European Medicines Agency
Press office

London, 01 May 2007
Doc. Ref. EMEA/193640/2007

PRESS RELEASE
European Medicines Agency launches EudraGMP – the Community GMP database

The European Medicines Agency (EMEA) has launched a new database designed to facilitate the exchange of information on compliance with good manufacturing practice (GMP) within the European medicines network.

The database, called EudraGMP, will enhance the ability of national competent authorities in the European medicines network to supervise the quality of medicines. It contains information on all manufacturing and importation authorisations issued by the national competent authorities within the network, i.e. the EU Member States and Iceland, Liechtenstein and Norway. It also contains information on GMP certificates, which the competent authorities issue following each GMP inspection conducted either within the network or in third countries.

The availability of EudraGMP is expected to greatly improve the sharing of information and coordination of action in the area of manufacturing authorisations and GMP certificates between national competent authorities. Efficiency gains are anticipated through the elimination of duplication of work between national competent authorities. The database is also expected to facilitate information sharing on the outcome of EU inspections with certain regulatory authorities outside the EU.

Access to EudraGMP is only available for national competent authorities, the European Commission and the EMEA. The system was designed and developed by the EMEA in close cooperation with the national competent authorities. It is part of the EU telematics strategy for pharmaceuticals, which was agreed between the Members States, the European Commission and the European Medicines Agency.

With around 15,000 importers and manufacturers in the countries concerned, it is expected that data from up to 7,000 new GMP certificates will be included in the database each year. With the addition of third-country inspections and following the introduction of new GMP requirements for active substances, the database will grow rapidly over the coming years.

--ENDS--

NOTES:

1. The data collected in EudraGMP relates to human and veterinary medicinal products.
2. The legal basis for EudraGMP is Directive 2004/27/EC, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, and 2004/28/EC, amending Directive 2001/82/EC on the Community code relating to medicinal products for veterinary use.
3. The database content is based on the Community formats for the authorisation and GMP certificate documents.
4. This press release, together with other information about the work of the European Medicines Agency, can be found on the EMEA website: www.emea.europa.eu.

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail: press@emea.europa.eu