U.S. Food and Drug Administration European Commission **European Medicines Agency**

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PUBLIC STATEMENT
EU (European Commission and EMEA) and FDA extend confidentiality arrangements for five more years

The European Commission (EC), the European Medicines Agency (EMEA) and the U.S. Food and Drug Administration (FDA) have extended their confidentiality arrangements related to medicinal products for human and veterinary use for five more years, following the positive experience gained since the initial arrangements were signed in September 2003.

The confidentiality arrangements allow the EC/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.

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NOTES:
1. The September 2003 public statement together with the text of the Exchange of Letters between the European Commission, EMEA and FDA can be found here.
2. An implementation plan for the confidentiality arrangements as regards medicinal products for human use was agreed and published in 2004 and can be found here.
3. A pilot programme allowing companies to obtain parallel scientific advice from the two agencies for the development of medicinal products for human use was part of the first phase of implementation. A general principles document can be found here.
4. The confidentiality arrangements cover medicinal products that are subject to evaluation or authorised under the centralised procedure as well as medicinal products that are authorised at national level by the EU Member States and that are subject to official European Community arbitrations and referrals.
5. 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 U.S. Food and Drug Administration (FDA) click here; for the European Medicines Agency click here.

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