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London, 4 October 1999

PRESS RELEASE

Twenty-third meeting of the Management Board

The Management Board of the EMEA met on 29 September 1999 under the chairmanship of Mr Strachan Heppell. This was followed on 30 September by a meeting with heads of agencies from Central and Eastern European countries as part of the Pan-European Regulatory Forum (PERF).

Pending adoption of the proposed European Parliament and Council Regulation on orphan medicinal products, the Management Board considered interim measures to ensure that the delay in adopting the Regulation does not lead to orphan medicines already approved being forced to disappear from the market. The Board will finalise its position at the December meeting.

The Board provisionally approved the EMEA Code of Conduct. Intended to complement the Code of Conduct currently being developed by the European Commission, the EMEA Code incorporates and develops existing practice and provides specific guidance concerning conflicts of interest, confidentiality and discretion, and gifts and invitations. The EMEA Code applies to members of the Management Board and scientific committees, European experts and EMEA members of staff. The document will shortly be published on the EMEA Internet site for consultation until the end of October. The Board will return to the Code at its next meeting once the Commission document has been adopted.

Members of the Board welcomed progress in the costing exercise. Further to the work of a working group on fees and costing (see press release of 21st meeting of 10 February 1999) and a number of visits to national competent authorities, an approach to analytical accounting to identify the costs of EMEA activities was endorsed by the Board. The working group will now focus on the costing of activities of the national competent authorities. The costing exercise has been requested by the European Parliament and Court of Auditors and the results will be submitted in 2001 as part of the revision of fees payable to the EMEA.

The Board considered a number of additional items, including a Supplementary and Amending Budget for 1999 (totalling € 1.3 million) to take into account the increase in revenue from the future participation of Iceland and Norway in the EMEA and the Agency's role in the organisation of the PERF initiative.

The first meeting with the heads of agencies of EU candidate countries from Central and Eastern Europe was held on 30 September. This was the first in a series of four meetings to discuss the topic of mandate and competencies of competent authorities. Further details on the PERF programme and the first announcement of the public conference to be held on 2-4 February 2000 are attached.

The next meeting of the Management Board will be held on 1 December 1999.

-- ENDS --

NOTES FOR EDITORS:

1. This press release, together with other information about the work of the EMEA, may be found on the Internet at the following location: *http://www.eudra.org/emea.html*
2. Fees payable to the EMEA are laid down in Council Regulation (EC) No 297/95. This was last amended in 1998 and will be revised in 2001. Article 12(4) of the Regulation provides that any future revision shall be based on a comprehensive evaluation of the Agency's and national competent authorities' costs.

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PRESS RELEASE

Pan-European Regulatory Forum Brings Together East and West

East and West will come together in Budapest early next year at the start of a new millennium for Europe's medicines regulatory environment. A public conference will be held on 2-4 February 2000 in the Hungarian capital to present the activities and direction of the Pan-European Regulatory Forum on Pharmaceuticals (PERF).

The ultimate aim of the PERF is the transposition of all EU technical requirements into the national legislation of the EU candidate countries of Central and Eastern Europe (CEE). In this context, the PERF is designed to establish an internationally open dialogue, design working mechanisms to facilitate adoption of the common technical requirements, ensure effective implementation and identify areas where additional action may be required.

The PERF is supervised by a Steering Committee and Executive Board, both of which consist of Heads of the Drug Regulatory Agencies of EU and CEE country participants, representatives of the European Commission and of the European Medicines Evaluation Agency (EMEA). The EMEA acts as the PERF secretariat. The project is financed from the PHARE fund, which provides grant finance in support of the process of economic transformation of EU accession countries. Information about PERF will be accessible through the web sites of the European Commission (Pharmaceutical Unit) and the EMEA.

The PERF comprises a series of meetings that began in September 1999 and will be completed by the end of March 2000; details of the meetings planned are given in the attached schedule. The Forum deals with six priority action areas; practical arrangements for implementing the *acquis communautaire*; dossier assessment (quality; safety and efficacy); pharmacovigilance; mandate of drug regulatory authorities, and various implementation topics (good manufacturing practice, telematics, maximum residue limits for veterinary products). Each of the priority action area working group meetings will be co-chaired by an EMEA representative and a CEE country delegate and attended by experts from the EU Member States, the participating CEE countries and the EMEA.

PERF Conference in Budapest
The PERF Conference in February 2000 provides a unique opportunity to track the progress of regulatory harmonisation for pharmaceuticals between the EU and future EU Member States of CEE.

The Association of the European Self-Medication Industry (AESGP), which has been very active in forging links between EU regulators and their CEE counterparts, will assist the PERF Secretariat with the practical arrangements for the Conference. It is open to all interested parties including representatives of government and regulatory agencies, the pharmaceutical industry, consumers' associations, academia and health professionals. Delegates and speakers will have the chance to share experiences, compare performances and explore future options, paving the way towards mutual recognition of regulatory decisions and scientific data throughout the European region.

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PERF Meetings Schedule

		1999 July	1999 August	1999 September	1999 October	1999 November	1999 December	2000 January	2000 February	2000 March
	Pharmaceutical C'ttee Meetings			27 - 28						
	EMEA CPMP Meetings	27 - 29		21 - 23	19 - 21	16 - 18	14 - 16	18 - 20	15-17	14 - 16
	EMEA CVMP Meetings	13 - 15	17 - 18	14 - 16	12 - 14	9 - 11	7 - 9	11 - 13	8 - 10	7 - 9
	EMEA Vth anniversary Meeting							26		
H	**Pharmacovigilance**									
	EMEA PhV Meetings			29 - 30		**23 - 24**		**24 - 25**		
	PERF meeting dates			8 - 10 Prague	12 - 14 Paris	**23 - 25 London**		**24 - 26 London**		1 - 3 Vilnius
H + V	**Implementation of the Acquis**									
	Notice to Applicants meeting				**27 - 28**					
	PERF meeting dates			8 - 10 Brussels	**26 - 28** Brussels	30 - 2 Helsinki		11 - 13 Riga	22 - 23 Vienna	
H + V	**Dossier - Quality**									
	EMEA QWP Meetings				**26-28**			**5 - 6**		
	EMEA BWP Meetings					**9 - 10**			8 - 9	
	EMEA BPWP Meetings					**10 - 11**				
	PERF meeting dates			8 - 10 Bucharest	**27 -29 London**	**10-12 London**		**5 - 7 London**	23 - 25 Bratislava	
H	**Dossier - Efficacy & Safety**									
	EMEA SWP Meetings					**10 - 11**		**12 - 13**		
	EMEA EWP Meetings					**4 - 5**		**26 - 27**		
	PERF meeting dates					**10 - 12**		**12 - 14**		
	PERF meeting dates				11 - 13 Lisbon	**3 - 5 London**		**26 - 28 London**		
H + V	**Mandate of Competent Authorities**									
	Heads of Agencies Meetings				**5 - 6**	26			**14 - 15**	
	Management Board			**13 & 29**		**1**				
	PERF meeting dates			**30 London**		**29 - 30 London**		31 Budapest	**16 - 17** Lisbon	
	Implementation topics									
	EMEA GMP Meetings			15 - 17		25 - 26				
	EMEA SRWP Meetings					17-18				
H	PERF meeting dates - GMP			**15 - 17 London**		**24 - 26 London**		18 - 20 Warsaw		
V	PERF meeting dates - MRL					3 - 5 Tallin		19 - 21 London		
H	PERF meeting dates - Telematics					23 - 25 London		5 - 7 Sofia		
	Conference									
	PERF meeting dates								2 - 4 Budapest	
	Executive Board									
	PERF meeting dates		9 Brussels				To be confirmed London			W/e 18 Brussels
	Steering Committee									
	PERF meeting dates	9 Brussels					To be confirmed London		1 Budapest	

H = Human; V = Veterinary

Meetings **in bold** *are those that are connected to existing Management Board, CxMP, Working Party or Heads of Agencies meetings;*