Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede, šumarstva i vodoprivrede,
Uprava za veterinu

Republic of Serbia
Ministry of Health
Ministry of Agriculture, Forestry and Water Management,
Veterinary Directorate

alims
Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/663451/2010

Human and veterinary pharmaceuticals regulation

Conference programme

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belgrade, Serbia

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IPA Programme overview

The European Commission has set up an Instrument for Pre-accession Assistance (IPA) Programme to support pre-accession activities of the Beneficiaries, i.e. Croatia, the former Yugoslav Republic of Macedonia, Turkey, Albania, Bosnia and Herzegovina, Montenegro, Serbia and Kosovo (under UNSC Resolution 1244/99), in the activities of the European Medicines Agency.

This IPA Programme involves a number of meetings, training sessions and conferences throughout the year, designed to assist these national competent authorities with the preparations for their future involvement in the Agency's activities.

Main objectives

The aim of this project is to build contacts and relationships between the European Medicines Agency and the Beneficiaries mentioned above, in preparation for these countries' future collaboration in the EU regulatory network.

This project aims:

- to prepare the National Competent Authorities of the Beneficiaries that are active in the field of medicinal products for their future participation in the Agency's networks;
- to contribute to the creation of communication and information exchange systems enabling the future participation of the Beneficiaries in the Agency's networks.

The project is designed to establish with the Beneficiaries an internationally open dialogue and working mechanisms that help to facilitate the adoption of common technical requirements, to identify areas where additional action might be needed to ensure the smooth transposition of the EU *acquis communautaire* into national legislation in the Beneficiaries, and to prepare for those countries' participation in the work of the European Medicines Agency's committees.

This project also ensures appropriate exposure and involvement in the EU's telematics initiatives to foster compliance with legislated requirements (primarily, but not exclusively, Regulation 726/2004 and Directive 2001/20/EC), and to enable the Beneficiaries to become part of the electronic network upon accession.

Welcome to Belgrade! Dobro Došli u Beograd!

On behalf of the European Medicines Agency, I am pleased to invite you to this regulatory conference in Belgrade, Serbia.

The conference is supported by the European Commission, as part of the preparation for the enlargement process and organised in collaboration with the National Competent Authorities in Serbia active in the field of medicinal products, i.e. the Ministry of Health and the Ministry of Agriculture, Forestry and Water Management under the umbrella of the Medicines and Medical Devices Agency of Serbia (ALIMS).

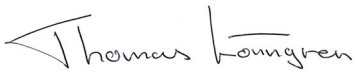
The conference will provide key information about legislative, procedural and scientific aspects of medicines regulation in the EU such as the *acquis communautaire*, with a view to informing the full cross-section of stakeholders in Serbia.

It is also a great opportunity for us to get to know our esteemed Serbian colleagues better, and to discuss with you in detail your views, expectations and reservations about the challenges and opportunities that lie ahead.

I am confident that this conference will establish the cooperation between Serbia and the European regulatory network in order to support your efforts towards EU membership.

I look forward to welcoming you in Belgrade.

Yours sincerely,



Thomas Lönngren

Executive Director
European Medicines Agency

alims
Agencija za lekove
i medicinska sredstva Srbije
Medicines and Medical Devices
Agency of Serbia

Dear Colleagues and Friends,

I am proud to welcome you to this conference, organized with European Medicines Agency (EMA) in the frame of IPA 2009-2011 and for the first time co-hosted by Serbia.

This conference is organized by the EMA, the Medicines and Medical Devices Agency of Serbia (ALIMS), the Ministry of Health of the Republic of Serbia and the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management of the Republic of Serbia.

As partners on this conference and in this programme, the EMA and Serbian authorities work on a common goal - better and safer medicines for patients in Serbia and Europe through integrated legislation and regulatory networking.

It is also part of the continuous effort made by our employees to maintain the same high level of commitment in their everyday tasks - never letting the interest of the patient out of sight. Therefore, we can say, with good arguments, that we have already achieved European and international standards, in almost all aspects of the medicines and medical devices market, that are regulated and supervised by our national and government institutions.

In the last six years, ALIMS became a healthy and strong national regulatory body concerned about its self-development, especially focused in human resources investment which is even more important than investment in equipment.

Fruitful and comprehensive support from the EMA and bilateral and multilateral international cooperation helped us to develop our capacities, to go towards EU accession but even further, towards the ideas implemented in our mission, vision and basic values.

I am convinced that, thanks to the privilege of being part of this conference, we will all learn much and not only during the lectures. Having this rare opportunity to be together today, we can discuss the issues we are all concerned about, exchange opinions, experiences and ideas, create a constructive dialogue and strengthen the cooperation and, in all these ways, really make a difference which can influence and benefit millions of patients.

Kindest regards,

Tatjana Šipetić

Managing director
ALIMS

Additional information

Questions and answers

Each session includes a 15-minute period for questions and answers.

Visit of ALIMS on Tuesday, 30 November, at 13.15

The Medicines and Medical Devices Agency of Serbia (ALIMS) has the pleasure in inviting the Invited speakers and the other Beneficiaries to visit the Agency and the laboratories. Transfer and lunch will be provided. Please inform the organiser of your attendance.

Monday, 29 November 2010

Human and veterinary medicines — Main auditorium 'Studenica' room

9.00 Welcome address

Andreas Pott, Head of Administration, EMA
Tatjana Sipetic, Director, ALIMS, Serbia

9.30 Keynote address

Perisa Simonovic, State Secretary of the Ministry of Health, Serbia
Zoran Micovic, Director, Ministry of Agriculture, Forestry and Water Management, Serbia
Alexksandar Stefovski, Representative of the City of Belgrade, Serbia
Ferenc Simon, First Counsellor and Head of Operations Section, Representative of the Serbian Delegation of the European Commission in Serbia, Serbia

10.30 Coffee break

11.00 Acquis communautaire: Perspectives from regulators*

Vincenzo Salvatore, EMA

11.30 Acquis communautaire: Perspectives from Member States*

Jasmina Mircheva, Bulgarian Drug Agency, Bulgaria

12.00 Acquis communautaire: Perspectives from Industry*

Hubertus Cranz, AESGP
Eszter Teleki, EFPIA
Beata Stepniewska, EGA
Richard Clayton, IFAH-Europe

13.30 Buffet lunch (restaurant)

* Simultaneous interpretation in English and Serbian.

Monday, 29 November 2010

Human medicines — 'Studenica' room

14.30 Specific regulatory issues

- 'Phasing in' issues – Impact on nationally authorised products MA status from traditional herbal to advanced therapy medicinal products

Speakers:

- **Tony Humphreys**, EMA
- **Romaldas Mačiulaitis**, State Medicines Control Agency, Lithuania

16.00 Coffee break

16.30 eSubmission

- Managing eCTD Lifecycle Management (LCM) in the CP, MRP, DCP and national procedures
- EU NeeS guidelines, validation, the future of NeeS
- eCTD current status and expected implementation dates

Speakers:

- **Pieter Vankeerberghen**, Federal Agency of Health and Medicinal Products, Belgium

17.00 Paediatrics

- Adult medicines in paediatric use
- Clinical trials of paediatric medicines
- Paediatric investigation plan (PIP)
- Paediatric research network
- Short overview of EU Paediatric Regulation (Regulation (EC) No 1901/2006): Impact on regulators and industry
- Paediatric Committee (PDCO) responsibilities, organisation and results
- Paediatric use marketing authorisations (PUMAs)

Speakers:

- **Paolo Tomasi**, EMA
- **Ljiljana Milosevic-Kapetanovic**, AFSSAPS, France

19.00 – 19.30 Orphan drugs

- Committee for Orphan Medicinal Products (COMP) activities

Speakers:

- **Paolo Tomasi**, EMA

20.30 Conference dinner at the Hyatt Regency

Tuesday, 30 November 2010

Human medicines — 'Studenica' room

9.00 – 10.00 Inspections and supervision

- Quality defects, falsified products and rapid alerts
- GMP inspection system in the EEA – EudraGMP
- GMP inspection in Serbia

Speakers:

- **Jacques Morenas**, AFSSAPS, France
- **Jelica Vasic**, Ministry of Health, Serbia

10.00-11.00 Pharmacovigilance

- Eudravigilance and risk management
- The use of Eudravigilance: perspective from an NCA

Speakers:

- **Thomas Goedecke**, EMA
- **Lennart Waldenlind**, MPA, Sweden

11.00 Coffee break

11.30-12.30 Pharmacovigilance (contd.)

- Highlights of the new Pharmacovigilance legislation
- Pharmacovigilance in Serbia

Speakers:

- **Miguel Angel Macia**, ALMPS, Spain
- **Marija Petronijevic**, ALIMS, Serbia

12.30 Closure of the conference

Speakers:

- **Sylvie Bénéfice**, Head of Meeting and Conference Management, EMA
- **Tatjana Sipetic**, Director, ALIMS, Serbia

Monday, 29 November 2010

Veterinary medicines — 'Ostrog' room

14.30 Authorisation of veterinary medicines

- Impact of the single market and availability of veterinary medicines:
  - Industry's perspective
  - Member State perspective
- Immunologicals/new developments

Speakers:

- **Erik de Ridder**, Elanco Animal Health, Chairman of IFAH-Europe Technical and Regulatory Committee
- **Judita Hederova**, Department of State Control of Veterinary Biologicals and Medicaments, Slovak Republic
- **Nikolaus Kriz**, EMA

16.00 Coffee break

16.30 – 17.15 Quality of veterinary medicines
Preparing documentation about quality and guidelines

Speakers:

- **Teresa Potter**, EMA

17.15 – 18.30 Antimicrobial resistance

- Overview of CVMP activities on antimicrobial resistance
- Exchange of experiences in controlling antimicrobial resistance development

Speakers:

- **Pascal Sanders**, ANSES, France
- **Ivana Lohman**, DVM, Croatia

18.30 – 19.00 User safety
Environmental risk assessment

Speakers:

- **G. Johan Schefferlie**, CVMP, The Netherlands

20.30 Conference dinner at the Hyatt Regency

Tuesday, 30 November 2010

Veterinary medicines — 'Ostrog' room

9.00 – 10.00 Inspections and supervision – **Studenica room**

- Quality defects, falsified products and rapid alerts
- GMP inspection system in the EEA – EudraGMP
- GMP inspection in Serbia

Speakers:

- **Jacques Morenas**, AFSSAPS, France
- **Jelica Vasic**, Ministry of Health, Serbia

10.00-11.00 Safety of veterinary medicines

- MRLs and consumer safety
- Control of residues in EU
- MRLs and residue control in Serbia

Speakers:

- **Isaura Duarte**, EMA
- **Pascal Sanders**, ANSES, France
- **Slobodan Sibalic**, Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate, Serbia

11.00 Coffee break

11.30-12.30 Pharmacovigilance

- Outline of the EU pharmacovigilance system
- EudraVigilance Vet. in Serbia

Speakers:

- **Peter Ekstrom**, CVMP, Sweden
- **Vladimir Raketic**, Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate, Serbia

12.30 Closure of the conference – **Studenica room**

Speakers:

- **Sylvie Bénéfice**, Head of Meeting and Conference Management, EMA
- **Tatjana Sipetic**, Director, ALIMS, Serbia

Glossary

AESGP	Association of the European Self-Medication Industry
AGEMED/AELMP	Spanish Agency for Medicines and Medical Devices
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé, French regulatory Agency
ALIMS	Serbian Medicines and Medical Devices Agency
ANSES	French Agency for Veterinary Medicines
BDA	Bulgarian Drug Agency
BfARM	German Federal Institute for Medicines and Medical Devices
CHMP	Committee for Medicinal Products for Human Use
CVMP	Committee for Medicinal Products for Veterinary Use
COMP	Committee for Orphan Medicinal Products
DG	Directorate-General of the European Commission
DVM	Ministry of Agriculture, Fisheries and Rural Development, Veterinary Directorate, Croatia
EDQM	European Directorate for the Quality of Medicines & HealthCare
EFPIA	European Federation of Pharmaceutical Industry Associations
EGA	European Generic Medicines Association
EMA	European Medicines Agency
EU	European Union
FAGG	Belgian Federal Agency of Health and Medicinal Products
GCP	Good clinical practice
IFAH-Europe	International Federation for Animal Health
MA	Marketing authorisation
MHRA	Medicines and Healthcare products Regulatory Agency, UK regulatory agency
MPA	Medical Products Agency, Swedish regulatory agency
NCA	National competent authority
PDCO	Paediatric Committee
SAGAM	Scientific Advisory Group on Antimicrobials