The European Agency for the Evaluation of Medicinal Products
Press Office

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Press release
EMEA releases recommendations for better information for patients

The EMEA has released recommendations on improving information for patients. Drawn up in collaboration with patients' organisations, the recommendations fall into three main areas; providing information adapted to patients' needs, developing appropriate communication tools, and increasing public awareness on the use of drugs and EMEA activities. Interested parties are invited to submit comments by 15 July 2004.

Patient information is a priority for the EMEA and the Agency has continuously strengthened its interaction with patients since its creation in 1995. An EMEA/CPMP working group with patients' organisations was set up in 2003 to look at issues including further improvements in the areas of transparency and dissemination of information, product information, pharmacovigilance and interaction between the EMEA/CPMP and patients' organisations.

The group has now made detailed recommendations and proposals for action. Some recommendations, such as the provision of patient-friendly general and product-specific information material or the re-structuring of the EMEA website to facilitate access to information for patients can be implemented within the current legal framework, while others such as public hearings during the scientific evaluation process would require amendments to legislation. Several of these recommendations require consultation with the European Commission and Member States' competent authorities in order to arrive at a harmonised approach at European Union level. This includes harmonisation of the information provided on the package leaflet or improvement of public access to information on adverse drug reactions.

Patient information has also been put at the top of the political agenda as a result of the recent review of EU pharmaceutical legislation, the work of the G10 High Level Group on Innovation and the Provision of Medicines, and recent discussions in the Council of Health Ministers. The recommendations from the EMEA working group are the first element of the Agency's response to the G10 recommendations and the resolution of the Council of Health Ministers of 1 and 2 December 2003.

Comments on the recommendations should be sent to patients@emea.eu.int by 30 June 2004.

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1. The document 'EMEA/CPMP Working Group with Patients Organisations – Outcome of Discussions: Recommendations and Proposals for Action' (EMEA/CPMP/5819/04/Final) is available at http://www.emea.eu.int, together with other information about the work of the Agency.

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