The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

EMEA and EU accession countries meet ahead of enlargement

The European Agency for the Evaluation of Medicinal Products (EMEA) and heads of medicines agencies in the EU accession countries responsible for human medicines met on 17 September 2003 as part of the preparations ahead of EU enlargement on 1 May 2004.

Preparation for enlargement has been highlighted by EMEA Executive Director, Thomas Lönngren, as one of the Agency's priorities for 2003 and 2004. In particular the objective is to ensure a smooth transition for the 10 new Member States joining the EU without slowing down the centralised procedure.

The heads of the accession countries' authorities identified a number of challenges to be resolved ahead of enlargement. Of these the requirement to bring existing marketing authorisations into compliance with current EU pharmaceutical law – the so-called *acquis communautaire* – remains an issue for the agencies.

Pharmacovigilance is another priority action area ahead of enlargement and has been an important focus of the 'Pan-European Regulatory Forum' (PERF) training and exchange programme that has run since 1999. Discussion is also underway for the involvement of regulators and industry from the new Member States in the EudraVigilance safety reporting system.

Other priority areas include active preparations for connection to the secure IT system that allows communication between national authorities, European Commission and EMEA – the EudraNet. Participation of the new Member States in the EU telematics strategy and implementation plan for a number of important new projects was also discussed.

The meeting addressed other issues such as translations of patient and prescribing information into the languages of the new Member States. It was proposed that two processes should be put in place: one for already authorised medicines (i.e. products that are already subject of a Commission decision on marketing authorisation up to and including 30 April 2004) and another for applications pending at the time of EU enlargement (i.e. from 1 May 2004 onwards) where in principle the process in place for existing Member States should be applied.

The European Commission representative announced that there will be a Commission Communication in the last quarter of 2003 addressing these practical issues ahead of enlargement.

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The next meeting in this series will be with heads of candidate countries' agencies regulating veterinary medicines products, on 3 October 2003. A further meeting with heads of agencies before enlargement is planned for March or April 2004.

--ENDS--

NOTES:

1. The 10 accession countries are Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia. They are set to join EU on 1 May 2004. Since 1 April 2003, they participate as active observers in EMEA scientific committees and working parties.

2. The agenda and list of participants are attached for information.

3. The telematics projects include EudraNet, EudraVigilance, EuroPharm, clinical trials databases (EudraCT and EVCTM), e-submissions and CTS (EudraTrack).

4. Useful reference web sites include:
   EMEA: http://www.emea.eu.int
   PERF: http://perf.eudra.org
   European Commission Pharmaceuticals Unit: http://pharmacos.eudra.org/F2/home.html
   EMEA enlargement page: http://www.emea.eu.int/euenlargement.htm#
   EMEA links: http://www.emea.eu.int/exlinks/exlinks.htm

The European Agency for the Evaluation of Medicinal Products

Meeting of EMEA and heads of agencies of accession countries

17 September 2003, 09:00 – 16:00

AGENDA

Chair : **Thomas Lönngren,** EMEA Executive Director

09h00	Welcome address EMEA preparation for EU enlargement *Thomas Lönngren*
09h20	Tour de table Major challenges of pre-accession period as identified by ACs *Heads of Agencies of Acceding Countries*
09h50	Invitation for a national expert on secondment *Thomas Lönngren*
10h00	Telematics Implementation plan Eudranet, Eudralink *Introduction by Hans-Georg Wagner. Discussion*
10h40	Coffee break
11h00	Involvement in Pharmacovigilance, including participation in the EudraVigilance project *Introduction by Noël Wathion. Discussion*
11h40	Phasing in of Commission Decisions on Marketing Authorisations granted via centralised procedure Translation check procedure *Introduction by Anthony Humphreys. Discussion*
12h30	Lunch break
13h30	Phasing in to the scientific review processes From observers to full members of CxMPs and WPs *Introduction by Patrick Le Courtois. Discussion*
14h30	IQM benchmarking for enlarged EU, interim feedback *Introduction by Dagmar Stará. Discussion*
15h00	Coffee break
15h10	Communication about preparation for EU enlargement *Introduction by Dagmar Stará. Discussion*
15h40	Closing remarks
16h00	End of the meeting

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Meeting of EMEA and Heads of Agencies of Accession Countries
17 September 2003, 09:00 – 16:00

LIST OF PARTICIPANTS

Heads of agencies of accession countries

Louis Panayi	Cyprus
George Antoniou	Cyprus
Milan Šmíd	Czech Republic
Kristin Raudsepp	Estonia
Tamás L Paál	Hungary
Janis Ozolins	Latvia
Vyautas Basys	Lithuania
Lilian Wismayer	Malta
Katarzyna Kazanowska	Poland
Ľudevít Martinec	Slovak Republic
Stanislav Primožič	Slovenia

European Commission

Nils Behrndt

UNISYS

Trevor Green

EMEA

Thomas Lönngren	Dagmar Stará
Andreas Pott	Emer Cooke
Hans-Georg Wagner	Isabelle Moulon
Noël Wathion	John Purves
Patrick Le Courtois	Agnès Saint-Raymond
Marijke Korteweg	Dirk Detken
Anthony Humphreys	Sarah Faircliffe
Arielle North	Sandra Vanlievendael