U.S. Food and Drug Administration

European Commission

European Medicines Agency

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# PRESS RELEASE
## Medicines regulators on both sides of the Atlantic confirm commitment to cooperation on medicines

The European Commission (EC), the European Medicines Agency (EMEA) and the United States Food and Drug Administration (FDA) have affirmed their commitment to regulatory cooperation and to intensifying their interactions in several new areas.

Meeting in London on 30 September and 1 October 2008 for the annual review of cooperative activities undertaken under the scope of their confidentiality arrangements, the European Union and United States authorities agreed to expand cooperation in the areas of advanced-therapy medicines and nanotechnology-derived medicinal products, as well as on the exchange of pharmacovigilance information. This builds on achievements made previously in areas such as oncology, vaccines, orphan medicines and paediatric medicines.

Notable progress has been made on implementing the Transatlantic Administrative Simplification initiative since its launch in November 2007, particularly in the areas of inspections, qualification of biomarkers, paediatrics and advanced-therapy medicines.

The EU-US confidentiality arrangements on medicines for human use were first signed in September 2003 and extended for a further five years in September 2005. Similar arrangements covering veterinary medicines, which allow the EC/EMEA and the FDA to exchange confidential information as part of their regulatory processes relating to the veterinary sector, were signed in May 2008.

Having been in place for five years, both sides concur that the transatlantic cooperation activities continue to be successful in protecting and promoting global human and animal health, reducing the regulatory burden and costs so that innovative medicines can be brought to patients in a timely manner, while also allowing critical safety information about medicines to be shared between the US and EU regulatory authorities.

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NOTES:

1. The confidentiality arrangements allow the European Commission/EMEA and the FDA to exchange information as part of their regulatory processes. The types of information covered by the arrangements include legal and regulatory issues, scientific advice, orphan-drug designation, inspection reports, marketing-authorisation procedures and post-marketing surveillance. They cover medicinal products that are subject to evaluation or are authorised

under the centralised procedure. In addition, they cover medicinal products authorised at national level by the EU Member States that are subject to EU arbitration and referral procedures.

2. The September 2003 public statement, together with the text of the Exchange of Letters and the extension to the confidentiality arrangements in September 2005 between the European Commission, EMEA and FDA, can be found here.
3. The implementation plan for the confidentiality arrangements regarding medicinal products for human use was agreed and published in 2004 and revised in June 2007. The updated implementation plan can be found here.
4. The implementation plan for the confidentiality arrangements regarding medicinal products for veterinary use was agreed and published in May 2008 and can be found here.
5. The Transatlantic Administrative Simplification Action Plan can be found here.
6. More information on the work of the three bodies can be found on the internet. For the European Commission's Pharmaceuticals Unit click here; for the US Food and Drug Administration click here; for the European Medicines Agency click here.

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