2nd DIA/EMA Innovation Forum: Is the EU regulatory framework ready?

ID #10105
29-30 November 2010
Hotel London Marriott West India Quay, London, UK

Programme Advisor

Patrick Le Courtois, Head of Human Medicines Development and Evaluation, European Medicines Agency, EU

Programme Co-Chairs

Iman Barilero, Divisional Director, Regulatory Development Strategy and Policy, H. Lundbeck A/S, Denmark

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Programme Committee

Eric Abadie, Chair, CHMP, Chair Pharmacogenomics Working Party, European Medicines Agency; General Directorate, Afssaps, France

Solange Corriol Rohou, Director, Regulatory Affairs, AstraZeneca, France representing EFPIA

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Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, EU

The 2nd Innovation Forum will provide an opportunity to address the progress of innovative medicines in legal, organisational and technical aspects of the pharmaceutical framework in Europe. It will address the implementation of the EMA/CHMP Think-tank report on innovative medicines and look at the direction of the Agency's road map 2015. This forum will involve stakeholders such as patient representatives, academia delegates, regulators and industry scientists.

Key Topics

- Current activities at EU level to ensure innovation in science translate into benefit for the patients and to public health. This includes the new pharmaceutical package, paediatric medicines, gene therapy and stem cells, information to patients and European Commission impact assessment of the clinical trial directive
- Impact of the implementation of the 2007 Think-tank report on the Agency's activities and road map to 2015 to support enhanced regulatory decision-making and access to medicines
- Innovation in the pharmaceutical industry: looking for examples of innovative approaches in portfolio selection for R&D strategy
- Innovative medicines availability and unmet medical needs: role of regulators and policy makers

Background

- Progress in legal, organisational and technical aspects of the pharmaceutical framework
- Implementation of the EMEA/CHMP Think-tank report on Innovative Medicines
- Progress with IMI
- European Medicines Agency road map 2015 and directions to support innovation

Objectives

- Present current activities at EU level to ensure innovation in science translate into benefit for the patients
- Assess the impact of the implementation of the Think-tank report on the Agency's activities
- Address the implementation of the Agency's road map 2015 to support enhanced regulatory decision-making and access to medicines
- Enhance communication between the stakeholders

Who Will Attend

- Patient Groups
- Health Authorities
- Policy Makers
- Pharmaceutical Industry

Continuing Education

DIA meetings are generally approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the registration desk.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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MONDAY | 29 NOVEMBER 2010

08:00 **Registration and welcome coffee**

09:00 **Welcome address and introduction**
Patrick Le Courtois, Head of Human Medicines Development and Evaluation, European Medicines Agency, EU

Innovative Medicinal Product Developments in Pharmaceuticals
Eric Abadie, Chair, CHMP, Chair Pharmacogenomics Working Party, European Medicines Agency; General Directorate, Afssaps, France

09:30 **Session 1**

THE PHARMA PACKAGE: UPCOMING CHALLENGES FOR THE EMA

Session Chairperson:
European Medicines Agency representative invited

Future of Pharmacovigilance in Europe
Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

Information to Patients: Innovative approaches
Isabelle Moulon, Head of Medical Information, European Medicines Agency, EU

Stakeholder Views on the Pharmaceutical Package
Panel Discussion with session speakers and
- Mary G. Baker, President, European Federation of Neurological Associations (EFNA), Belgium
- Industry representative invited

11:00 **Coffee break**

11:30 **Session 1 continued**

Developments in the Area of Clinical Trials
Fergus Sweeney, Head of Sector, Compliance and Inspection, European Medicines Agency, EU

Advanced Therapy Medicinal Products (ATMP): Gene therapy and stem cells tourism
Academic representative invited

Panel Discussion with session speakers and
- Mary G. Baker, President, European Federation of Neurological Associations (EFNA), Belgium
- Wilfried Dalemans, Vice President Regulatory Affairs and Corporate Qualitiy, TiGenix, Belgium
- Ingrid Klingmann, Managing Director, Pharmaplex bvba, Belgium
- Martine Zimmerman, Director, Pharmaceutical Affairs, EMEA, Alexion Europe, France

13:00 **Lunch**

14:00 **Session 2**

INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Session Chairperson:
Iman Barilero, Divisional Director, Regulatory Development Strategy and Policy, H. Lundbeck A/S, Denmark

Innovation in Pharmaceutical Development
EFPIA representative invited

How can Industry contribute to Innovative Medicines?
From clinical-biology links to portfolio selection for R&D strategy
Anders Gersel Pedersen, Executive Vice President, Drug Development H. Lundbeck A/S, Denmark

Innovative Medicines Initiative (IMI): Progress and opportunities
Elisabetta Vaudano, Principal Scientific Manager, Innovative Medicines Initiative (IMI), Belgium

Panel Discussion with session speakers and
- IMI PROactive: COPD Project
  Solange Corriol-Rohou, Director, Regulatory Affairs, AstraZeneca, France representing EFPIA

15:30 **Coffee break**

16:00 **Session 3**

THE EUROPEAN MEDICINES AGENCY'S RESPONSE TO CHALLENGES

Session Chairperson:
Eric Abadie, Chairman, CHMP, Chair Pharmacogenomics Working Party, EMEA, EU, General Director, Afssaps, France

Impact of the EMA/CHMP Think-tank Recommendations and the CHMP Work Programme: An overview
Eric Abadie, Chairman, CHMP, Chair Pharmacogenomics Working Party, EMEA, EU, General Director, Afssaps, France

Innovative Medicines and their place in the EMA Road Map to 2015: EU coordinated actions for stimulating, measuring and valorising pharmaceutical innovation
Bruno Flamion, Chair, Scientific Advice Working Party, Vice-Chair Pharmacogenomics Working Party, Professor, Clinical Pharmacology, University of Namur, Belgium

Panel Discussion with session speakers and
- Stephane André, Head of EU/ROW Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland
- Mira Pavlovic, Deputy Director for Medical Evaluation of Health Technologies, Autorité de Santé (HAS), French Health Technology Assessment Agency, France
- Constantinos Ziogas, Scientific Administrator, Pre-authorisation Evaluation of Medicines for Human Use Unit, European Medicines Agency, EU

17:30 **Drinks Reception**

18:00 **End of Day 1**

TUESDAY | 30 NOVEMBER 2010

08:00 **Welcome coffee**

09:00 **Session 4**

INNOVATIVE MEDICINES DEVELOPMENT AND GLOBAL INTERACTIONS

Session Chairperson:
Marisa Papaluca Amati, Head of Scientific Support and Projects, European Medicines Agency, EU

Innovation and Benefit to Public Health: Orphan Medicinal Products (OMPs) as an example
Stiina Aarum, Scientific Administrator, Orphan Medicinal Products, European Medicines Agency, EU

NanoMedicine: What does nano technology have in store for patients and doctors?
Academic representative invited

Developing an EU Vision for Implementing Personalised Medicine for European Patients
Irene Norstedt, Head of Sector Medicines for the Future, European Commission, EU

Panel Discussion with session speakers and
- Janice Soreth, FDA liaison at the European Medicines Agency, EU
- Yoshikazu Hayashi, MHLW/PMDA Liaison at the European Medicines Agency, EU
- Detlef Niese, Head Development, External Affairs Novartis Pharmaceuticals AG, Switzerland

11:00 **Coffee break**

11:30 **Session 4 continued**

SMEs Office: Incentives to SMEs during development
Constantinos Ziogas, Scientific Administrator, Pre-authorisation Evaluation of Medicines for Human Use Unit, European Medicines Agency, EU

Scientific Advice and Interactions in a Global Drug Development
Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, EU

Panel Discussion with session speakers and additional panellists

13:00 **Lunch**

14:00 **Session 5**

INNOVATIVE MEDICINES AVAILABILITY AND UNMET MEDICAL NEEDS: ROLE OF REGULATORS AND POLICY MAKERS
Session Chairperson:
European Medicines Agency representative invited

Incentives for Innovative Medicines: How to make them work
European Medicines Agency representative invited

Innovative Aspects of Benefit–Risk Assessment and Decision Making
Academic representative invited

Emerging Clinical Needs: Aging and the future of mental health
Cyril Höschl, EBC Board Member/Past President, European Psychiatrists Association (EPA) and Director, Prague Psychiatric Centre, Czech Republic

Panel Discussion with session speakers and
- Carole Longson, Director, Centre for Health, Technology Evaluation, NICE, UK
- Filip Mussen, Vice-President, Psychiatry and EU RED Regulatory Affairs, Johnson & Johnson Pharmaceutical R&D, Belgium

15:45 **Summary of the Discussions and ways to move forward**

16:15 **End of conference**

TRAVEL INFORMATION

Edgware Road Station on the Bakerloo line and Circle line is a five-minute walk to the hotel.

London Heathrow
Take the Heathrow Express rail link to Paddington Station. Take the Bakerloo Line towards Elephant & Castle Underground Station and change to the Jubilee Line towards Stratford Underground Station, leave at Canary Wharf Underground Station.

London Gatwick Airport
Take First Capital Connect towards Bedford Rail Station change for the Jubilee line in London Bridge Underground Station, taking you directly to Canary Wharf Underground Station.

London City Airport
Take the DLR train to Canning Town, change for the Jubilee line taking you directly to Canary Wharf Underground Station.

For more details please visit: www.tfl.gov.uk or use the map provided http://www.tfl.gov.uk/assets/downloads/dlr-route-map.pdf.

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

The London Marriott West India Quay Hotel
22 Hertsmere Road
Canary Wharf I London E14 4ED, UK
http://www.marriott.co.uk/hotels/travel/loncw-london-marriott-hotel-west-india-quay/

at the special rate of:
£169 inclusive of breakfast, exclusive of VAT and services

To make your reservation please
Use this link: http://cwp.marriott.com/loncw/diaeurope2010/
Tel: + 44 20 70931000
Fax: + 44 20 70931001
Please quote the booking reference: diaeurope2010

Important: Please complete your reservations by 15 October at the latest. Reservations requested after this date will be subject to hotel availability and room rate may vary.

In case of cancellation:
Cancellation of the hotel bedroom booking must be made in writing directly to the hotel no later than 4 PM GMT on the arrival date. Any cancellation made less later than 4 PM GMT or no shows will be subject to the first night being charged at the full agreed rate.

REGISTRATION FORM

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ID # 10105

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes lunch and coffee breaks

Early-Bird rates available for Members: Deadline on or before 22 October 2010

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.
Does not apply to government/academia/non-profit members

Early-Bird Fee (on or before 22 October 2010)	FEE
Join DIA now to qualify for the Early-Bird Rate	€ 115.00 ❑
Early-Bird Industry	€ 1'165.00 ❑

CATEGORY	Member (after 22 October 2010) FEE
Industry	€ 1'365.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ 1'024.00 ❑
Government (Full-Time)	€ 683.00 ❑

	Non-Member FEE
Industry	€ 1'480.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ 1'139.00 ❑
Government (Full-Time)	€ 798.00 ❑

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES___ NO___

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

GROUP DISCOUNTS, STUDENT FEES AND SPECIAL DISCOUNT FOR SME (STATUS CONFIRMED BY EMA) AVAILABLE. PLEASE CONTACT DIA EUROPE. 10105DIA

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are our preferred payment method.

❑ Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to: D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 10105 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on 19 November 2010

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. 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 reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

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

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

HOW TO REGISTER

The DIA 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.

Online	Fax	Email	Mail
www.diahome.org	+41 61 225 51 52	diaeurope@diaeurope.org	DIA European Office Postfach, 4002 Basel, Switzerland