European Medicines Agency
Communications and Networking

London, 5 November 2008
Doc. Ref. EMEA/589654/2008

Welcome address from Sylvie Bénéfice to the Rijeka conference

Welcome

- Dr Dragen Jurković - State Secretary
- Ms Nada Turina – Deputy of the county prefect
- Ms Dorotea Pechić Boukovac - President of the city council
- Dr Tomić – Director of the Croatian agency for medicinal products and medical devices – ALMP
- Mr Terberger – Head of pharmaceutical at the European commission
- Ladies and gentlemen

on behalf of Thomas Lönngren, Executive Director of the EMEA, it is my pleasure to welcome you all to this conference.

Thanks

This conference is organised for the 5th anniversary of the Croatian Agency for Medicinal Products and Medical Devices, under the framework of the Transition Instrument for Pre-accession Assistance programme of the European Commission, designed for supporting pre-accession activities of the Candidate Countries.

Thus, I would first like to extend my thanks to all those who have made this conference possible:

- To the European Commission for making finances available through the IPA programme.
- To the Croatian authorities who are hosting and co-funding this event, and who have welcomed us so warmly to this beautiful city of Rijeka.
- And to my other EMEA colleagues who have worked hard to organise this conference.

Ambitions for the conference

It is my expectation that this conference will contribute towards achieving the aims of the IPA programme, with the overall objective of preparing the groundwork for cooperation in the field of medicines regulation between Croatia and the European Union.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 01
E-mail: conferences@emea.europa.eu http://www.emea.europa.eu

It is very important that this preparation is done well in advance of any future accession of Croatia to the EU, as effective cooperation between partners is a requirement for a successful operation of the European regulatory system. Without it, we cannot fulfil our mission to protect health in the countries we represent through the availability of safe and effective medicines.
It is therefore my hope that this conference will contribute towards providing the necessary information, knowledge and understanding on which cooperation between our countries can be built, for the common benefit of our citizens.

In particular, I hope that this conference will allow us:

- To strengthen personal contacts with our colleagues from the Croatian Agency for Medicinal Products and Medical Devices (ALMP),
- To gain a better understanding of the current regulatory environment for pharmaceuticals in Croatia,
- To provide an overview of how the European medicines network operates and who does what between the Member States, the European Commission and the EMEA,
- To present in some detail the standards and practices that are used to regulate pharmaceuticals in the European medicines network.

Specific topics

Ladies and gentlemen, as part of these preparations, we will now have two days of presentations and discussions, covering some of the most important aspects of the European regulatory system for medicines. In particular:

- The Pharmaceutical regulation, with the Pharmaceutical Policies, the new EDQM road and the EMEA-CHMP Think-Tank Group on innovation, Research and Drug Development,
- The specific experiences of countries that recently joined the EU as part of the previous wave of enlargement, which therefore have valuable and relevant insights to offer as contributing EU Member State Regulatory Authorities,
- the transatlantic simplification of administrative procedures,
- The priorities and the efficiency of the EU Regulatory network and the progress of Croatia in its compliance with the EU system in this context.

We will also be looking at a range of specific regulatory affairs, including the overview of the review process, the impact of the new variation system on National Competent Authorities and e-submission.

Specific medicinal products will be highlighted with the description of the role of the Paediatrics Committee, of the Advanced Therapies and of the revised guideline of bioequivalence.

A session will be devoted to Pharmacovigilance with the presentation of the European Commission's proposal for Pharmacovigilance, EudraVigilance and Risk-management plans.

Inspections activities to be discussed will include GCP inspections, counterfeit medicines, GMP and Pharmacovigilance inspections.

Closing comments

I hope that, over the next two days, we will share perspectives and insights, knowledge and information, understanding of the challenges and opportunities, which are the building blocks for effective cooperation between us, and I hope that we can lay some of these blocks as the foundation for a future EU medicines system that includes Croatia as a partner in our shared mission for better health in Europe.

Ladies and gentlemen, I thank you for your time. I thank you all very much for participating in this conference, and look forward to spending the next two days together with you all.

It is now my pleasure to invite Dr Sinisa Tomić to say a few words.