London, 31 October 1997

PRESS RELEASE

Workshop on transparency and access to documents of the EMEA 30 October 1997

A Workshop was held at the EMEA, London, on 30 October 1997 to examine the questions of transparency and access to documents of the EMEA. The meeting was chaired by Mr Strachan Heppell, Chairman of the EMEA Management Board, and Prof. Dr Dietrich Henschler, a European Parliament representative on the Management Board, acted as Rapporteur.

Invited participants included Member State competent authorities, European interest groups representing patient, consumer and pharmaceutical industry, and representatives of the specialised media. The European Parliament and European Ombudsman were also represented, as were the US Food and Drug Administration and the Nordic Council on Medicines. A list of participants is attached.

Previous audit meetings, in October 1995 and 1996 under the chairmanship of Dr Martin Bangemann, focused on the scientific activities of the EMEA. This meeting verified the level of transparency achieved by the EMEA, and examined the contribution of the EMEA in making the decision-taking process more open.

One of the primary concerns of the EMEA must now be the proper communication of information on medicines to patients, health care professionals and, in the case of veterinary medicines, to farmers. The EMEA, with the help of national authorities, will continue to work on how best to improve user information - including better involvement of consumer, patient and other relevant groups.

The EMEA is only one part of the larger global European medicines approval system. Recent initiatives of Member State national authorities were welcomed, including meetings with interested parties and press releases from the Mutual Recognition Facilitation Group. Representatives of national authorities indicated that consideration will be given by Heads of national agencies as to how some of the practices of the centralised and decentralised procedures could be converged.

It was pointed out that changes are needed in the attitudes of individuals to make sure that transparency policy becomes a reality. The freedom of information policy put in place in Sweden was discussed by the Workshop and was seen as a potential model for other European countries.

A similar experience of freedom of information was presented by the US FDA, which raised two important points. First, that effective transparency and communication has significant resource implications and, secondly, that about three-quarters of requests for information under the US

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Freedom of Information Act are made by or behalf of the pharmaceutical industry and only 4 percent by the general public.

The wide use of the Internet by the EMEA was welcomed as an important means of allowing access by a wide public to EMEA documents. It is expected that some 3 million 'hits' will have been recorded by the end of the 1997 since the launch of the EMEA website in 1995.

The regular and timely publication of European Public Assessment Reports (EPARs) was recognised as a major advance in opening up decision-taking in the European system. Building on the experience gained to date, a workshop will be held with concerned interested parties in early 1998 on how EPARs could be further improved.

The publication by the EMEA of provisional rules on access to documents was welcomed, in particular by the European Ombudsman. They will be presented on 3 December 1997, together with a report on the results of the Workshop, to the Management Board for discussion and finalisation.

Regular quarterly meetings between interested parties and scientific committees have been held since the creation of the EMEA in 1995. Other ways of involving interested parties in the work of the EMEA were considered by the Workshop, including Info-Days. Current initiatives by CPMP and CVMP to explore how they can make themselves more open to the wider scientific community and European and international learned societies were welcomed.

Communication with the media was also discussed. The primary point of contact for the press should be the Head of Unit for Human or for Veterinary Medicines Evaluation, or their nominated representative, for matters arising from CPMP or CVMP meetings. In the particular case of pharmacovigilance, the CPMP has recently adopted a crisis management and communication plan which details spokespersons at EMEA and national authority level.

As a follow-up to the Workshop, contributions from interested parties and EMEA actions will be published. A report from Prof. Henschler and the Executive Director will be considered by the EMEA Management Board at its meeting on 3 December 1997. The Chairman also announced the possibility of holding a similar meeting in 1998 to measure progress.

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This press release, together with the documents mentioned in it, can be found on the EMEA Internet site at the following address: http://www.eudra.org/emea.html

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List of participants

Representatives from national competent authorities, EMEA Management Board, CPMP and CVMP:

Mr Strachan Heppell	Chairman, Management Board
Ms Anne Peeters	Belgium
Dr Jörg Schuster	Germany
Ms Arielle North	France
Dr Ernst Luszczak	Austria
Mrs Sirpa Ahtila, Mr Risto Salmi	Finland
Dr Anders Broström	Sweden
Dr Michael Rutter, Mr Alan Davey and Mr Peter Dunlevy	United Kingdom
Prof. Gianmartino Benzi	EP representative
Prof. Dr Dietrich Henschler	EP representative
Prof. Dame Rosalinde Hurley	EP representative
Prof. Jean-Michel Alexandre	CPMP Chairman
Prof. Dr Reinhard Kroker	CVMP Chairman

Representatives of European and international institutions:

European Parliament	Prof. José-Luis Valverde López, MEP
European Ombudsman	Mr Ian Harden
US Food and Drug Administration	Dr Les Weinstein
Nordic Council on Medicines	Ms Christina Janzon

Interested parties:

BEUC	Ms Barbara Moretti
EAGS	Mr Alastair Kent
HAI-Europe	Mr Bas van der Heide
FEDESA	Dr Johan Vanhemelrijck & Dr Jochen Wieda
EFPIA	Mr Brian Ager
AESGP	Dr Hubertus Cranz
EGA	Mr Greg Perry
ISDB	Ms Ellen ‘t Hoen
Scrip/Animal Pharm	Mr Ian Schofield
Droit & Pharmacie	Dr Philippe Conquet
OTC Bulletin	Ms Deborah Wilkes
Eurovet Media Group	Mr Eric Vandaële

EMEA Secretariat:

Mr Fernand Sauer	Executive Director
Prof. Rolf Bass	Head of Unit for Evaluation of Human Medicines
Dr Peter Jones	Head of Unit for Evaluation of Veterinary Medicines
Prof. Josep Torrent Farnell	Head of New Chemical Entities Sector, Human Medicines Unit
Dr Isabelle Moulon	Principal Scientific Administrator, Human Medicines Unit

and other colleagues from the EMEA Secretariat.