DEUTSCHE
GESELLSCHAFT
FÜR
REGULATORY AFFAIRS

Biosimilars Workshop

- **Regulatory issues**
- **Pharmacoeconomic aspects**

DGRA Workshop for members
on September 26, 2013
at Paul-Ehrlich-Institut,
Paul-Ehrlich-Str. 51-59, 63225 Langen

9:30 a.m. – 5:00 p.m.

Moderation: Dr. Ulrich Granzer, Granzer Consulting

Speakers: **Dr. Marie-Christine Bielsky,**
Medicines and Healthcare Products Regulatory Agency, MHRA UK
Dr. Brigitte Brake, Bonn
Dr. Pascale Burtin, Sandoz
Dr. Pekka Kurki, Finnish Medicines Agency
Dr. Gabriele Reichmann, Langen
Prof. Burkhard Sträter, Law Firm Sträter Lawyers

Programme:

09:30 a.m. I. Overarching Guideline - the concept of a "Biosimilar medicinal product"
- Revision of "Guideline on similar medicinal products"
- Selection of reference products

Dr. Pekka Kurki, Finnish Medicinces Agency,
Former Chair of the Biosimilar Medicinal Products Working Party (BMWP) EMA

10:30 a.m. . coffee break

11:00 a.m. II. From Comparability to Biosimilarity –quality aspects

- Requirements of quality dossiers
- Comparative characterization – which differences are acceptable?

Dr. Brigitte Brake, Bonn

11:45 a.m. III. Development of biosimilar products from the substance category of monoclonal antibodies

- Non-clinical aspects

Dr. Gabriele Reichmann, Langen
Expert of the Biosimilar Medicinal Products Working Party (BMWP) EMA

12:30 p.m. Lunch break

1:30 p.m. IV. The experience with biosimilars - how does it influence current clinical requirements

- Acceptance of surrogate parameters with regard to efficacy
- Patient population in pivotal studies

Dr. Marie-Christine Bielsky, MHRA UK
Member of the Biosimilar Medicinal Products Working Party (BMWP) EMA

2:15 p.m. V. Industrial perspective and experience

- Sandoz Biosimilar experience and concepts
- Technical versus Clinical development
- Challenges encountered
- Harmomization between regulatory jurisdictions
- Pharmacovigilance and risk management
- Education of medical community

Dr. Pascale Burtin, Sandoz

3:00 p.m. coffee break

3:30 p.m. VI. Traceability, substitution, impact on Reimbursement financed by the German Statutory Health Insurance System (GKV)

- Identification of products in ADR reporting - requirements acc. Art. 102 (Directive 2001/83)
- Additional monitoring black triangle for biosmimilars?

Prof. Burkhard Sträter, Kanzlei Sträter

4:15 p.m. **VII. Panel discussion**

all speakers and participants

around 5:00 p.m. end

(Program subject to change without prior notice)

further information **p.t.o.**

Date:
Thursday, September 26, 2013
Start: 9:30 a.m.
End: around 5:00 p.m.

Venue
Paul-Ehrlich-Institut, Paul-Ehrlich-Str. 51-59
D-63225 Langen, phone: 06103 – 77-0

Cost contribution:
For DGRA members and students of M.D.R.A. Course 14/15: € 270

The Casino of DFS near by (DFS Deutsche Flugsicherung - German Air Traffic Services) is open for lunch (not included).

Cancellations terms:
Up to two weeks before the first day of the conference (September 12,-2013): € 50; up to one week before the first day of the conference (September 19, 2013): 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.

Workshop language:
English

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

- **Hotel Steigenberger, Langen**
  Phone: 0049 - 06103 - 9720
- **Achat Comfort Hotel, Langen**
  Phone.: 0049 – 6103 756 0

Further hotel reservations can be made directly via internet portals e.g. www.carisma-engine .de, www.hrs.de

Note:
Photographers will accompany the workshop. Some photographic material will be published.

Workshop documents will include a list of participants.

Registration:
As a DGRA member please use the application form at www.dgra.de or contact us at info@dgra.de

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