

9th DGRA Annual Congress

on 12 and 13 June 2007 in Bonn

- **Medicinal Products for Pediatric Use**
 - **Purpose and scope of the new EU-regulation**
 - **Pediatric Committee**
 - **Pediatric Investigation Plan**
 - **Ethical Considerations for Clinical Trials Performed in Children**

- **Electronic Regulatory Submission in the EU**
 - **From the point of view of France, Austria, UK and Germany**

With

Dr. Adam Aparicio

Merck KGaA, Darmstadt

Dr. Daniel Brasseur

European Medicines Agency, EMEA, London

Dr. Aziz Diop

French Health Products Safety Agency, afssaps, Saint Denis

Dr. Julia Dunne

Medicines and Healthcare Regulatory Agency, MHRA, London

Dr. Reinhard Feneberg

Pediatric Unit of the KKS Heidelberg
Pediatric Network PAED-Net

Dr. Klaus Menges

German Federal Institute for Drugs and Medical Devices, BfArM, Bonn

Dr. Dirk Mentzer

Paul Ehrlich Institute, PEI, Langen

Dr. Agnès Saint Raymond

European Medicines Agency, EMEA, London

Dr. Max Wegner

Bayer Healthcare, Wuppertal

Dr. David Wheeler

Medicines and Healthcare Regulatory Agency, MHRA; London

Dr. Christa Wirthumer-Hoche

Federal Agency for Safety in Health Care, AGES PharmMed, Wien

Chair: Burkhard Sträter

Attorney, Bonn

The Programme on 12 June 2007

Moderation: B. Sträter, Attorney

09.30 am Welcoming Speech by Prof. Dr. K.-W. Glombitza,
President of the DGRA

09.45 am Medicinal Products for Pediatric Use:

Purpose and scope of the new EU-regulation

- Affected Products
- Consequences for line extensions
- Provisions

Dr. Julia Dunne, MHRA, London

Pediatric Committee – PC

- Scope
- Composition
- Procedures
- Inventory of existing studies
- Workload Management

Dr. Daniel Brasseur, EMEA, London

11.00 am Legal Framework for Incentives

- Patented Products
- Rules and requirements for SPC-Extension
- Provision
- Orphan Medicinal Products
- Incentives for PUMAs

RA Burkhard Sträter, Bonn

11.30 am Coffee break

12.00 am Pediatric Investigation Plan - PIP

- Affected Products and authorisation procedures
- Content
- Structure
- Time lines

Dr. Agnès Saint Raymond, EMEA, London

12.30 pm Panel-Discussion
with Dr. Dunne, Dr. Brasseur, RA Sträter, Dr. Saint Raymond

1.00 pm Lunch break

**2.30 pm Ethical Considerations for Clinical Trials Performed
in Children**

New recommendations of the Ad hoc group for the development of implementing guidelines for Directive 2001/20/EC - State of play

Dr. Dirk Mentzer. PEI, Langen

3.15 pm Special considerations for clinical trials in the paediatric population – psychosocial, medicinal, scientific and organizational challenges

- Obtaining informed consent and educating motivated patients
- Development and growth
- Small and diverse populations
- Large, multinational, long running studies

Dr. Reinhard Feneberg, Pediatric Unit of the KKS Heidelberg, Pediatric Network PAED-Net

4.00 pm Coffee break

**4.30 pm Consequences for the Pharmaceutical Industry
Panel-Discussion with Dr. Mentzer, Dr. Feneberg, Dr. Wegner**

(Ends at around 5.30 pm)

7.00 pm Evening Programme

Award of the Walter Cyran Medal

Followed by: Reception and buffet (end open)

The Programme on 13 June 2007

**9.30 am Electronic Regulatory Submission (ERS) in the EU –
Overview**

Dr. A. Aparicio, Merck KGaA, Darmstadt

**10.00 am ERS from the Point of View of the National Drug
Agencies**

- Regional requirements
- Mandatory or non-binding
- Electronic submission technologies
- Electronic documents and data
- Perspectives for the future

A. France

Dr. Aziz Diop, afssaps, Saint-Denis

B. Austria

Dr. Christa Wirthumer-Hoche, AGES PharmMed, Wien

11.00 am Coffee break

11.30 h C. United Kingdom

Dr. David Wheeler, MHRA, London

12.00 am D. Germany

Dr. K. Menges, BfArM, Bonn

12.30 am Panel Discussion with all speakers

1.00 pm End

2.00 pm DGRA Members' Meeting

(Programme subject to change without prior notice.)

Dates:

**12 June 2007 Wasserwerk 9.30 am
Haus der Geschichte 7.00 pm**

**Presentations and discussions
Award of the Walter Cyran Medal, reception**

**13 June 2007 Wasserwerk 9.30 am
Followed by 2.00 pm**

**Presentations and discussions
DGRA members' meeting**

Venue:

**Wasserwerk Bonn
Hermann-Ehlers-Strasse
Entrance V
D-53113 Bonn**

**Haus der Geschichte
Museumsmeile
Willy-Brandt-Allee 14,
53113 Bonn**

Cost contribution:

**For DGRA members: € 450
For non-members: € 590**

**For students of the DRA course (MDRA
VIII) and delegates of bodies who are
members of the DGRA: € 240**

Cancellation terms:

Up to two weeks before the first day of the conference: € 50; up to one week before the first day of the conference: 50% of fee; later cancellations: full conference fee if a substitute participant (DGRA member) cannot be put forward. In the event of cancellation by the organizer, any fees already paid will be fully reimbursed.

Conference languages:

English and German

Room reservation:

A limited number of rooms are available for participants at special rates in the hotels listed below. When making reservations please refer to this event.

**Hotel (Günnewig) Bristol
Prinz-Albert-Strasse 2
D-53113 Bonn
Tel.: +49 (0) 228/26 98-0
Fax: +49 (0) 228/26 98-2 22**

**Hotel Hilton
Berliner Freiheit 2
D-53111 Bonn
Tel.: +49 (0) 228/72 69 - 0
Fax: +49 (0) 228/260 15 29**

**Hotel (Günnewig) Residence
Kaiserplatz 11
D-53113 Bonn
Tel.: +49 (0) 228/2697-0
Fax: +49 (0) 228/2697-777**

**Hotel Königshof
Adenauerallee 9
D-53111 Bonn
Tel.: 0228/26 01-0
Fax: 0228/26 01-529**

**Hotel Maritim
Godesberger Allee
D-53175 Bonn
Tel.: +49 (0) 228/81 08 845
Fax: +49 (0) 228/81 08 765**

**Hotel Kanzler
Adenauerallee 148
D-53113 Bonn
Tel.: 0228/68 44-0
Fax: 0228/68 44 180**

Registration:

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