ❑	**€ 468.00**	€ 130.00	€ 598.00 ❑	**€ 598.00**	€ 598.00 ❑
Government (Full-Time)	**€ 390.00**	€ 390.00 ❑	**€ 390.00**	€ 130.00	€ 520.00 ❑	**€ 520.00**	€ 520.00 ❑

❑ **TOTAL AMOUNT DUE:** € _____ **NOTE:** Payment of registration fees must be received before commencement of the meeting.

* **For this meeting, DIA will offer a reduced registration fee for small to medium-sized enterprises (SMEs). Please contact DIA Europe at diaeurope@diaeurope.org for more information.**

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