Future Direction for Orphan Drugs in Europe

Event #10117 | 3 November 2010
Hotel Radisson Blu Charles de Gaulle Airport, Paris, France

Programme Co-Chairs
Catarina Edfjäll, Senior Director Head of Regulatory Strategy Europe, Celgene International SARL, Switzerland
Kerstin Westermann, Senior Expert, Medical Products Agency, Sweden COMP Chairperson, European Medicines Agency

Programme Committee
Emmanuel Chantelot, Executive Director, European Biopharmaceutical Enterprises, Belgium
Wills Hughes-Wilson, Senior Director, Health Policy Europe, Genzyme, Belgium
Yann Le Cam, Chief Executive Officer, EURORDIS, Europe
Jordi Llinares, Head of Orphan Medicines, European Medicines Agency, European Union
Patrick Salmon, Senior Medical Officer, Irish Medicines Board, Ireland
Irish Delegate to COMP

2nd Health Technology Assessment (HTA) Conference

Building a new System to get Effective Treatment to European Patients

Event #10111 | 4-5 November 2010
Hotel Radisson Blu Charles de Gaulle Airport, Paris, France

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Catarina Edfjäll, Senior Director Head of Regulatory Strategy Europe, Celgene International SARL, Switzerland
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Special discount available
Delegates are encouraged to register for both conferences to take advantage of valuable crossover sessions. Benefit from a combined rate and a chance to save up to €600! All rates are applicable to VAT. Contact the DIA in Europe for more information by phone +41 61 225 51 51 or email diaeurope@diaeurope.org or complete the registration form (online registration will not be possible).

Attend 1 Day 3 November Orphan Drugs starting from €850.00
Attend 1.5 Days 4-5 November HTA or 3-4 November Orphan Drugs & HTA starting from €1100.00
Attend 2.5 Days 3-5 November Orphan & HTA starting from €1350.00

A special discount for qualified SMEs is also available, please contact the DIA in Europe.
Future Direction for Orphan Drugs in Europe

Event #10117 | 3 November 2010

Overview
This 1st DIA conference on Orphan Drugs will reflect on the experience gained in the first 10 years of the European Orphan Medicinal Products (OMP) Regulation. It will review current developments in orphan drug research, look at points of collaboration between regulatory and HTA bodies and provide an outlook on future developments.

Since the adoption of the EU’s OMP Regulation, more than 60 new medicines have received a positive opinion for EU Marketing Authorisation, more than 700 orphan designations have been granted and, along the way, a huge body of experience and expertise has been built up in the EU.

We will soon be 2 years on from the High Level Pharmaceutical Forum’s conclusions and recommendations on Orphan Drugs; and, additionally, 2 years on from the publication of the European Commission’s Communication on “Rare Diseases: Europe’s Challenges”. The European Medicines Agency’s Road-Map to 2015 is under discussion and the European Commission’s DG SanCo is formally looking into potential methodologies for conducting a common assessment of the Clinical Added Value of Orphan Drugs and examining ways in which Member States can cooperate to share information in order to increase access to orphan drugs.

So to what extent have the expectations of stakeholders – rare disease patients, regulators, governments, researchers, industry and payers – been met? What incentives are in place for research institutes and companies to research and develop orphan drugs? How will existing European rules interact with current initiatives to facilitate uniform access to rare disease patients for innovative treatments which work?

The time is right to look into where we are and where we are headed – this conference will provide the opportunity for all stakeholders to come together and review the key opportunities and challenges for the coming years.

Key Topics
• Orphan Designation: What have we learnt and what has changed in the course of the first 10 years?
• Marketing Authorisation for Orphan Drugs: Significant benefit, similarity, market exclusivity and other challenges
• Opportunities and Challenges in Orphan Drug Research and Development
• Market Access and HTA: Particular challenges and opportunities for orphan drugs

Who Will Attend
The aim of this one-day conference is to bring together patients, academia, researchers, industry and regulators to share experiences with the development of orphan medicinal products in Europe. Opportunities and challenges will be discussed while addressing various aspects from designation to market access of orphan medicinal products.

Credits
The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the Orphan Drugs Conference with 6 credits.

2nd Health Technology Assessment (HTA) Conference

Building a new System to get Effective Treatment to European Patients

Event #10111 | 4-5 November 2010

Overview
The Health Technology Assessment (HTA) landscape in Europe is under the spotlight more than ever before. It is changing, evolving and is in an increasingly dynamic state of flux, as agencies in Europe and across the globe try to find the right path forward to ensure that the right treatments are made available to patients in sustainable healthcare frameworks.

HTA is, therefore, increasingly becoming the focus of stakeholders involved at all stages of the medicine development process. Patients are proactively engaging with evaluators and payers. Innovative medicines manufacturers are working to build understanding of the value of their products – not only value to the patients, but also to the healthcare systems and to society as a whole. Decision-makers in the countries, whether they are governments or payers, are working to understand how to evaluate whether what they are paying for is worth the price-tag that is being asked. And, increasingly, countries are working together to create a more coordinated HTA assessment model.

The time is more than ripe to start figuring out how all of these different forces are going to work together in practice, and what the resulting outcomes will mean for patients, innovators, governments and payers alike. Because, while 10 years ago, the EU created a single market in reviewing and approving medicines from a clinical scientific perspective to facilitate uniform access to European patients, increasingly the subsequent scientific evaluation of the value of a product is fragmented into different methodologies and different approaches post-approval. This means that, if we are to continue to realise the concept of a single EU and to support equity between patients in Europe, something must be done to have some degree of similarity in the approach.

The question is: how is all this going to be achieved and in what framework? Where are the multiple cooperative and EU-coordinated projects in HTA going? And how can we ensure that they do achieve this ultimate aim of getting needed, innovative treatments to the waiting patients?

This conference will bring together all stakeholders: from regulators to governments, from national competent authorities to the European Medicines Agency in London and from industry, payers and – the ultimate beneficiary of a successfully functioning system – the patients who stand to benefit from the fruits of innovative R&D. The objective is to move from a “What is happening?” to “How will we make this ‘what’ into a functioning reality that achieves the multiple different objectives from all involved stakeholders?”

Key Topics
• Mapping the HTA Landscape in Europe
• Innovative Patient Access Schemes
• Risk-sharing Schemes and Conditional Reimbursement
• Methodologies to Generate the Right Data
• Building “Benefit Management Plans”
• Building a New System to get Effective Treatments to EU Patients

Who Will Attend
The aim of this one and a half day conference is to bring together professionals working in the following areas:
• Pharmacoeconomics/Quality of Life/Health Economics/Outcomes Research/Managed Healthcare
• Public Policy/Law
• Regulatory Affairs/Policy/Drug or Device Approval
• Clinical Research and Development
• Research and Development/Strategic Issues
• Government

Credits
The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the 2nd DIA Health Technology Assessment Conference with 9 credits.
The Development of Orphan Medicinal Products is a long and complex process. The EU legislation provides a period of protection to allow sponsors time to recoup their investment and to stimulate further investment. At the same time, the law says that patients should be able to benefit from improvements in treatment possibilities. How "exclusive" is the market in reality? And how "significant" does a benefit need to be to warrant breaking this protection? This session will review the experience over the past 10 years and look to the future of orphan drug R&D and what can be done to stimulate more focus in this area, where there still remains a high level of unmet medical need.

Rare Disease Research in Europe: Trends and determinants
Segolène Aymé, Director of OOPD's Grants Program, FDA, USA

Unmet Medical Needs
Lesley Greene, Patient Advocate, EURORDIS, Europa and CLIMB, UK

Orphan Drugs in a Broad Research Portfolio
Adam Heathfield, Director Science Policy, Pfizer Ltd., UK

The FDA Perspective
Katherine Needleman, Director of OOPD's Grants Program, FDA, USA

Q&A

MARKET ACCESS AND HTA: PARTICULAR CHALLENGES AND OPPORTUNITIES FOR ORPHAN DRUGS GENERATING THE LEVEL OF EVIDENCE NEEDED FOR DECISION MAKING ON THE VALUE OF ORPHAN DRUGS IN THE THERAPEUTIC STRATEGY OF A RARE DISEASE
Session Co-Chairs:
Yann Le Cam, Chief Executive Officer, EURORDIS, Europa
Wills Hughes-Wilson, Senior Director, Health Policy Europe, Genzyme, Belgium

The European Commission's DG SanCo is formally looking into potential methodologies for conducting a common assessment of the Clinical Added Value of Orphan Drugs (CAVOD). One key area will be to examine how Member States can cooperate to share information, in order to increase access to these urgently needed treatments, at a time when the available clinical data package may be small. This session will address the current situation around the implementation of the CAVOD principles and its related policy programme, the "Post-Marketing Authorisation Benefit Management Plan" concept. It will also review the Member States' approaches to turning these principles into reality – both before, during and after Marketing Authorisation.

The Clinical Added Value of Orphan Drugs and Current State of Play
Wills Hughes-Wilson, Senior Director, Health Policy Europe, Genzyme, Belgium

What Could be the Benefit Management Plan for Orphan Drugs
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, European Union

The Concept of Early Access Management Plan
Hilde Stoop, General Manager, Genzyme, Belgium

Q&A
Looking forward, the Working Party could also work with Member States to identify gaps in knowledge and, together with all relevant stakeholders, including the developer of the treatment, could identify a road-map for building up data based on in-use experience. Given the current interest in personalised medicines, conditional marketing authorisations and the need for Member States to have robust data sets for advanced treatments, could this orphan model give us some lessons that could be useful in a broader setting? And what needs to happen to make this system – for orphans or otherwise – successful?

**Panellists**

Giulia Del Brenna, Head of Unit, Competitiveness in the Pharmaceuticals Industry and Biotechnology, DG Enterprise, EU Commission, European Union

Wills Hughes-Wilson, Senior Director, Health Policy Europe, Genzyme, Belgium

Hilde Stoop, General Manager, Genzyme, Belgium

Nicola Magrini, Director of CeVEAS, Emilia Romagna Regional Health System, Italy

**13:00 Lunch**

**14:00 SESSION 3**

**MAPPING THE EU HTA LANDSCAPE – WHERE DO WE STAND?**

**Session Chairperson:**

Alicia Granados, Director HTA Europe Middle East Africa & Canada, MSD, Spain

HTA bodies across Europe present a diverse landscape and are at various stages of development. But they are increasingly seeking to work together. This session will provide a comprehensive picture of the differences and similarities between the different national HTA bodies, with a focus on the scope of the different country HTA assessments, the work processes and the impact of an HTA on decision-making. It explores if and how further standardisation could be achieved.

**HTA Landscape and Knowledge-mapping**

Laura Sampietro-Colom, Deputy Director for Innovation, HTA Clinic Group, University of Barcelona, Spain

**Future Perspectives of HTA in Europe**

Jérôme Boehm, Policy Officer - Health systems, Health and Consumers Directorate General, European Commission, European Union

**15:30 Coffee break**

**16:00 SESSION 4**

**INNOVATIVE PATIENT ACCESS SCHEMES – STATE OF THE ART**

**Session Chairperson:**

Giulia Del Brenna, Head of Unit, Competitiveness in the Pharmaceuticals Industry and Biotechnology, DG Enterprise, EU Commission, European Union

Earlier access to new medicines is in the best interest of European patients and must be the overall objective of innovative reimbursement schemes. This session will examine the different existing initiatives: assess their status, their individual features and their likelihood of success or failure in meeting the overall objective of facilitating access to the patients who are likely to benefit from the treatments.

**Innovative Access Schemes – What is working well?**

Michael Ruhl, Vice President, Booz & Co., Germany

**Managed Entry Agreements – discussions in the HTAi Policy Forum**

Chris Henshall, Chair of HTAi Policy Forum and Associate Professor Brunel University, UK

**Industry Experiences - Temporary reimbursement of hospital products**

Jan Oltooyt, Senior Policy Advisor Health Economic, Nefarma, The Netherlands
Innovative Patient Access Schemes – How do we implement in practice?

Session Chairperson:
Kevin Loth, Senior Director External Relations, Europe, Celgene, UK

Over the last few years, an increasing number of Member States have set up innovative access schemes. These schemes allow competent authorities and pharmaceutical companies to build experience on the clinical value of medicines that might not normally be eligible for reimbursement on the basis of knowledge available at the time of Marketing Authorisation. Such innovative reimbursement practices allow budget control and the identification and reward of valuable innovative medicines. At the same time, they provide access for patients to highly innovative treatments. What are the challenges of implementing such programmes? How do they work in practice? And which gaps must be closed to achieve a consistent outcome?

UK Experiences
Eric Low, Chief Executive, Myeloma UK

German Experiences
Claudia Palme, Strategic Management Consulting, Germany

Italian Experiences
Luca De Nigro, Project Manager RFOM, AIFA, Italy

10:30 Coffee break

11:00 Session 6

What are the right methodologies to generate the right data?

Session Chairperson:
Clare McGrath, Senior Director HTA Policy Europe/ROWD, Pfizer Ltd., UK

Gathering reliable and trusted data of clinical in-use outcomes and evidence will be a key element of building a successful conditional access scheme. Medical evidence, or recommendations that are based on evidence, can be of different quality. The methods of collecting data might also differ according to the disease/condition in question and the type of therapy. Sources of evidence range from small laboratory studies or case reports, to well-designed large clinical studies. Since poor-quality evidence can lead to recommendations which are not in the patients’ best interests, it is essential to know if a recommendation is strong or rather weak. This session outlines several methods to generate evidence from clinical use, which could be used to inform conditional reimbursement decisions.

The Ground-rules and Infrastructure – What needs to be there in order to set this up?
Experiences gathered from the Swedish Presidency pilot project
Nils Feltelius, Senior Medical Officer, Medical Products Agency, Sweden

How to Set-up and Use Data from Registries – The Nordic registries example
Nils Feltelius, Senior Medical Officer, Medical Products Agency, Sweden

The Role of Observational Studies
Judy Kempf, Vice President, Epidemiology Center of Excellence, Genzyme, USA

Patient Reported Outcomes (PROs) in a Real-life Setting
Steve McKenna, Director of Research, Galen Research, UK

Grading Systems Used in Healthcare – GRADE group
Nicola Magrini, Director, CeVEAS, Emilia Romagna Regional Health System, Italy

Panel Discussion and Q&A
with all speakers

13:30 End of conference

TRAVEL INFORMATION

The Radisson Blu Hotel Charles de Gaulle is situated approx. 3 km away from the airport Paris Roissy Charles de Gaulle and the train station for TGV and RER.

Shuttle Service: a private and free shuttle connects the airport to the hotel in 7 minutes.

Terminal 1 & 3 (departure from the hotel every 30 minutes);
Roissypole station

Terminal 2 (departure from the hotel every 20 minutes);
TGV station, level 5 (hotels shuttles exit) – this is the only stop at terminal 2

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:
Radisson Blu Hotel Charles de Gaulle Airport
Rue de La Chapelle
Le Mesnil Amelot - Ile de France - 77990 Paris, France
www.radissonblu.com/hotel-parisairport

at the rate of: EUR 155.00 inclusive of breakfast, exclusive of VAT

Please book your room directly by using the following email address:
radissonblu@hotels-res.com - Phone: +33 1 6003 6300 - Fax: +33 1 6003 7440

Or use the hotel reservation form which will be available shortly

Please quote the booking reference: DIA November 2010

Important: Please complete your reservations before 6 September 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 hotel room bookings must be made in writing directly to the Hotel. All no shows will be billed for the entire stay.

CANCELLATION POLICY | EVENT#10111

All cancellations must be in writing and received at the DIA office by 17:00 CET on 26 October 2010

CANCELLATION POLICY | EVENT#10117

All cancellations must be in writing and received at the DIA office by 17:00 CET on 27 October 2010

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academic/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.
Register for upcoming DIA events in Europe

1st Joint DIA/EMA Workshop on Statistical Methodology in Clinical R&D
27-29 September 2010 | Vienna, Austria

Joint EFGCP Children’s Medicines Working Party 6th Annual Conference and
DIA 4th Paediatric Forum
Current and Future Medical Child Care: Visions, Daily Challenges, Ways Forward
28-29 September 2010 | London, UK

Joint DIA/EFGCP Pharmacovigilance Audit and Inspection Workshop -
Opportunities for Patient Safety
1 October 2010 | London, UK

4th Annual Clinical Forum and Exhibition - Navigating the Future
11-13 October 2010 | Lisbon, Portugal

4th European Cardiac Safety Conference and Exhibition
25-26 October 2010 | Nice, France

Combination Products – Finding the Right Regulatory Strategy
9 November 2010 | Zurich, Switzerland

Register for upcoming DIA Training Courses in Europe

Clinical Research
Advanced GCP Study Monitoring
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs
An Introduction to Product Information Management (PIM)
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration
Procedures and Variations: Expert Overview
6-8 October 2010 | Prague, Czech Republic | ID 10573

CTD Dossier Requirements: Focus on EU Module 1 and
Quality Module 3
5-7 December 2010 | Dubai, United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
10-12 November 2010 | Zurich, Switzerland | ID 10547

Quality by Design: A Hands-on Short Course for Pharma
4-5 November 2010 | Graz, Austria | ID 10565

Training Course for eCTD Submissions in Switzerland
30 September 2010 | Basel, Switzerland | ID 10571
9 December 2010 | Zurich, Switzerland | ID 10572

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Safety and Pharmacovigilance
Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
7 October 2010 | London, United Kingdom | ID 10538

How to Prepare for Pharmacovigilance Audits and Inspections
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
19 October 2010 | London, United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product
Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, UK and selected
European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance >
Click on Related Courses

Non-Clinical Sciences
Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas
Crisis Management
14-15 October 2010 | Paris, France | ID 10564

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COMBINED REGISTRATION FORM WITH SPECIAL DISCOUNT
Future Direction for Orphan Drugs in Europe | 2nd Health Technology (HTA) Conference
3 November 2010 and 4-5 November 2010 | Hotel Radisson Blu, Charles de Gaulle Airport, Paris, France

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

I wish to register for the Orphan Drugs Conference - and for two morning sessions of the HTA Conference (1.5 days - 3 and half day on 4 November 2010):

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

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REGISTRATION FORM FOR ORPHAN DRUGS CONFERENCE
Future Direction for Orphan Drugs in Europe
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☒ 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: D.I.A.” including your name, company, Meeting ID# 10117-10111 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.

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

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