

1ST SOUTH EAST EUROPE PHARMACEUTICAL SYMPOSIUM 2005

HILTON SOFIA, BULGARIA

MEETING THE EUROPEAN CHALLENGE FOR THE NATIONAL DRUG REGULATORY AGENCIES AND THE GENERIC MEDICINES INDUSTRY

21 APRIL 2005 – HILTON HOTEL SOFIA

Organised by the Association of Bulgarian Pharmaceutical Manufacturers (ABPhM) with the kind participation of the Bulgarian Drug Agency (BDA) and the European Generic Medicines Association (EGA)



Bulgarian Drug Agency
Ministry of Health



General Sponsors:



Wednesday	20 April 2005	Hilton Sofia
20:00	Welcome cocktail reception	
Thursday	21 April 2005	Hilton Sofia
08:00	Registration and coffee	
09:00	<u>I Session – Open part</u>	Co-Chairs: ABPhM, BDA, EGA

Opening speeches: Ministry of Health, Bulgarian Drug Agency, Parliamentary Commission on Health, EGA, ABPhM

- Key Note Speech: "Managing the Balance in the National Health Policy": A. Shterev, Chairman of Bulgarian Parliamentary Commission on Health
- "Impact of EU Enlargement on Generic Industry": Gorazd Hladnik, Slovenian Pharmaceutical Manufacturers Association
- "Measures to Promote Generic Medicines in EU – Industry Perspective": Greg Perry, Director General, EGA

10:15 - 10:30 Coffee Break

- **“Challenges of the EU Accession for the Drug Regulation in Romania”:** *Rodica Badescu – Head of the Evaluation and Authorisation Department, Romania*
- **“Challenges of the EU Accession for the Romanian Generic Medicines Industry”:** *Laszlo Kelemen- Gedeon Richter Romania*
- **“Role of generic medicines in public health in South East Europe”:** *Ljiljana Stojanovic, International Cooperation and Development Manager, Medicines and Medical Devices Agency, Serbia*
- **“Challenges of the EU Accession for the Bulgarian Generic Medicines Industry”:** *Vladimir Afenliev, Member of the ABPhM Board, Actavis - Bulgaria*
- **“Challenges of the Accession for the Bulgarian Drug Agency”:** *Emil Hristov, Executive Director, Bulgarian Drug Agency*

12:30 - 13:00 Press Conference

13:00 - 14:00 Networking Lunch

14:00 II Session – Closed part
EGA Round Table Discussion

Chair: Greg Perry, EGA

Future environment for generics in South East Europe

“Experience of the CADREAC Agreement “*Tamas Paal- OGYI Hungarian Agency for Medicinal Products*

“How to cope with the changes in regulatory and legal environment? – Experience of the Drug Regulatory Agencies”-
Vesna Koblar - Slovenian Agency for Medicinal Products

Experience from negotiation process of the new Member States: *Representatives of Drug Regulatory Agencies, EU Accession negotiators and Generic Medicines Industry from new Member States*

Exchange of views and experiences by: *Representatives of Drug Regulatory Agencies, EU Accession negotiators and Generic Medicines Industry from Bulgaria, Romania, Macedonia, Croatia, Serbia, Bosnia and Hercegovina, Turkey, Poland, Slovenia, Hungary*

Key points to be discussed:

- Data Exclusivity
- SPC
- Update of the existing dossiers
- Bolar provision
- Transitional measures

17:30 End of Conference

19:00 Dinner