



**Medical University – Sofia
Faculty of Public Health,
Faculty of Pharmacy – Sofia,
*Kindly supported by Faculty of Public Health and
DGRA e.V., German Association for Drug Regulatory Affairs***

**Workshop on drug policy, new pharmaceutical procedures in EC
Hall “Maxima” (St. Ekaterina - University Hospital)
Sofia, 18 - 19 April, 2007
Chairman: Burkhard Sträter, Attorney at Law**

- Parliament – Health Commission
- Ministry of Health - Minister/Vice-minister
- Medical University (Sofia) - Prof. V. Ovcharov, rector
- Faculty of Public Health (MU-Sofia) - Prof. Z. Vodenicharov, dean
- Faculty of pharmacy (MU-Sofia) - Prof. St. Nicolov, dean
- Bulgarian Drug Agency

**18 April 2007
8.45 Opening**

New European pharmaceutical Legislation in 2005

9.00 General Principles - Major changes in the pharmaceutical legislation in 2005:

- The New Decentralised Procedure – global marketing authorization
- Introduction of the European reference drug product
- Implementation of the decree “Sunset”
- Procedures for transparency

Dr. S. Keitel, BfArM

9.45 Experience in the implementation of the new European pharmaceutical legislation - in data exclusivity and transparency rules

B. Sträter, Attorney at Law

10.15 Advantages and challenges in the pharmaceutical legislation 2005 for generics

Dr. T. Benisheva, Faculty of Public Health

10.45-11.15 Coffee Break

EU Marketing Authorisation (MRP+DP+CMD/h/)

11.15 Industry regulatory perspectives - Challenges for generics in the new European *environment*

Dr. Th. Faust, Hexal AG

12.00 Presentation and discussion of the Guideline “Potential risk to public health” concerning medicines

Dr. B. Lehmann, BfArM

Discussion

13.00 – 14.00 LUNCH

- 14.00** CMD(h) Procedures and challenges – one year experience
Dr. P. Bachmann, BfArM
- 14.45** An industry perspective/Challenges for the implementation of the pharmaceutical Review 2005 in Bulgaria
Dr. A. Mladenov, Bulgarian pharmaceutical industry
- 15.10** Ten years European regulatory frame for changing the classification of the medical product (OTC-Switch) for human use (analysis and Member State examples)
Dr. I. Getov, Dr. G. Petrova, Faculty of Pharmacy

15.30 – 16.00 Coffee Break

Pharmacovigilance

- 16.00** European Legislation - Changes in the Pharmacovigilance system in the Review 2005
- 17.30** New Pharmacovigilance obligations in the authorisation procedures:
- The Pharmacovigilance System
 - The Risk Management System (ICH E2E)
- Dr. A. Thiele, BfArM; Dr. B. Borissov, Prescriptia Ltd*

19 April, 2007

Clinical Trials

9.00 Paediatric Medicines – the European regulatory framework, objective for the Regulation, Committee for clinical trials

The new Pediatric Regulation - Establishment and Role of the Pediatric Committee

Dr. D. Brasseur, Belgium

10.30 - 11.00 Coffee Break

11.00 Paediatric Medicines – the European regulatory frame, objective for the Regulation

- System of Incentives for paediatric research
- Extension of Supplementary Protection Certificate, Data exclusivity for Paediatrics Marketing Authorization – PUMA
RA. B. Sträter, Attorney at Law
- Consequences for drug development
Dr. K. Rose, Roche, Basel

12.00 – 13.00 Lunch Breack

Directive for clinical trials

13.00 The EU Clinical Trial Directive – legal background
Dr. B. Lehmann, BfArM

13.30 The authorization procedure for clinical trials –
implementation in Germany
Dr. H. Krafft, PEI

14.30 Panel Discussion

- Changes in the EU Pharmaceutical Legislation – chances and challenges for the Pharmaceutical Industry in Bulgaria

15.00 Closing Remarks

Dates:

18 April 2007 8.45 a.m. –5.30 pm

19 April 2007 9.00 a.m. – 3.00 p.m.

Venue:

**Hall "Maxima", Multifunctional Hall
St. Ekaterina - University Hospital
Penzo Slaveikov Str. 52 A
Sofia**

Cost contribution:

€ 60

BGL 120

Hotel Rila

Booking code: R: № 3 6 2 1 1

(Preis EZ: 50 - 60 E)

Tel: +359/2/93 79 130

Fax: +359/2/980 48 13

e-mail: rila@mbox.contact.bg

<http://www.online.bg/rila/index-en.htm>

**Stadtmitte, nur 4-5 Stationen mit
der Straßenbahn bis zum St.
Ekaterina University Hospital**

Hotel Central (4 Sterne)

Booking code: Medical University

(Preise, EZ : 70 - 90 E)

Sofia 1000, 52 Hristo Botev

Tel: +359/2/981 23 64

Fax: +359/2/986 45 61

e-mail: cental@central-hotel.com

www.central-hotel.com

**Stadtmitte, nur 4-5 Stationen mit
der Straßenbahn bis zum St.
Ekaterina University Hospital**

Central Hotel Forum (4 Strene)

Booking code: Medical University

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Tel: +359/2/954 44 44

Fax: +359/2/954 33 33

e-mail: cental@central-hotel.com

www.central-hotel.com

**Mit dem Taxi zum St. Ekaterina
University Hospital (ca. 2-3 Euro)**

Hotel Anel (5 Sterne)

Booking code: MU/DGRA

(Preis EZ: 90 - 110 E)

14 Todor Alexandrov Blvd.

Tel: +359/2/911 99 00

Fax: +359/2/911 97 61

hotelanel@hotelanel.com

www.hotelanel.com

**Mit dem Taxi bis St. Ekaterina
University Hospital (ca. 3-4 Euro)**

Registration: Dr. Natalia Shtereva, E-mail: mu_dgra@abv.bg,

office phone: +359/2/943 23 89, Fax: +359/2/943 21 27



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Sofia, 18 - 19 April, 2007
Chairman: Burkhard Sträter, Attorney at Law**

Please, e-mail to mu_dgra@abv.bg or fax to : +359 2 9432 127

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Conference fee: 60 Euros or 100 BGL + 20 BGL VAT

The Conference registration fee covers: registration, participation in the workshop, coffee breaks,
Please note that lunches & dinner are not covered.

Payment:

I will pay by *Credit card*
 Bank transfer
 Directly at the start of the workshop

(You will receive registration and the form for money transfer)

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