US Food and Drug Administration | European Commission | European Medicines Agency

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Press release
Cooperation on medicines regulation intensified

The EU-FDA confidentiality arrangement was reviewed at a meeting in Brussels on 13 March 2006 of the European Commission, the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA). The implementation plan for the arrangement was judged by all parties to have been a success.

Following positive feedback from both regulators and industry that parallel scientific advice can facilitate the development of safe and effective medicines, it was agreed to extend the pilot phase for this process. Another area of particular benefit is pharmacovigilance, where close collaboration on a number of important issues has enhanced patient safety.

This review resulted in an agreement to intensify transatlantic cooperation in the area of medicinal products, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children, medicines for rare diseases ('orphans'), oncology and pharmacogenomics. Other public health priority areas will be explored in the coming months, such as counterfeit drugs.

The arrangement has strengthened interactions between the regulatory authorities and contributed to improving the promotion and protection of public health.

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NOTES:

1. The confidentiality arrangement allows the European Commission/EMEA and the FDA to exchange information as part of their regulatory processes. The types of information covered by the arrangement include legal and regulatory issues, scientific advice, orphan drug designation, inspection reports, marketing authorisation procedures and post-marketing surveillance.
2. The September 2003 public statement together with the text of the Exchange of Letters and the extension to the arrangement in September 2005 between the European Commission, EMEA and FDA can be found here.
3. The implementation plan for the confidentiality arrangement as regards medicinal products for human use was agreed and published in 2004 and can be found here.
4. A pilot programme allowing companies to obtain parallel scientific advice from the two agencies (EMEA and FDA) for the development of medicinal products for human use is described in a general principles document that can be found here.
5. The confidentiality arrangement covers medicinal products that are subject to evaluation or authorised under the centralised procedure. In addition it covers medicinal products that are authorised at national level by the EU Member States but that subject to official European Community arbitrations and referrals. More information on the work of the three bodies can be found on the Internet. For the European Commission's pharmaceutical unit click here; for the US Food and Drug Administration click here; for the European Medicines Agency click here.

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