



Agency for Medicinal Products
and Medical Devices



European Commission



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PRESS RELEASE

Successful Rijeka conference strengthens EU-Croatian cooperation on medicines regulation

A two-day conference in Croatia has enabled regulatory authorities from the European Union (EU) and Croatia to make good progress on preparing for Croatia's integration as an equal partner in the EU regulatory network for medicines upon its eventual accession to the EU.

The conference, held in the Croatian seaport of Rijeka on 13 and 14 November 2008, was co-hosted by the Croatian Agency for Medicinal Products and Medical Devices (ALMP) and the European Medicines Agency (EMA).

Organised as part of the fifth anniversary celebrations of the ALMP, and funded through a European Commission programme to assist pre-accession activities of the EU candidate countries, the main themes of the conference were:

- The *acquis communautaire* (the body of EU law) and its application in the regulation of medicines
- Harmonisation of existing Croatian pharmaceuticals legislation with EU legislation
- Practical measures to promote the smooth integration of Croatia into the EU medicines network upon accession

It also provided a forum for discussion and information exchanges between EU regulatory and scientific experts and their Croatian counterparts on a range of specific topics, which included advanced-therapy medicines, paediatric medicines, risk-management and safety-monitoring of medicines (pharmacovigilance), and tackling counterfeit medicines.

Presentations and panel discussions were led by experts from the European Commission, the EMA, the ALMP and the regulatory authorities of several existing EU Member States, including the National Medicines Agency of Romania, which, as one of the most recent members of the EU medicines network, had valuable post-accession experience to offer the Croatian authorities.

The conference attracted some 320 participants, representing the whole cross-section of stakeholders in Croatia, including regulators, academics and pharmaceutical industry players.

In their closing addresses, the speakers for the European Commission, the EMA and the ALMP all agreed that the conference had been fruitful in promoting understanding between the EU and Croatian authorities and in facilitating future cooperation.

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Notes:

1. Further information about the Rijeka conference, including the programme, is available at:
<http://www.emea.europa.eu/htms/euenlargement/programs/IPA/events.htm>

2. The Rijeka conference was funded through the European Commission's Transition Instrument for Pre-Accession Programme. Further information about the programme is available at: http://www.emea.europa.eu/htms/euenlargement/programs/IPA/ipa_index.htm
3. Further information about the EMEA's activities relating to EU enlargement is available at: <http://www.emea.europa.eu/htms/euenlargement/euenlargement.htm>
4. Further information about the Croatian Agency for Medicinal Products and Medical Devices is available at: <http://www.almp.hr>
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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