



European Medicines Agency
Press office

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PRESS RELEASE

EudraGMP 2.0 gives public access to information about good manufacturing practice (GMP)

Following the launch of a new version the EudraGMP database is now providing public access to information about manufacturing, importation authorisations and Good Manufacturing Practice (GMP) certificates. EudraGMP can be accessed using the following URL
<http://eudragmp.emea.europa.eu>.

The EudraGMP database was initially launched in April 2007 in order to facilitate the exchange of information on compliance with good manufacturing practice (GMP) among the competent regulatory authorities within the European medicines network. The database contains information on 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 European Economic Area or in third countries.

Version 2.0 of the database will now also contain Non-Compliance Statements. These statements will be issued in cases where the reporting inspection service is of the opinion that a manufacturer's non-compliance with GMP is so severe that regulatory action is required to remove a potential risk to public or animal health.

In a drive for more openness and transparency, the European Medicines Agency and the national competent authorities have decided to give the general public access to the information contained in the database, with the exception of commercial and personal information that is considered confidential taking into account the rules on access to EMEA documents.

The information contained in the EudraGMP database will be completed and updated on an ongoing basis by the national competent authorities. For some national competent authorities, the publicly available information in the database is limited at this time. Due to the timing of national inspections and the fact that the normal inspection cycle is about 3 years, as well as different approaches to technical implementation of the database at a national level, public access will be phased in from 30 July 2009 onwards, as individual national authorities become ready. The deadline for public access to data from all national authorities will be January 2011.

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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. Public access to the information in EudraGMP is in line with the [Rules for Implementation](#) of Regulation (EC) 1049/2001 on Access to EMEA documents.
4. Authorisation and certificate formats together with relevant procedures are harmonised and published in the [Compilation of Community Procedures](#).
5. 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.

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