



CEE - Regulatory Challenges in the Pharmaceutical Market
 3rd & 4th December 2003 Jurys Hotel, Great Russell Street, London, UK
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Standard Fee
 £1099 plus VAT @ 17.5% (£192.33) = £1291.33 £ _____

Special price for delegates travelling from accession countries * - £200 discount!
 £899 plus VAT @ 17.5% (157.33) = £ 1056.33 £ _____

* Delegates based in Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia & Slovenia may be eligible for the £200 discount. Discounts are at the discretion of IBC.

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"All hot topics concerning accession countries were covered in detail"
GlaxoSmithKline, CEE Regulatory 2002

£200 discount for all delegates from accession countries.
See booking form for details

Central & Eastern Europe - Regulatory Challenges in the Pharmaceutical Market

Wednesday 3rd & Thursday 4th December 2003, Jurys Hotel Great Russell Street, London, UK

Equip yourself with the most up-to-date information to fulfil May 2004 EU regulatory requirements. 5 key reasons to attend:

- ✓ Timely information for those involved in the final critical stages of preparation for the May 2004 accession deadline:
 - EU review: Updates and implications for accession countries
 - CADREAC and PERF update: Review of 2003 and changes for 2004
 - 10 country updates on the practical aspects pre and post EU accession
 - Registration challenges for the pharmaceutical industry in accession countries: Views of multinational and domestic companies
- ✓ Latest updates & head-to-head comparisons from **10** accession countries
- ✓ Tried and tested approaches to transform EU standards into daily working practices: Practical advice and first hand insights to ensure a smooth transition to EU compliance
- ✓ Learn from those at the cutting edge of regulatory reforms:
 - Pharmaceutical case studies
 - Regulators from accession countries
- ✓ The annual meeting place for those involved in Pan-European pharmaceutical regulation. **Now in its 11th year**, over 1000 people from 40 countries have benefited from this series to date

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The enlargement of the EU with the accession of ten new member states is only months away. The planned accession date of 1st May 2004 means that there is little time left to deal with the outstanding issues to ensure that all regulatory aspects are in line with EU procedures. Many complex issues still remain to be resolved, and this 11th IBC conference on 'Central and Eastern Europe - Regulatory Challenges in the Pharmaceutical Market' will cover many of these topics in the practical and professional manner which is the standard for this conference.

The EU Review will impact considerably on the ten accession countries and the conference will start with an update on this crucial issue. The work done through CADREAC and PERF will also be presented.

As progress with regulatory issues in each of the accession countries is different, the conference will give an update of each of the ten accession countries:

Cyprus • Czech Republic • Estonia • Hungary • Latvia • Lithuania • Malta • Poland • Slovakia • Slovenia

The views of the multinational pharmaceutical industry and domestic CEE pharmaceutical industry on registration issues in acceding countries will also be presented.

IBC's CEE regulatory conferences have always been well attended and have been considered to be extremely professional, well run and organised, and provide useful practical guidance on how to quickly and successfully register products in these countries. You cannot afford to miss this prestigious conference.

Day 1: Wednesday 3 December 2003

09.00 Registration and Coffee

09.30 Chair's Introduction

Chairman: **Prof Tamas Paal**, Director, **National Institute of Pharmacy**, Hungary

09.40 **EU Review: Update and Implications for Acceding Countries**

- State of play in the legislative process, expected time schedule and outcomes
- Derogation clauses and 'specific mechanism' in the Accession Treaties
- Elements of Review 2001 with specific relevance for acceding countries before accession and after accession
- Possible implications for markets, health care systems and public health of accession and of Review 2001

John Lissman, Policy Advisor, **Medicines Evaluation Board**, The Netherlands

10.20 **CADREAC and PERF Update: Review of 2003 and Changes for 2004**

- What are the changing requirements?
 - CADREAC simplified authorisation procedures
 - Practical examples of current problems
 - Access to relevant information
 - Insights into 2004
 - Continuation of PERF
 - Essentials for the pharmaceutical environment
- invited speaker: **Dr Michal Pirozynski**, Director, **Office of Medicinal Products, Medical Devices and Biocides**, Poland

11.00 Morning Coffee

Country Updates on Practical Aspects Pre and Post EU Accession

As regulatory progress in each of the accession countries is different, the conference will give an update of each of the ten accession countries. Each country will give an update on the following:

- Transitional periods and procedures
- Practical arrangements for phasing in CP and MRP
- Deadlines for submitting CADREAC simplified procedure applications
- Handling of pending applications – practical details
- Referrals before and after accession
- Re-use MRP window for period 1.5.2004-31.12.2004 for EU format of the dossier
- Updating of dossiers
- Planned procedures for handling parallel import applications
- Progress with CTD
- SmPC harmonisation
- Patent and data exclusivity

11.30 **Czech Republic**
invited speaker: **Dr Milan Smid**, Director, **State Institute for Drug Control**, Czech Republic

12.10 **Slovakia**
Prof L'udevit Martinec, Director, **State Institute for Drug Control**, Slovakia

12.50 Lunch

14.05 **Estonia**
Dr Kristin Raudsepp, Director General, **State Agency of Medicines**, Estonia

14.45 **Latvia**
Mr Janis Ozolins, Director, **State Agency of Medicines**, Latvia

15.25 Afternoon Tea

15.55 **Lithuania**
Professor Vytautas Basys, Head, **Lithuanian State Medicines Control Agency**, Lithuania

16.35 **Slovenia**
Dr Vesna Koblar, Counsellor to the **Government Agency for Medicinal Products**, Slovenia

17.15 Close of Day One and Drinks Reception



Practical Information to Meet May 2004 Accession Requirements

Day 2: Thursday 4 December 2003

- 09.00 Coffee
- 09.25 Chair's Introduction
Chairman: **Nigel Petter**, Head of Regulatory Affairs for Emerging Markets, **AstraZeneca**, UK

Registration Challenges for the Pharmaceutical Industry in Acceding Countries

- 09.30 **Views of a Multinational Pharmaceutical Company**
This session will address the main challenges for multinational pharmaceuticals operating in CEE and highlight the impact of May 2004 on regulatory processes.
Nigel Petter, Head of Regulatory Affairs for Emerging Markets, **AstraZeneca**, UK

- 10.10 **Views of a CEE Based International Pharmaceutical Company**
- Market environment
 - Key challenges & opportunities in Poland
 - International regulatory and development
 - Manufacturing & quality
 - Partnering with regulatory agencies
 - 5 years forward - a new map
- Martin Oxley**, General Manager, **Pliva**, Poland

- 10.50 Morning Coffee

Country Updates on Practical Aspects pre and post EU Accession

- 11.20 **Hungary**
Prof Tamas Paal, Director, **National Institute of Pharmacy**, Hungary
- 12.00 **Poland**
invited speaker: **Dr Michal Pirozynski**, Director, **Office of Medicinal Products, Medical Devices and Biocides**, Poland
- 12.40 Lunch
- 13.55 **Cyprus**
Speaker to be announced.
Please visit www.abc-lifesci.com/ceeregulatory
- 14.35 **Malta**
Lilian Wismayer, **Medicines Regulatory Unit, Health Division**, Malta
Anne Gray, **Pharmaceutical Assessor, Irish Medicines Board**, Ireland

- 15.15 Afternoon Tea

- 15.45 **Conclusions and Recommendations**
This round up session will feature the speakers from the past 2 days. They will collectively address the key questions that have arisen from the meeting and highlight future recommendations. This will be followed by an interactive Q&A session giving attending delegates a final opportunity to flush out any remaining concerns.

- 16.30 Close of conference

Panel Session

Tackling the Most Topical Themes - Proven Event Quality

For the past 10 years "CEE - Regulatory Challenges in the Pharmaceutical Market" has consistently been providing the regulatory community with key information to keep in step with changing requirements. Past delegate feedback includes:

"Very well organised conference. All hot topics concerning accession countries were covered in detail" CEE 2002

"A very good opportunity to get an overview of the current situation and requirements in the region and be informed about future trends" CEE 2001

"A very interesting update of regulatory issues facing the ECC candidate countries" CEE 2000

"It was certainly worth the time and money. One of the best organised conferences I've been to" CEE 1999

The Meeting Place for the CEE Regulatory Community - Proven Attendee Quality

Interact with key regulatory figures and benefit from the experience of industry peers. Over 100 participants from 27 countries attended this conference in 2002



- Regulatory Associate 11%
- Head of Regulatory Affairs 10%
- Registration Manager 8%
- Regulation Manager 13%
- Regulatory Advisors/Specialist 10%
- Lawyers/of Counsel 8%
- Project Leaders 8%
- CEO/VP/Director/Senior Manager 28%
- Other 4%

source: IBC CEE Regulatory Challenges in the Pharmaceutical Market 2002

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IBC's regulatory series is a portfolio of leading conferences, exhibitions and vocational training courses with a global track record of over 15 years. The Series presents senior audiences with the timely identification of critical changes and the fastest, most cost-effective route to full compliance. Our high-quality independent programmes are a time-efficient way for industry to keep in step with the regulators. www.abc-lifesci.com/regulatory.

Forthcoming events in this series that may be of interest to your or your colleagues include:

- **Clinical Trials in central and Eastern Europe** 21 - 22 October 2003, Vienna, Austria
- **Parallel Trade, Patents and Generics in Central and Eastern Europe**, 23 - 24 October 2002, Vienna, Austria
- **Registration of Pharmaceuticals in Europe: Requirements of the CTD Dossier** 24 - 27 November 2003, Vienna, Austria
- **Drug Safety in 2004** 1 - 2 December 2003, Munich, Germany