

Press Release

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Subject: MHRA data to be available to medicines regulators across the EU

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MHRA data to be available to medicines regulators across EU

The Medicines and Healthcare products Regulatory Agency (MHRA) alongside information management partner Accenture, has introduced a new system allowing the automatic transfer of data from the MHRA Sentinel database to the European Medicines Agency (EMA).

Using the standard for data exchange published by EMA in 2008, information on Manufacturing and Importation Authorisations (MIA) and post-inspection Good Manufacturing Practice certificates (GMPc) issued by the MHRA will automatically be transferred to the EMA maintained EudraGMP database.

MHRA Director of Information, Alison Davis, said the introduction of these systems will ensure UK information in EudraGMP will remain current while reducing the burden of data transfer.

“This is a great example of the UK taking a lead to support EU joint working, which has future benefits for other projects in terms of the positive lessons learned.” she said.

MHRA is the first EU National Competent Authority (NCA) to deploy systems for automated transfer of information into EudraGMP.

Ends

Notes to Editor

1. All EU National Competent Authorities (NCA) are responsible for licensing and inspection activities relating to manufacture and import of medicines within their jurisdiction. MHRA has one of the larger remits within the EU. It is responsible for more than 650 manufacturers and importers licences; almost 600 inspections of manufacturers and importers were conducted in the last year.
2. The EMEA launched EudraGMP on 27 April 2007. The pharmaceutical legislation specifically refers to a number of information technology systems for which EMEA was given the responsibility to implement. Directives 2004/27/EC and 2004/28/EC provide for a database on manufacturing and import authorisations, GMP certificates and non-GMP compliance information. The GMP inspection services group, chaired by EMEA, is responsible for practical and technical requirements and implementation of this database.
3. This database, known as EudraGMP, contains information on all manufacturing and importation authorisations issued by EEA competent authorities. It also contains information on GMP certificates, which member states issue following each GMP inspection.
4. Further information about EudraGMP can be obtained from the European Medicines Agency (<http://www.emea.europa.eu/Inspections/EudraGMP.html>).
5. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgments to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone –the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk