



The European Agency for the Evaluation of Medicinal Products
Directorate

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EU enlargement countries to join EMEA as observers from 1 April 2003

The ten accession candidate countries expected to join the European Union in May 2004 will begin work with the EMEA on 1 April 2003 as observers on the Agency's scientific committees and working parties.

The national competent authorities responsible for medicines for human and veterinary use in the accession countries were invited in January 2003 by Thomas Lönngren, EMEA Executive Director, in consultation with the European Commission. This invitation ahead of accession builds on the successful preparatory training and exchange programme (Pan-European Regulatory Forum or 'PERF') that the Agency has led since 1999.

Welcoming this new phase of cooperation between the Agency, current EU Member States and the ten countries, Thomas Lönngren said, "One of the Agency's priorities is the successful integration of the new Member States into the operation of the European regulatory system and maintenance of our rhythm of work with no significant slow down in the centralised procedure. I am confident that this period ahead of accession will ensure a smooth transition."

As part of the ongoing preparations for accession, the EMEA has also put in place a programme of benchmarking visits to the national authorities of the accession countries, including Bulgaria and Romania. The visits are intended to enhance the implementation of an integrated quality management system to ensure good regulatory practices in the EU and provide targeted audit training for participating quality professionals in the EU and accession country agencies.

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NOTES:

1. The 10 accession candidate countries participating are Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia. They are set to join the EU on 1 May 2004. Bulgaria and Romania are currently negotiating for accession to the EU in 2007.
2. See <http://europa.eu.int/comm/enlargement/index.htm> for more information on EU enlargement.
3. See <http://perf.eudra.org> for more information on the PERF programme. The current third phase of the PERF programme (PERF III) runs from January to December 2003. The candidate countries involved in the PERF programme are Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia. The purpose of PERF III is to help candidate countries prepare their regulatory systems before accession to the EU. The European Commission PHARE programme funds the benchmarking visits for the 10 central and eastern European candidate countries. Cyprus and Malta participate without financial support from PHARE.

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