

**“Communicating the Risk in Pharmacovigilance:  
Are We Going in the Right Direction?”  
1-2 October, Hotel Kolovare, Zadar**

**Thursday, October 1, 2009**

**Official language: English**

- 8:00-9:00      Registration
- 9:00-9:20      Welcome address
- Moderator:      Selma Arapović*
- 9:20-9:45      Communicating the Risk in Pharmacovigilance: Are We Going in the Right Direction?  
*(Viola Macolić Šarinić, Agency for Medicinal Products and Medical Devices-ALMP, Croatia)*
- 9:45-10:10     The WHO Global Pharmacovigilance Programme and its Communication Challenges  
*(Sten Olsson, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala)*
- 10:10-10:20    Panel discussion
- 10:20-10:50    Coffee break
- Moderator:      Viola Macolić Šarinić*
- 10:50-11:15    Pharmacovigilance Communications: A Regulator's View  
*(Mick Foy, Medicines and Healthcare Products Regulatory Agency-MHRA, UK)*
- 11:15-11:40    The Development and Performance of Pharmacovigilance Inspections  
*(Nele Matthijs, Federal Agency for Medicines and Health Products-Fagg/Afmps, Belgium)*
- 11:40-12:05    Risk Perception and Communication in Serbia  
*(Marija Petronijević, Agencija za lekove i medicinska sredstva Srbije-ALIMS, Serbia)*
- 12:05-12:30    Sharing Pharmacovigilance Information in a Complex Communication Environment  
*(Niamh Arthur, Irish Medicines Board-IMB, Ireland)*
- 12:30-12:40    Panel discussion
- 12:40-14:00    Lunch
- Moderator:      Marinko Bilušić*
- 14:00-14:25    A Global Approach to Benefit-Risk Assessment throughout the Life-Cycle: Roche –  
A Case Study  
*(Michele Bortolini, Roche/Croatian Association of Research-based Pharmaceutical Companies-CARPC)*
- 14:25-14:50    Alkaloid AD – Skopje: Overview of Pharmacovigilance System and  
Pharmacovigilance Activities *(Natasha Nasteva, Alkaloid AD Skopje, Macedonia)*

- 14:50-15:15 No Adequate Risk Management without Adequate Risk Communication  
(*Vladimir Sužnjević, Genzyme/Croatian Association of Research-based Pharmaceutical Companies-CARPC*)
- 15:15-15:25 Panel discussion
- 15:25-15:45 Coffee break
- Moderator: Dubravka Nikšić*
- 15:45-16:10 Communication of Risk in Pharmacovigilance - Current Practice at BSP  
(*Helmut Oberender, Bayer Schering Pharma/Croatian Association of Research-based Pharmaceutical Companies-CARPC*)
- 16:10-16:35 Pharmacovigilance System and Risk Management – Roles and Responsibilities of Pharmaceutical Industry in Croatia  
(*Tatjana Ajhler Đuretek, Belupo d.d./Pharmaceutical Manufacturers Associations within the Croatian Employers' Association-HUP, Croatia*)
- 16:35-16:45 Panel discussion
- 18:00 Tourist tour of Zadar
- 20:00 Conference dinner

**Friday, October 2, 2009**

*Moderator: Darko Krnić*

- 9:00-9:30 Genie in a Bottle – How Fruit Juices Interact with Drug Treatment  
(*Christoph Ritter, Institut für Pharmazie, Ernst-Moritz-Arndt-Universität, Greifswald, Germany*)

**Official language: Croatian**

- 9:30-10:30 Workshop- New Ordinance on Pharmacovigilance (*ALMP*)
- 10:30-10:45 Coffee break

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- 10:45-12:00 Workshop-EudraVigilance (*EMEA-Sabine Brosch, Suresh Ramachandran and ALMP*)
- 12:00-13:30 Lunch

**Official language: Croatian**

- 13:30-16:00 Workshop-Safety Variations and PSUR/Discussion (*ALMP*)