Gain invaluable insight into:

- What has the first year of accession brought to the market and healthcare systems?
- How CE countries are implementing Pharma Review into national legal frameworks.
- New data exclusivity for generics and IP protection trends.
- Regulatory challenges in CEE.
- How can companies from other regions enter the CEE market?
- How to expand beyond local markets.
- Czech reimbursement systems.
- What impact has EU enlargement made on the Polish pharma industry.

Key benefits of attending:

- Informal networking with regulators and market leaders.
- Benchmarking a variety of company experiences and approaches.
- Regulator’s point of view.

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Day 1
13th October 2005

08:30 Registration and Coffee
09:00 Opening Remarks from the Chair

09:10 Keynote Presentation
What has the First Year of Accession Brought to the Market and Healthcare Systems
- What happened in the last year – an international outlook
- General trends in the pharmaceutical industry
- The first year after accession – Evaluation of the outcome: Developments affecting the industry
- Assessing the impacts of EU enlargement after one year
- Challenges of post EU enlargement – How it affected local industry competitiveness
- Update on regulatory affairs proceedings in the new EU. How does the EU regulatory system work?
- How to stay competitive in the changing world?

Gyorgy Thaler
Development Director
Gedeon Richter, Hungary

FOLLOW-UP ASSESSMENT OF THE IMPACT OF EU ENLARGEMENT UPON CEE PHARMACEUTICAL MARKETS

09:50 Czech Republic Reimbursement System
- The comparison of the reimbursement system in the Czech Republic with other countries
- Reimbursement system in the Czech Republic: strengths and weaknesses
- Reimbursement system in the Czech Republic – improving the quality of healthcare system

Katarina Bartikova
Director of Pharmaceutical Department
Ministry of Health, Czech Republic

10:30 Morning Coffee and Networking

10:50 Hungary in the Enlarged Europe
- Priority setting in the drug reimbursement system
- Price volume agreements between manufacturers and the Government
- Experiences with the implementation of the EU Directive 89/105/EEC on transparency

Imre Boncz
Head of Department of Health Policy and Co-ordination
National Health Insurance Fund, Hungary

11:30 Healthcare Reforms in Slovakia – Setting Up an Innovative Reimbursement System
- Changes in pharmaceutical policy
- Affordable reimbursement system
- Criteria for reimbursement

Angelika Szalayova
Drug Policy Specialist
Health Policy Institute, Slovakia

12:10 Luncheon
13:10 Coffee and Networking

13:30 How CE Countries are Implementing Pharma Review into National Legal Frames
- New pharmaceutical legislation in the EU and the implications
- How are new member states going to harmonise the directive

Lumir H. Krocik
Executive Director
Czech Association of Pharmaceutical Firms (CAFF)

14:30 Hungary: Examination of the Pharmaceutical Industry after Accession
- Impact assessment
- Regulatory issues
- Current trends and future directions

Prof. Tamas Paal
Director General
National Institute of Pharmacy, Hungary

15:10 Afternoon Tea and Networking

IDENTIFYING OBSTACLES AND MAPPING OUT THE SOLUTIONS

15:30 New Data Exclusivity for Generics and IP Protection Trends
- Major new features of new data exclusivity law under EU Directive 2004/27
- Impact of new features on the generic industry
- Relationship between data exclusivity and patent rights, with particular reference to so-called “second indication inventions”

Dr. Attila Mandi
Head of Patent Department
Egis, Hungary

15:50 Polish Perspective: Local and Regional Markets
- What impact has EU enlargement made on the Polish pharma industry
- Regulatory environment: harmonisation challenges
- Targeting other pharma markets
- Opportunities and risks in the Polish market

Jacek Glinka
CEO
Polpharma, Poland

16:30 Regulatory Challenges in CEE
- Access to the market: key parameters
- Regulatory issues
- IP protection

Radunka Cvejic
External Affairs Director
AstraZeneca, Poland

17:10 Slovenian Pharmaceutical Market – Comparison with Other CEE Markets
- Overview of the local market and comparison with other pharma markets
- Competitiveness of the local pharmaceutical industry
- How to succeed in new markets (CEE/EU/CIS/US)

Gorazd Hladnik
President
Slovenian Pharmaceutical Manufacturers Association

17:50 Transparency

Pavol Mazan
Executive Director
MAFS, Czech Republic

18:30 Closing Remarks from the Chair and Close of Day One
Tax and legal risk management (TR&LM) in pharmaceutical companies
- Regulatory environment – need of public consultations:
  - Forms of dialog between companies and state authorities
  - Active participation of pharmaceutical industry
- “Margin dispute” and its impact on TR&LM in Poland:
  - Business structures used by pharmaceutical companies
  - Uncertainty of interpretation and application of the law
- TR&LM internal procedures:
  - Sample procedures related to marketing activities
- Practical problems – potential solution

Agnieszka Tasiakiewicz
Tax Partner
Ernst & Young

SCG, Macedonia and Bosnia and Herzegovina: Comparative Analysis of the Regional Pharma Markets
- Regional regulatory authority – what are the chances?
- Unified market-realistic prospects?
- Latest trends

Marko Milojicic
Head of Industrial Property Department
Hemofarm, Serbia & Montenegro

Romanian Pharma Market: New Pharma Legislation and the Implication on Candidate Countries
- Changes in the national pharmaceutical legislation
- Challenges for the Drug Regulatory Authority
- Implication for the pharmaceutical sector
- Impact on health professionals and patients
- Perspectives of the local pharmaceutical industry

Rodica Badescu
Vice President
National Medicines Agency, Romania

Bulgarian Pharma Market
- Market overview
- Existing regulatory status and comparison with EU legislation
- Benchmarking with other candidate countries
- Forthcoming challenges of Bulgarian pharma companies
- Expectations of Bulgarian Manufacturers from the EU enlargement
- Opportunities in the Bulgarian pharma market for other EU members

Tahsin Yuksel
Country Manager
Actavis, Bulgaria

Building a New Company in CEE: The Amgen Experience
- Opportunity
- Entry strategies
- Structuring for success
- Selling model
- Distribution model
- Recruiting and managing the best team
- How to handle ethics and transparency

Richard Davies
General Manager CEE
Amgen, Austria

How to Compete in the Russian Pharmaceutical Market
- Market overview: trends and dynamics
- Regulatory issues and healthcare system reforming
- Competition profile: Products and manufacturers
- Key market players
- Drug promotion system: local features

Oleg Feldman
General Director
Comcon-Pharma, Russia

Potential Influence of Indian Generics on CEE
- East-West divide: science and technology benchmarks across Europe
- What we have and what we don’t, or maximising production with scarce resources
- The position of the CEE region on the global scene
- What we can capitalise on: innovativeness as counterbalance

Erno Duda
CEO and President
Solvo Biotechnology, Inc., Hungary

Zentiva’s Business Strategy and the Role of Corporate Governance
- Why corporate governance?
- Legal vs. managerial requirements
- Preparing and approving commercial strategy
- Legal structure – support business needs

Petr Polievka
Corporate Governance Director
Zentiva, Czech Republic

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