

11th DGRA Annual Congress

May 12 and 13, 2009 in Bonn

2010 Road Map: 2008 Pharmaceutical Package

- Counterfeit Medicines – Effects on Parallel Imports
- Information on Prescription Drugs
- Pharmacovigilance and Variation Procedure
- 15th Amendment to the German Drug Law

with

Dr. Karl Broich

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

Dr. Ulrich Hagemann

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

Dr. Christa Schröder

Paul Ehrlich Institute (PEI), Langen

Dr. Harald Tietz

Lilly Deutschland GmbH, Bad Homburg

Dr. Brigitte Keller-Stanislawski

Paul Ehrlich Institute (PEI), Langen

Dr. Regine Leo

GMP/GCP Inspectorate, Hanover

PD Dr. Walter Schwerdtfeger

German Ministry of Health (BMG),
Bonn/Berlin

Dr. Martin Terberger

EU Commission, Brussels

Matthias Wilken

German Pharmaceutical Industry Association
BPI, Berlin

Susanne Winterscheid

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

Chair: Prof. Burkhard Sträter

Attorney, Bonn

The Program on May 12, 2009

Moderator: Prof. Burkhard Sträter, Attorney

9.30 am Opening of the Annual Congress, Dr. Ulrich Granzer

9.45 am I. 2008 Pharmaceutical Package

- Aims of the EU Commission
- Implementation status
Dr. Martin Terberger, EU Commission

A. Consequences and Significance for the Pharmaceutical Market in Germany

PD Dr. Walter Schwerdtfeger, German Ministry of Health

11.00 am Coffee break

11.30 am B. Strengthening of Pharmacovigilance - Expectations and Requirements for a new system

Dr. Ulrich Hagemann, BfArM

C. PV-Risk Assessment Advisory Committee – PRAAC Responsibilities and Cooperation with NCAs

Dr. Brigitte Keller-Stanislawski, PEI

12.30 pm Panel discussion

01.00 pm Lunch break

2.30 pm II. Safety Measures in the new Pharmaceutical Vigilance System

- Steps of the procedure for nationally, decentrally and centrally authorized pharmaceutical products
- Evaluation
- Risk-management plans: content and function

Dr. Harald Tietz, Lilly Deutschland and

Dr. Brigitte Keller-Stanislawski, PEI

3.15 pm Coffee break

3.45 pm III. New Variation Regulation

- Structure of the new system
- How it applies to national authorizations
- Guideline for defining variation types
- Status of the consultation and procedure
Susanne Winterscheid, BfArM

4.30 pm **IV. Impact on Implementation by BfArM**
Dr. Karl Broich, BfArM

Panel discussion with all speakers

5.15 pm **8th Award of the Walter Cyran Medal**
(ends at around 6.00 pm)

7.00 pm **Pre-dinner speech**

Reception and buffet

The Program on May 13, 2009

9.30 am **V. 15th Amendment to the German Drug Law**

**Presentation of the content and Discussion with
the panel and participants**

- Introduction and general overview
Prof. Burkhard Sträter, Attorney
- Advanced Therapies
Dr. Christa Schröder, PEI

11.00 am **Coffee break**

- Tissue Engineering
Matthias Wilken, BPI
- Impact on “Länderbehörden”
Dr. Regine Leo, GMP/GCP Inspectorate Hanover

12.30 pm **Panel discussion with all speakers**

1.00 pm **Lunch/Snack**

2.00 pm **DGRA Members’ Meeting**

(Program subject to change without prior notice)

Dates:

May 12, 2009 Wasserwerk 9.30 am
Hotel Königshof 7.00 pm

Presentations and discussions
Pre-dinner speech, reception

May 13, 2009 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

Hotel Königshof
Adenauerallee 9
D-53113 Bonn

Cost contribution:

For DGRA members: € 460
For non-members: € 590

Student price: Students of DRA course
(MDRA X) and delegates of bodies who are
members of the DGRA: € 260

Cancellation terms:

Up to two weeks before the first day of the conference(28-Apr-09): € 50; up to one week before the first day of the conference (05-May-09): 50% of fee; late 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

Sternhotel
Markt 8
D-53111 Bonn
Tel.: +49 (0) 228/7267-0
Fax: +49 (0) 228/7267-125

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.: +49 (0) 228/26 01-0
Fax: +49 (0) 228/26 01-529

Hotel Maritim
Godesberger Allee
D-53175 Bonn
Tel.: +49 (0) 228/81 08
Fax: +49 (0) 228/81 08-811

Registration:

As a DGRA member please use the form at www.dgra.de or contact us at info@dgra.de
DGRA-Geschäftsstelle, Schedestrasse 9, D-53113 Bonn, Fax: +49 (0) 228/368 26 47