EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Utilisation of EudraGMDP database in regulatory procedures in the context of the MRA between Japan and the EU - impact on GMP certificates

EudraGMDP is a database containing manufacturing and import authorisations and good manufacturing practice (GMP) certificates. It also holds information with relevance to distribution of pharmaceutical products in the EU as well as registrations of active substance manufacturers, importers and distributors. The European Medicines Agency (EMA) launched the first release of the database with limited access for general public to information entered by the EU national competent authorities (NCA) in April 2007. The current version of EudraGMDP made it possible to provide comprehensive access for the general public with effect from 1st February 2011. EudraGMDP greatly improves the sharing of information and coordination of action in the area of authorisations and GMP certificates between the participating authorities by eliminating duplication of work and the administrative paper exchange.

Following an extensive data entry by the EU national competent authorities and the successful connection of the Japanese Ministry of Health Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) to EudraGMDP, it has been agreed that the use of GMP compliance information contained in the data base may replace the current practice of issuing paper GMP certificates as of 1st October 2013.

This measure aims to provide efficiency gains to all stakeholders, including importers, manufacturers and regulatory authorities as the GMP compliance status of manufacturing facilities can be readily verified on-line. MHLW and PMDA have received write access to the data base and will be entering GMP compliance information on Japanese manufacturers exporting to the EU.

As a consequence, it has been agreed that the regulatory requirement to provide original paper GMP certificates issued by EU or Japanese authorities may be replaced by either the provision of a reference to an entry in EudraGMDP or by means of a downloadable file or printout from the data base.

The details of the specific applicability of this measure depend on the respective regulatory procedures, e.g. as regards importation or marketing authorisation, and are clarified in relevant notices of each party.

In cases where a certificate of GMP compliance cannot be accessed via the EudraGMDP database, the document will have to be requested following the “traditional” procedures directly from the competent authority which inspected the manufacturer in question.

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Stakeholders can access the database and view and download certificates of GMP compliance of a manufacturer through **http://eudragmp.ema.europa.eu/**

Related information: new application procedure for GMP certification between the European Union and Japan http://www.pmda.go.jp/english/service/pdf/gmp/gmp-20130717.pdf