The European Agency for the Evaluation of Medicinal Products
Press office

London, 6 May 2004
Doc. Ref: EMEA/12589/04

PRESS RELEASE

EMEA launches EudraCT database

The EMEA has launched the new European clinical trials database (EudraCT) on schedule for the entry into force of EU legislation on clinical trials on 1 May 2004.

The clinical trials directive (Directive 2001/20/EC) and its detailed guidance documents apply to all clinical trials of medicinal products, with at least one clinical trial site in the Community, and for which applications to the Ethics Committee and competent authority are made on or after 1 May 2004.

The EudraCT database provides national competent authorities with a common set of information on clinical trials taking place in the Community. This will contribute to improving the supervision of clinical trials throughout the European Community and to the protection of individuals participating in these trials.

The EudraCT system comprises a website (http://eudract.emea.eu.int) available to clinical trial sponsors and a secure database available only to the competent authorities of the Member States, the Commission and the EMEA.

The process includes the following steps:

- Sponsors use the web-based tool to obtain their unique EudraCT number, prior to applying for permission to conduct a trial. The number provides the unique identifier of each trial in the regulatory systems in Europe and in the database.
- Sponsors then create and save data sets (in .xml format on their local computer system) and print the completed clinical trial application form. The signed application form, the electronic data file and other supporting documents are submitted to the competent authorities for authorisation to conduct the trial.
- Member State competent authorities enter the data set into the secure EudraCT database. They complete information on their authorisation of the trial, the ethics committee opinion, amendment, the end of the trial and on inspections.

The EMEA has worked closely with stakeholders from both commercial (pharmaceutical industry) and non-commercial (academic) clinical trial sponsors and representatives of the Member State competent authorities in developing the system.

The EMEA will continue to work, in cooperation with these stakeholders, on maintaining and improving the system.

--ENDS--

Media enquiries only to Martin Harvey Allchurch

Tel (44-20) 74 18 84 27, Fax (44-20) 74 18 84 09, Email: press@emea.eu.int

1. The EMEA was created in 1995 by Council Regulation (EEC) No 2309/93. The new Regulation (EC) No 726/2004 will replace this Regulation. The new Directives 2004/27/EC and 2004/28/EC introduce amendments to the existing Community Codes on human and veterinary medicines (Directives 2001/83/EC and 2001/82/EC).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 27 Fax (44-20) 74 18 84 09
E-mail: press@emea.eu.int http://www.emea.eu.int

2. Directive 2001/20/EC can be found at http://eudract.emea.eu.int/docs/Dir2001-20_en.pdf. The detailed guidance documents can be found at http://eudract.emea.eu.int/document.html
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int/