EU Regulatory Network

Challenges and Opportunities for Croatia

5th anniversary of the ALMP

13-14 November 2008

Croatian Cultural Centre at Sušak, Rijeka, Croatia

REPUBLIKA HRVATSKA
REPUBLIC OF CROATIA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

The conference is organised within the framework of the Transition Instrument for Pre-accession Assistance Programme of the European Commission, designed to support pre-accession activities of Candidate Countries and of the Croatian Agency for Medicinal Products and Medical Devices (ALMP), under the auspices of the Croatian authorities.

The primary objectives of this conference are to continue the international dialogue on medicines, to give an overview of EU legislation governing the regulation of medicines, and to provide feedback on the practical application of the *acquis communautaire* and legal aspects of its implementation.

The conference will also be an opportunity to identify differences between existing legislation in Croatia and in the EU, and to discuss issues that may be encountered as Croatia moves towards membership of the European Union.

This conference, organised for the 5th anniversary of the ALMP, targets scientific audiences, and will include specific activities with a view to informing the full cross-section of stakeholders in Croatia.

Welcome to Rijeka! Dobro Došli u Rijeku!

On behalf of the European Medicines Agency (EMEA), I am pleased to invite you to this regulatory conference in Rijeka, Croatia.

As part of wider European efforts to prepare for the eventual accession of Croatia to the European Union (EU), the EMEA has been working closely with the Croatian authorities — particularly the Agency for Medicinal Products and Medical Devices (ALMP) — on matters relating to the regulation of medicines in Europe.

At our first conference, in Split, in April 2007, we were able to establish some of the necessary groundwork for cooperation between Croatia and the relevant EU regulatory authorities in this area, and were subsequently able to invite Croatian experts to participate as observers in several EMEA scientific meetings, workshops and training courses.

Building on this initial success, the Rijeka conference will be a further opportunity to strengthen contacts between the EU and Croatian regulatory authorities, to promote understanding of the legislation and regulatory practices that underpin the European regulatory system, and to discuss practical measures that will help to ensure Croatia's eventual integration into the European medicines network will go smoothly.

I hope you will be able to join us in Rijeka.

Yours sincerely,

Thomas Lönngren

Executive Director, EMEA

Dear Participant,

Allow me to give you a warm welcome to this conference, co-organised by the EMEA and the ALMP.

This also marks the fifth anniversary of the establishment of the Agency for Medicinal Products and Medical Devices. We are very proud of our many accomplishments to date in regulating the healthcare-products market in our country.

However, this success would not be possible if we did not constantly invest in the education of our staff, particularly during this period of harmonisation with the more and more dynamic *acquis communautaire*.

Therefore, cooperation with the European Medicines Agency and the medicines agencies of the EU Member States is of the utmost importance, in order to ensure that we are as prepared as possible to function in the integrated European regulatory network.

I believe that this conference will be an excellent opportunity for us all, regardless of whether we come from competent authorities, industry or academia, to exchange experiences and to expand our knowledge in the field of pharmaceutical legislation that is so essential to the protection of our patients.

Best regards,

Siniša Tomić

Agency for Medicinal Products and Medical Devices, Croatia

Programme overview

Thursday, 13 November 2008

09.30 – 10.30	**Welcome address and keynote address ***
	Award in pharmacovigilance
10.45 – 11.15	***Coffee break***
11.15 – 12.45	**Pharmaceutical regulation**
	Pharmaceutical policies
	New EDQM road
	EMEA-CHMP Think-Tank on Innovation, Research and Drug Development
12.45 – 14.00	***Lunch***
14.00 – 16.00	**EU regulatory authorities**
	The post-accession experience
	How can non-contributing agencies be encouraged to participate
	Transatlantic simplification of administrative procedures
16.00 – 16.30	***Coffee break***
16.30 – 18.00	**EU regulatory network**
	Priorities of the regulatory authorities
	Development of an efficient regulatory system in Europe – point of view of an NCA
	Advances in Croatia's rapprochement to the EU
19.00 – 20.00	***Welcome reception***
20.00 – 22.00	***Conference dinner***

* simultaneous interpretation

Programme overview

Friday, 14 November 2008

09.00 – 10.30	**Medicinal products**
	The role of the PDCO
	Advanced therapies
	Revised guidelines on bioequivalence
10.30 – 11.00	***Coffee break***
11.00 – 12.30	**Regulatory affairs**
	Overview of review process interactions
	Impact of new variation system on NCAs
	E-submission
12.30 – 14.00	***Lunch***
14.00 – 15.15	**Pharmacovigilance**
	European Commission's proposal for pharmacovigilance
	EudraVigilance
	Risk-management plans
15.15 – 15.30	***Coffee break***
15.30 – 17.15	**Inspections**
	GCP inspections
	Fighting pharmaceutical crime and counterfeit medicines
	GMP
	Pharmacovigilance inspections
17.15	***Closure of the conference***

Programme details – Thursday, 13 November 2008

Conference Moderation

Gloria Fabijanić Jelović

09.30 **Welcome address**

Sylvie Bénéfice, EMEA

Siniša Tomić, ALMP, Croatia

09.50 – 10.30 **Keynote address**

Initiative of the EU Commission: Public consultation

Martin Terberger, European Commission, DG Enterprise

Croatian authorities

10.30 **Award in pharmacovigilance**

Musical interlude

10.45 – 11.15 ***Coffee break***

11.15 – 12.45 **Pharmaceutical regulation**

Chair: Xavier Luria, EMEA

Co-chair: Milena Jadrijević Mladar Takač, FBF, Croatia

11.20 **Pharmaceutical policies**

Milan Smid, WHO

11.40 **New EDQM road**

Susanne Keitel, EDQM

12.00 **EMEA-CHMP Think-Tank on Innovation, Research and Drug Development**

Xavier Luria, EMEA

12.20 **Panel discussion**

12.45 – 14.00 ***Lunch***

Programme details – Thursday, 13 November 2008

14.00 – 16.00 EU regulatory authorities

Chair: Arielle North, EMEA

Co-chair: Maja Jakševac Mikša, HFD, Croatia

14.05 The post-accession experience

Rodica Badescu, Romanian NMA, Romania

14.35 How can non-contributing agencies be encouraged to participate

Kristin Raudsepp, Estonian State Agency

15.05 Transatlantic simplification of administrative procedures

Arielle North, EMEA

15.35 Panel discussion

16.00 – 16.30 Coffee break

16.30– 18.00 EU regulatory network

Chair: Aginus Kalis, Dutch Medicines Board

Co-chair: Siniša Tomić, ALMP, Croatia

16.05 Priorities of the regulatory authorities

Aginus Kalis, Dutch Medicines Board

16.35 Development of an efficient regulatory system in Europe:

Point of view of an NCA

Jean Marimbert, AFSSAPS, France

17.05 Advances in Croatia's rapprochement to the EU

Siniša Tomić, ALMP, Croatia

17.35 Panel discussion

19.15 – 20.00 Welcome reception

20.00 – 22.00 Conference dinner

Hotel Kvarner, P. Tomašića 1-4, HR-51410 Opatija

For more information about the schedule and pick-up location, please refer to the transfer board at the main entrance.

Programme details – Friday, 14 November 2008

09.00 – 10.30 Medicinal products

Chair: Gérard Pons, Hôpital Saint-Vincent de Paul,
Service de Pharmacologie Périnatale et Pédiatrique, France

Co-chair: Dinko Vitezić, MF Rijeka, Croatia

09.05 The role of the Paediatric Committee

Gérard Pons, Hôpital Saint-Vincent de Paul,
Service de Pharmacologie Périnatale et Pédiatrique, France

09.25 Advanced therapies

Anthony Humphreys, EMEA

09.45 Revised guidelines on bioequivalence

Monica Edholm, MPA, Sweden

10.05 Panel discussion

10.30 – 11.00 Coffee break

11.00 – 10.30 Regulatory affairs

Chair: Anthony Humphreys, EMEA

Co-chair: Anita Filipović Sučić, ALMP, Croatia

11.05 Overview of review process interactions

Anthony Humphreys, EMEA

11.25 Impact of new variation system on NCAs

Susanne Winterscheid, BfArM, Germany

11.45 E– submission

André Lhoir, AFMPS/FAGG, Belgium

12.05 Panel discussion

12.30 – 14.00 Lunch

Programme details – Friday, 14 November 2008

14.00 – 15.30 Pharmacovigilance

Chair: Thomas Goedecke, EMEA

Co-chair: Viola Macolić Šarinić, ALMP, Croatia

14.05 **European Commission's proposal for pharmacovigilance**

Martin Terberger, European Commission, DG Enterprise

14.25 **EudraVigilance**

Thomas Goedecke, EMEA

14.45 **Risk-management plans**

Stella Blackburn, EMEA

15.05 **Panel discussion**

15.15 – 15.30 ***Coffee break***

15.30 – 17.15 Inspections

Chair: Gabriele Schwarz, BfArM, Germany

Co-chair: Hrvoje Tumir, ALMP, Croatia

15.35 **GCP inspections**

Gabriele Schwarz, BfArM, Germany

15.55 **Fighting pharmaceutical crime and counterfeit medicines**

Roy Vancauwenberghe, FAGG/AFMPS, Belgium

16.15 **GMP**

Lorraine Nolan, Irish Medicines Board, Ireland

16.35 **Pharmacovigilance inspections**

Johanna Piper, MHRA, UK

16.55 **Panel discussion**

17.15 ***Closure of the conference***

Sylvie Bénéfice, EMEA

Siniša Tomić, ALMP, Croatia

Glossary

AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé, French Regulatory Agency
AFMPS / FAGG	Federal Agency for Medicines and Health Products, Belgian Regulatory Agency
ALMP	Croatian Agency for Medicinal Products and Medical Devices
BfARM	Federal Institute for Medicines and Medical Devices, German Regulatory Agency
CHMP	Committee for Medicinal Products for Human Use
DG	Directorate General
EDQM	European Directorate for the Quality of Medicines & HealthCare
EMEA	European Medicines Agency
EU	European Union
GCP	Good clinical practice
MHRA	Medicines and Healthcare products Regulatory Agency, UK
MPA	Medical Products Agency, Swedish Regulatory Agency
NCA	National competent authority
NMA	National medicine agency
PDCO	Paediatric Committee
WHO	World Health Organization