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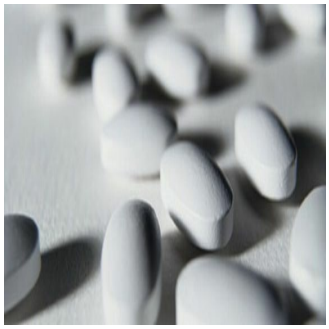
Key Deliverable of Falsified Medicines Directive Achieved



The European Medicines Agency has upgraded its EudraGMP database so that it now contains information on good distribution practice (GDP) in addition to good manufacturing practice (GMP).

The new database, now called EudraGMDP, is a key deliverable of the new European Falsified Medicines Directive, which came into force in January 2013. It will make the supervision of manufacturing and distribution of medicines more robust by allowing all the actors in the supply chain to check information available on their suppliers.

EudraGMDP will be gradually updated by medicines regulatory authorities in European Union (EU) Member States with distribution-related information and maintained on an ongoing basis. The additional information will include:

- Wholesale distribution authorisations;
- GDP certifications;
- Statements of non-compliance with GDP; and
- Registrations of manufacturers, importers (including information on their suppliers) and distributors of active substances.

EudraGMDP is a modification of the EudraGMP database, which was launched in April 2007 to facilitate the exchange of information on compliance and non-compliance with GMP among the regulatory authorities within the European medicines network.

The new system follows the introduction of a new module on planning GMP inspections in countries outside of the EU in December 2012. This module, which is not publicly accessible, was developed in order to make better use of inspection resources by sharing of information among EU regulators and avoiding redundant inspections.

The public has access to most information contained in EudraGMDP, and even more information will be accessible in the coming months, including GMP non-compliance statements. Information of a commercially or personally confidential nature is not released to the public. The decision on which information can be made public is made by the medicines regulatory authority in the Member State that uploads the information to the database.

For more information, please visit: www.ema.europa.eu

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