



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency and U.S. Food and Drug Administration extend confidentiality arrangements indefinitely

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have extended their confidentiality arrangements related to medicinal products for human and veterinary use, following the positive experience gained since the initial arrangements were signed in September 2003. This cooperation will now continue indefinitely without the need for further renewal.

The confidentiality arrangements allow both Agencies to exchange confidential information as part of their regulatory and scientific processes. Their aim is to promote public and animal health and to protect European and U.S. patients. The types of information covered by the arrangements relate to scientific advice, orphan drug designation, paediatric development, good manufacturing practice (GMP) and good clinical practice (GCP) inspection planning and reports, marketing authorisation procedures and subsequent changes to the marketing authorisations together with post-marketing surveillance.

The confidentiality arrangements cover medicines that are subject to evaluation or authorised under the centralised procedure as well as medicines that are authorised at national level by the EU Member States and that are subject to official European Community arbitrations and referrals.

These new commitments are based on the achievements of the previous arrangements between the EMA, the European Commission and the FDA.

The current implementation plan remains in force.

Notes

1. Statement of authority and confidentiality commitment from the [EMA](#) and from the [FDA](#).



2. This confidentiality arrangement replaces the previous arrangement between the European Commission, EMA and FDA. The European Commission's Directorate-General for Health and Consumers has a separate confidentiality arrangement with the FDA.
3. [Public statement on the initial confidentiality arrangement between the European Commission, EMA and FDA made in 2003](#)
4. The current implementation plan for the confidentiality arrangements as regards medicines for human and veterinary use and further arrangements made in relation to parallel scientific advice, orphan drugs, paediatric medicines, GMP and GCP can be found on [the EMA dedicated website on interactions with the FDA](#).
5. More information on the work of the U.S. Food and Drug Administration (FDA) can be found on the [FDA website](#).
6. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu.

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